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NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

National Health Mission
FREE DIAGNOSTICS SERVICE INITIATIVE

Guidance Document for Implementing Laboratory Services in States

Ministry of Health & Family Welfare
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सबका साथ, सबका विकास, सबका विश्वास
Sabka Saath, Sabka Vikas, Sabka Vishwas

सत्यमेव जयते

डॉ हर्ष वर्धन
Dr Harsh Vardhan

स्वास्थ्य एवं परिवार कल्याण, विज्ञान और प्रौद्योगिकी व पृथ्वी विज्ञान मंत्री, भारत सरकार
Union Minister for Health & Family Welfare, Science & Technology and Earth Sciences Government of India

Message

Accessible quality Laboratory services are indispensable when it comes to alleviating the health of citizens of a country. Such services have become extremely feasible, given the advances made in field of Science and Technology and in the field of research. However, time and again, concern has been raised for high Out of Pocket Expenditure (OOPE) incurred by people across the country on healthcare, especially on diagnostics. To address this concern, the Ministry of Health and Family Welfare, Government of India, had launched Free Diagnostics Service Initiative (FDSI) in the year 2015 with a view to reduce OOPE on diagnostics. This initiative has made a great difference in the lives of our citizens. I must appreciate the efforts of States/UTs in providing such free diagnostics services to the population, especially to the most vulnerable and marginalised section of the society.

2. The Guidelines issued as part of the initiative, envisaged free provision of a set of essential diagnostics tests at various levels of public health facilities. This guidance document paved the way in providing accessible, affordable, quality and timely diagnostics services to the people up to the last mile through Hub and Spoke model.

3. With Ayushman Bharat scheme in place, it is imperative to boost the capacity, capability as well as quality of our laboratories in order to reach unserved populations and disease groups. Provision of quality diagnostics services free of cost will enable evidence based patient care; improve clinical outcomes and further reduce Out of Pocket Expenditure.

4. I, therefore, urge the States/UTs to monitor the provision as well as quality of such free diagnostic services with a view to ensure rationality of care and effective and efficient utilisation of public health facilities for the benefit of our people.

(Dr. Harsh Vardhan)

New Delhi,
August 19, 2019.

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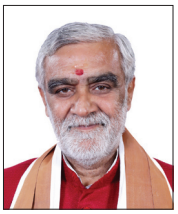

सत्यमेव जयते
सर्वेसन्तु निरामया

स्वच्छ भारत
एक कदम स्वच्छता की ओर

संदेश

भारत अपने समस्त नागरिकों को न्यायसंगत, सुलभ, किफायती और गुणवत्तापूर्ण स्वास्थ्य परिचर्या उपलब्ध कराने के उद्देश्य से यूनिवर्सल हेल्थ कवरेज की दिशा में प्रगति कर रहा है। वर्ष 2015 में प्रारंभ और कार्यान्वित की गई फ्री डाइग्नोस्टिक सर्विस इनीसिएटिव, जिसके द्वारा परिचर्या के विभिन्न स्तरों पर आवश्यक नैदानिक परीक्षणों की नि:शुल्क सेवा उपलब्ध कराई जाती है, यूनिवर्सल हेल्थ कवरेज के प्रति हमारी दृढ़ प्रतिबद्धता का साक्षी रही है। यह कार्यक्रम विशेष रूप से गरीबों तथा सरकारी स्वास्थ्य प्रणाली का उपयोग करने वाले लोगों के लिए नैदानिक सेवाओं को सुलभ बनाने और उनके आर्थिक बोझ को कम करने में सफल रहा है। परन्तु अभी अनेक राज्य ऐसे हैं जिनको अपनी प्रणाली में काफी बदलाव लाने हैं।

रोगी की प्रभावी परिचर्या और प्रबंधन के लिए की जाने वाली जांचों के विश्वसनीय और सामयिक प्रयोगशाला परिणाम रोगी परिचर्या के मूलभूत आधार होते हैं। सभी लोगों के लिए गुणवत्तापूर्ण प्रयोगशाला सेवाएं सुनिश्चित करने के लिए फ्री डाइग्नोस्टिक सर्विस इनीसिएटिव के अंतर्गत सेवा क्षेत्र को परिभाषित करते हुए मार्ग-दर्शन दस्तावेज तैयार किया गया है। मुझे विश्वास है कि यह मार्ग-दर्शन दस्तावेज राज्यों/संघ-राज्य क्षेत्रों को अपनी नैदानिक सेवाएं सुदृढ़ बनाने के लिए दिशा निर्देश दे सकेगा तथा प्रयोगशाला सेवाओं की एक संपूर्ण श्रृंखला उपलब्ध कराने के लिए उन्हें प्रोत्साहित करेगा। आयुष्मान भारत योजन के बेहतर क्रियान्वयन के लिए समग्र नैदानिक सेवाओं का प्रावधान करना अनिवार्य है।

मुझे पक्का विश्वास है कि यह दस्तावेज सभी राज्यों/संघ राज्य क्षेत्रों के लिए पूर्ण रूप से साधन संपन्न सिद्ध होगा तथा एक सुदृढ़ और स्थायी स्वास्थ्य प्रणाली के निर्माण में सहायक होगा।

(अश्विनी कुमार चौबे)

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Dated : 6th August, 2019

Preface

The implementation of Free Diagnostics Service Initiative has contributed to significant increase in OPD and IPD services in public health facilities. States have adopted different models (in-house, PPP or hybrid) based on their context. Based on the learning and experience acquired, and need to expand free diagnostics services, the accessibility and quality of diagnostics services being delivered could still be improved upon.

To ensure accessibility, availability, affordability and quality of laboratory services, this guidance document envisages Hub and Spoke Model and includes roadmap to strengthen laboratory services both in In-house and Public Private Partnership mode. The document is designed to guide the States/UTs on processes such as gap analysis of equipment, procurement and supply chain, human resources, quality control, monitoring and data management, which are indispensable for effective implementation of diagnostics services. It will be useful for program managers to understand the dynamics of diagnostics program and have measurable impact in early diagnosis and treatment, improved patient care, disease trends, and reduced Out of Pocket Expenditure.

I am positive that the States/UTs will achieve excellence in laboratory services at all level of health facilities with the intent to provide free quality diagnostics services.

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Foreword

The Free Diagnostics Service Initiative, launched in the year 2015, has marked its footprints in the health systems with the objective to provide affordable, accessible and quality diagnostic services in the States/UTs. So far, 32 States/UTs have identified/ notified varying number of Laboratory investigations/ tests to be provided free at each level of care. States/UTs have adopted different models contextualized to their needs (In-house/ Public Private Partnership/ Hybrid) for implementing this initiative. However, to maximize the reach and effect of this program, revising the guidelines based on experience and learning was an imperative step.

It is well known that provisioning of quality laboratory services in public health facilities is critical for ensuring evidence based quality patient care and reducing out of pocket expenditure. For robust implementation of the laboratory services, this guidance document propagates for Hub and Spoke model to ensure accessibility and affordability to maximum possible number of tests at various levels of care. States/UTs should assess their laboratory services and preferably, strengthen their In-house capacities in this fast pace of health care technology development and in view of providing comprehensive service package in Health and Wellness Centres under Ayushman Bharat. However, for supplementing the laboratory capacities, Service Providers should be chosen judiciously. The guidance document provides detailed workplan and processes to operationalize Free Laboratory Services and also Request for Proposal for engaging with Service Providers. Needless to say, States/UTs have flexibility in contextualizing these documents as per their needs.

I expect all the States and UTs to refer to this document for implementing/strengthening laboratory services under the Free Diagnostics Service Initiative.

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LIST OF ACRONYMS

AH : Area Hospital

AIIMS : All India Institute of Medical Sciences

AMC : Annual Maintenance Contract

ANC : Antenatal Care

ANM : Auxiliary Nurse Midwife

APL : Above Poverty Line

ASHA : Accredited Social Health Activist

ASO/ASLO : Anti-Streptolysin O

AYUSH : Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy

BME : Biomedical

BMW : Biomedical Waste Management

BPL : Below Poverty Line

B.Urea : Blood Urea

BIS : Bureau of Indian Standards

Blood C/S : Blood Culture and Sensitivity

BMMP : Biomedical Equipment Maintenance and Management Program

CBC : Complete Blood Count

CD : Compact Disk

CDS : Central Drug Store

CGHS : Central Government Health Scheme

CHC : Community Health Centre

CMC : Christian Medical College

CMC : Comprehensive Maintenance Contract

CRP : C-Reactive Protein

CTF : Common Waste Treatment Facility

DCA : Drugs Control Administration

DCHS : District Coordinator of Hospital Services

DH : District Hospital

DLC : Differential Leucocyte Count

DMHO : District Medical Health Officer

DMLT : Diploma in Medical Laboratory Technology

DPM : District Programme Manager

EBM : Evidence Based Medicine

EHR : Electronic Health Record

ELISA : Enzyme Linked Immunosorbent Assay

EQAS : External Quality Assurance Scheme

ESR : Erythrocyte Sedimentation Rate

FAQs : Frequently Asked Questions

FDS : Free Diagnostics Scheme

FDP : Fibrinogen Degradation Products

FNAC : Fine Needle Aspiration Cytology

FRU : First Referral Unit

GIS : Geographic Information System

GoI : Government of India

Hb : Haemoglobin

H&FW : Health and Family Welfare

HbA1C : Glycosylated Haemoglobin

HPLC : High Performance Liquid Chromatography

HIV : Human Immunodeficiency Virus

ICTC : Integrated Counselling and Testing Centre

ID : Identification

IDSP : Integrated Disease Surveillance Programme

IEC : Information Education Communication

IQC : Internal Quality Control

ILD : Inter-Laboratory Delivery

ILC : Inter Lab Comparision

ILPT : Inter-Laboratory Proficiency Testing

INR : International Normalized Ratio

INR : Indian Rupee

IPD : In-Patient Department

IQC : Internal Quality Control

ISO : International Organisation for Standardization

IT : Information Technology

JSSK : Janani Shishu Suraksha Karyakram

KFT : Kidney Function Tests

KPI : Key Performance Indicator

L1 : Level 1

L2 : Level 2

L3 : Level 3

LED : Light Emitting Diode

LFT : Liver Function Tests

LJ : Levey Jennings

LIS : Laboratory Information System

MIS : Management Information System

MBBS : Bachelor of Medicine, Bachelor of Surgery

MNPT : Mean Normal Prothombin Time

MO : Medical Officer

MoU : Memorandum of Understanding

MoHFW : Ministry of Health and Family Welfare

MP : Malarial Parasite

MPHW : Multi-Purpose Health Worker

MRA : Mutual Recognition Arrangement

MS : Medical Superintendent

MD : Doctor of Medicine

NABL : National Accreditation Board for Testing and Calibration Laboratories

NACP : National AIDS Control Programme

NHM : National Health Mission

NHSRC : National Health Systems Resource Centre

NPL : National Physical Laboratory

NRHM : National Rural Health Mission

NVBDCP : National Vector Borne Disease Control Programme

OOPE : Out-of-Pocket Expenditure

OPD : Out-Patient Department

PCR : Polymerase Chain Reaction

PCV : Packed Cell Volume

PHC : Primary Health Centre

PIP : Program Implementation Plan

PMSMA : Pradhan Mantri Surakshit Matritva Abhiyan

PPP : Public Private Partnership

PHD : Doctor of Philosophy

PT : Prothrombin Time

QA QT : Quality Assurance Quality Team

QC : Quality Control

RA : Rheumatoid Arthritis

RBS : Random Blood Sugar

RBSK : Rashtriya Bal Suraksha Karyakram

RFP : Request for Proposal

RMSCL : Rajasthan Medical Services Corporation Limited

RNTCP : Revised National Tuberculosis Control Programme

RO Plant : Reverse Osmosis Plant

S. Bilirubin : Serum Bilirubin

SDH : Sub-District Hospital

Semi-Auto : Semi-Automated

SGOT : Serum Glutamic Oxaloacetic Transaminase

SGPT : Serum Glutamate Pyruvate Transaminase

SI : Standard

SMS : Short Message Service

SOP : Standard Operating Procedure

TAT : Turnaround Time

T3 : Tri-Iodothyronine

T4 : Thyroxine

TAT : Turnaround Time

TB : Tuberculosis

TH : Tertiary Hospital

TLC : Total Leucocyte Count

TSH : Thyroid Stimulating Hormone

UHID : Unique Health Identification

UPS : Uninterrupted Power Supply

Urine R/M : Urine Routine and Microscopy

UTs : Union Territories

WHO : World Health Organisation

CONTENTS

FREE DIAGNOSTICS INITIATIVE

GUIDANCE DOCUMENT

FOR STATES FOR IMPLEMENTING LABORATORY SERVICES

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SECTION A

Guidelines for States for strengthening of In-house laboratory services for implementation of the Free Diagnostics Initiative

INTRODUCTION

To address the urgent need for accessible and quality diagnostics in public health facilities, the Ministry of Health and Family Welfare, Government of India under the aegis of National Health Mission launched the 'Free Diagnostics Initiative' in July 2015. The initiative is intended to provide a set of essential diagnostics at various levels of care so that providers can make rational decisions regarding treatment and patients can benefit by getting their tests conducted within the facility free of cost. The government envisages that this health intervention will reduce both direct costs and out-of-pocket expenditure.

Under this scheme, the National Health Mission is supporting all states to provide essential diagnostics – laboratory and radiology at their public health facilities, free of cost to all beneficiares. The range of tests offered in the public health facilities are categorized by the level of care - primary health centres (PHCs) offer 19 laboratory tests; community health centres (CHCs) have 39 laboratory and radiology tests; and sub-district and district hospitals offer 57 laboratory and radiology tests. A set of implementation guidelines has been formulated by the Ministry of Health and Family Welfare for states to ensure the availability of basic diagnostic services at public health facilities.

So far, 31 states/UTs have identified/notified varying number of investigations to be provided free at each level of facility. Since states have varying capacities in provision of diagnostics, different states are adopting different models (in-house/public private partnership) for implementing this initiative. For instance, Rajasthan and Madhya Pradesh have strengthened their in-house capacities (though recently, MP has floated tender for rental reagent model in PPP-mode) while Andhra Pradesh and Maharashtra have done a state-wide rollout of laboratory services under public private partnership arrangement.

To provide affordable, accessible and quality laboratory services to their populations, the states should strengthen their in-house capacities and use services of private provider (s), if and where required. To ensure effective implementation of the services, components such as list of tests provided at health facilities, *gap analysis of existing Equipment*, operational model (s), supply chain, procurement, human resources, quality control and data management need to be robust.

To support the states in this endeavour, NHSRC and WHO India have prepared a guidance document covering the key aspects of implementation of the initiative. This document was developed with contributions from experts from states, representatives from national health programmes, public health specialists (including PPP experts), and laboratory medicine experts. The models of implementation, best practices, and challenges in states of Andhra Pradesh, Gujarat, Rajasthan and Telangana were studied in-depth. This guidance document can be used by the states for rolling out or strengthening the free diagnostic services. Section A of the document provides guidance for strengthening the in-house laboratory services for implementation of the free diagnostics initiative, also indicating specific services which could be outsourced, if required. Section B of the document gives guidance on implementing laboratory services under the free diagnostics initiative in public-private partnership mode.

I. SCOPE OF SERVICES

The states should provide a comprehensive/expanded list of tests to cater to the diagnostics needs of the populations. The state should assess its in-house capacities for extent/status of availability of the laboratory services. It should be assessed that which all tests can be offered through in-house laboratories, at various levels of facilities, using the existing in-house capacities. The capacity of the state to further strengthen its in-house services should also be assessed. The tests which the state will be unable to provide even through strengthened capacities could be outsourced.

The state should strive to provide all rapid and routine tests through in-house laboratories. The states could decide to conduct all routine and all advanced tests in-house or conduct all routine tests in-house and outsource advanced tests. In both cases, the tests should be conducted using appropriate technology and the laboratory processes should be state-of-the-art and with minimal manual intervention.

II. OPERATIONAL MODEL

A hub and spoke model is suggested for providing laboratory services under the free diagnostics initiative. This will ensure availability of maximum possible number of tests at different levels of facilities in a cost-efficient way. Availability of comprehensive diagnostic services at all levels will improve patient care and minimize referral of patients because of unavailability of tests. This will also curtail patients' out-of-pocket expenditure on laboratory tests. Tests recommended to be made available for patients at each kind of facility and the equipment recommended for each type of test are listed in Annexure 1a. These tests could be conducted at the facility itself or transported to the hub laboratory for testing depending on the type of test.

Under the hub and spoke model, hub laboratories should be set up within all district and sub-district hospitals and large CHCs. The hub laboratories at large CHCs and SDHs and DHs should conduct all routine tests of the hospital/CHC in which they are located as well as of nearby PHCs and small CHCs. In addition, a mother laboratory should be set up which will cater to advanced tests (such as hormone assays, cultures, histopathology, cytology etc) from all health facilities of the district. The mother laboratory could be part of the in-house laboratory at the district hospital and also serve as the hub laboratory for its respective spoke facilities. Tests such as blood culture and urine culture should be available in mother laboratories of all districts. Other tests such as histopathology, cytology, bone marrow aspiration, electrophoresis, HPLC could be made available in mother laboratories of select districts in case of shortage of resources. In this case, samples for advanced tests from other districts will be transported to these mother laboratories. The advanced tests could also be outsourced to a private provider.

In the list of tests offered by PHCs and small CHCs, only rapid diagnostic tests and few basic tests including haemoglobin, blood sugar, urine analysis could be conducted at the facility and for remaining routine tests, the samples from these facilities could be transported to the nearest hub laboratory at CHC/SDH/DH.

For large CHCs and SDHs and DHs, all routine tests could be conducted at the hub laboratory located within the facility.

Samples for advanced tests (TSH, urine culture etc.) from PHCs, CHCs, SDHs and DHs should be transported to the mother laboratory. The samples for advanced tests coming from spoke facilities (PHCs, small CHCs) should be aggregated at their respective hub laboratory (located at large CHC/SDH/DH) and then transported from the hub laboratory to the mother laboratory.

For verification of results of routine and advanced tests, the diagnosticians of district hospitals/medical colleges/other government institutes could be leveraged. For basic/rapid diagnostic tests, MBBS doctor at the respective health facility could carry out the verification. Routine tests conducted at hub laboratories could be validated remotely. However, for all advanced tests, the diagnostician should be physically present at the mother laboratory for verification. In case there is a shortage of government doctors for verification of test results, a private doctor could be engaged only for test result verification. Else, doctors could be hired on a visiting basis as a temporary arrangement.

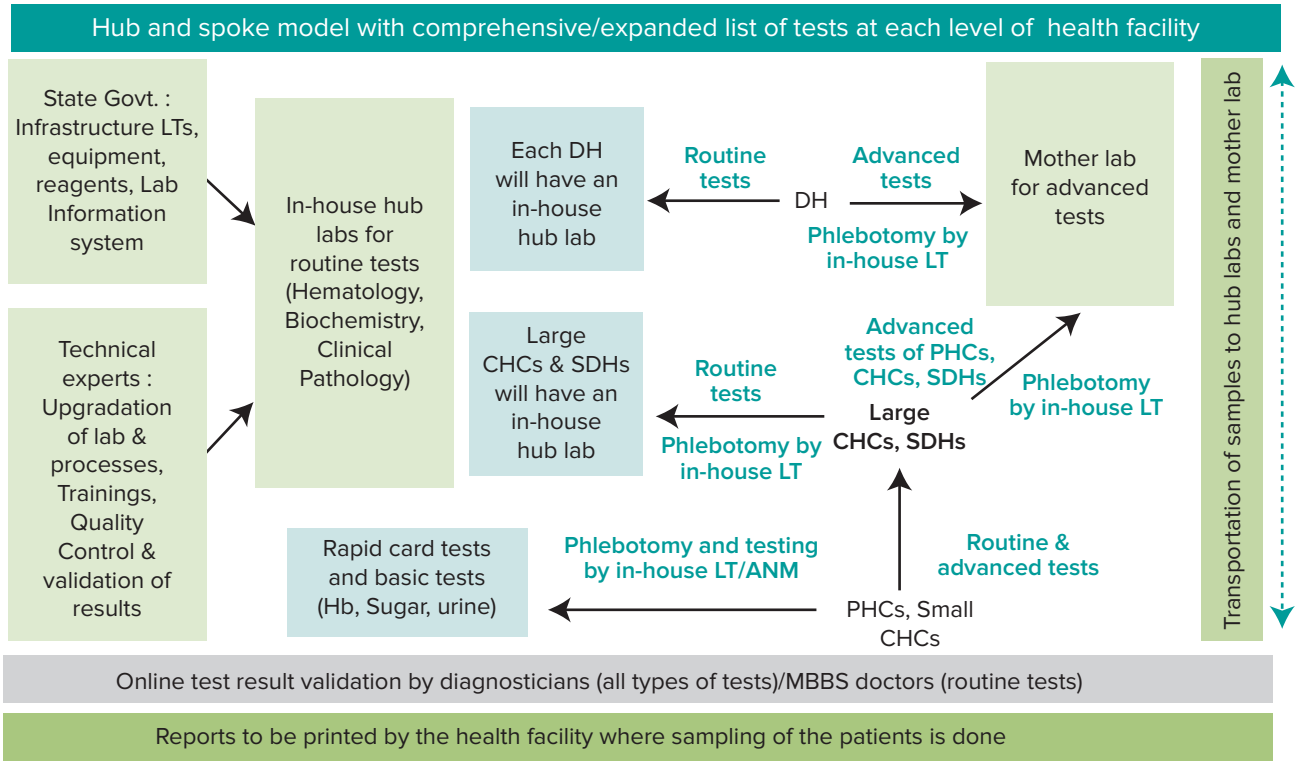
States which do not want to adopt a hub and spoke model could set up full-fledged laboratories at all health facilities (PHCs, CHCs, SDHs and DHs). The basic premise of providing comprehensive care through an expanded basket of tests at all health facilities should be maintained in this model. Cost and operational efficiency and feasibility of offering a larger variety of tests through laboratories at individual health facilities should be carefully assessed -- purchase of equipment for conducting large number of tests even at PHCs; supervision and monitoring of the laboratories; management of supply chain for delivery and management of inventory for reagents till the PHC level; training of laboratory technicians of all levels of health facilities including those of PHCs on conducting a variety of tests; management of quality control etc. However, in this model, the laboratories at lower facilities (PHCs and CHCs) will not be able to conduct few advanced tests made available to the patients at these facilities and the samples for these tests will have to be transported to a central laboratory.

Gujarat, Rajasthan and Andhra Pradesh are providing all tests listed in the free diagnostics initiative guidelines at their health facilities across the state. Telangana has launched the services in one district and is planning to roll out services in the remaining districts. Gujarat and Telangana are providing all designated tests through their in-house laboratories. Rajasthan is providing routine tests through its in-house laboratories and advanced tests through a service provider. Andhra Pradesh is providing basic tests through its in-house laboratories and remaining routine and all advanced tests through a service provider.

Andhra Pradesh (under public-private partnership) and Telangana (in-house) have implemented a hub and spoke model for provision of laboratory services. The hub laboratories are state-of-the-art and use modern technologies. Rajasthan is also using hub and spoke model for the outsourced advanced tests. In Gujarat, samples for few tests are transported to the district central laboratory from all health facilities. The in-house laboratories in Rajasthan and Gujarat use manual equipment at lower level health facilities.

Gujarat, Rajasthan, Telangana, Tamil Nadu and Kerala are providing services through in-house laboratories.

Planning (Hub and spoke model for service delivery)



III. PLANNING STAGE

The states should conduct a comprehensive gap analysis for its laboratory services. A suggestive template for doing this gap analysis is given in Annexure 2. The state should assess its capacities and preferably strengthen its in-house laboratories for diagnostic services. However, for supplementing capacity, services of private provider (s) could be considered for testing/support services. The states may also utilize their Medical corporation/Medical college experts for the gap assessment. All States/ UTs which have already executed biomedical equipment management and maintenance programme may leverage the available information.

For strengthening in-house services, the state should use the gap analysis to prepare the list of equipment and human resources required at each facility. The list should be prepared facility-wise and carefully validated by the facility in-charge to avoid any shortage of equipment, human resources, reagents and consumables at the time of rollout of the diagnostic services. Further to this, a plan for procurement of equipment, instituting supply chain management system, hiring of human resources, engagement of relevant experts (internal/external) should be formulated. The requisite budget for these activities should be prepared for rolling out diagnostics services across the state at all levels of facilities. The gap analysis for equipment and human resources should be made available to NHM as a prerequisite for approval of funds.

Gujarat and Rajasthan carried out an in-depth gap analysis for each health facility for civil work, equipment and human resources prior to rolling out diagnostic services.

IV. PRE-ROLLOUT PLAN

Once the budget is approved, the state government should carry out the following activities over a 6 - month preparatory phase.

A. 6 MONTHS BEFORE THE ROLLOUT

1. Institution of dedicated teams

- A dedicated state-level diagnostics team should be formed for managing the free diagnostics initiative in the state. This team should be formed under the leadership of a Joint Director. Members should include a nodal officer with good administrative experience; senior laboratory staff deputed from government medical colleges including a senior Pathologist (MD), a senior Biochemist (MD), a senior Microbiologist (MD), 2 senior laboratory technicians, 1 biomedical engineer; an accounts person; a senior IT person; and a data entry person. This team should be responsible for overall designing, implementation and monitoring of diagnostic services in the state.
- An expert technical committee should also be formed comprising of diagnosticians and senior technicians of government medical colleges of the state. The experts will support the state-level diagnostics team. They will provide guidance on relevance of new equipment/ technology for procurement along with other technical inputs; and provide oversight for implementing free diagnostic services.
- District diagnostics teams should also be formed comprising of laboratory nodal officers (diagnosticians and PhDs) of hub laboratories and 2 senior laboratory technicians of respective districts.
- For rolling out free diagnostics services, the state should assign an officer in-charge for each district.
- The states of Gujarat and Rajasthan set up dedicated teams for designing, implementing and monitoring of their diagnostic services. The teams comprised of administrative and technical experts. Gujarat set up a state level laboratory coordination cell which assessed requirement of equipment and reagents based on gap analysis; prepared lists of essential equipment and reagents and specifications and quality standards for procurement; and monitored purchase through the central procurement agency (corporation) and supply of the material; and supervised equipment maintenance. Similarly, Andhra Pradesh leveraged its existing state programme management unit for close monitoring of the service provider's services (in PPP).

2. Mapping of health facilities for hub laboratories and spokes

The health facilities where hub laboratories will be set up should be identified. All DHs and SDHs will have hub laboratories. In case of CHCs, hub laboratories will be set up mainly in large CHCs. Time to transport samples from spoke health facilities to hub laboratory will be an important criterion for mapping hubs and spokes. The spokes should be set up in a manner that cumulative sample transportation time from multiple health facilities to the primary receiving laboratory should not exceed 2 hours (starting from where pick-up started). An additional time could be factored in for transportation of advanced tests from hub laboratory to the mother laboratory.

Also, the hub laboratory should be mapped to the next nearest hub laboratory for sending samples for testing during its breakdown periods.

A detailed logistics plan should be prepared where spokes are mapped to the hub laboratory.

Telangana and Andhra Pradesh carried out an extensive exercise for mapping spoke health facilities and setting up hub laboratories for the respective spokes.

Local youth could be contracted for transportation of samples. A service provider could also be engaged, if required.

In Telangana, the transportation of samples from health facilities to in-house hub laboratory is partially outsourced. In Gujarat, the laboratory technicians transport samples on an occasional basis to higher level health facilities for testing. In Andhra Pradesh, the service provider which is providing testing services is managing the transportation of samples.

3. Setting-up/upgradation of laboratories

The health facilities should organise adequate space for their laboratory. For setting up adequate laboratory infrastructure, the state could release budget to the health facilities or ask the facilities to use their construction work budget in case of minor work. The PWD and state NHM should be accountable for completion of civil work.

A team of technical experts (government/private) could be engaged for providing technical support on setting up/upgrading the in-house laboratories as well as for providing training and handholding support for the functioning of laboratories on a short-term basis. The team of experts could take up the following tasks:

i. Guide on design of the laboratory – layout, functionality etc.

ii. Support for upgradation of in-house laboratories – infrastructure and operations.

iii. Training of in-house laboratory staff - induction, refresher and on-job; training on laboratory processes, quality control and data management.

iv. Set up processes in the laboratory including preparation and use of standard operating procedures.

v. Management of infection control etc.

Telangana engaged service providers for guidance on different aspects of setting up their in-house laboratories.

The infrastructure and processes of in-house laboratories should comply with and be in line with NABL standards and protocols. In addition, to ensure high quality in in-house laboratories, the state

diagnostics team, laboratory Nodal officers and relevant experts (if engaged for hand-holding) should visit and study best practices of reputed institutes like CMC, Vellore and AIIMS for laboratory processes (pre-analytical, analytical and post-analytical). Government of Andhra Pradesh directed the service provider of laboratory services to visit premier institutes such as CMC, Vellore and AIIMS, Delhi for learning their best laboratory practices.

A civil agency could be hired for setting up the desired infrastructure in the laboratory. For supervision of the civil work, a committee could be formed consisting of the civil agency, state-level diagnostics team and in-charges of each district assigned for implementation of diagnostic services.

The overall responsibility of completion of laboratory civil work will be of the facility in-charge (MO/CMHO/MS). The civil work will include the following:

i. Repairs and renovation of existing laboratories

ii. Need-based additional civil work/space

iii. Construction of shelves and cabinets to store reagents and consumables

iv. Platforms, work benches, sanitary fittings (basins, sinks etc.)

v. Counters for registration, sample collection and report dispatch

vi. Equipment installation work

vii. IT infrastructure – Local area network (LAN) for setting up laboratory information system including computers, server, peripherals; printer, barcode printer, scanner

viii. Office furniture – chair, table, rack, almirah etc.

ix. Electrical fitting and appliances - Refrigerator, UPS etc.

x. Creation of adequate waiting area with chairs for patients in waiting at all laboratories

xi. Display of names of Officer in-charge, laboratory technicians etc. outside the laboratories and list of tests undertaken at the institution with timings for sample collection and reporting and *IEC* for grievance redressal mechanism related to service delivery.

It would be important to ensure that:

i. Patient sample collection facilities have separate waiting and collection areas as well as a toilet facility.

ii. There is adequate access for the laboratory staff to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.

iii. The laboratory monitors, controls and records environmental conditions, as required by relevant specifications for factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.

iv. There is effective separation between laboratory sections in which there are incompatible activities. Procedures should be in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.

4. Instituting of a Laboratory Information Management System (LIMS) for the laboratories

The state should put in place a robust Laboratory Information System (LIS) for all its laboratories. The key features of LIMS will include patient registration, barcode generation and test report generation in all laboratories; and interfacing of equipment, barcode reading, report verification and quality control analysis in hub laboratories. Besides this, MIS and analytics should be made available at each health facility including number of patients tested, demographics of patients tested, number of tests conducted, number of test results outside biological reference interval, turnaround time of test results from time of sample collection, sample rejection rates, repeat orders and corrective and preventive actions taken.

In case the State already has LIS for in-house laboratories, it could leverage the same for outsourced laboratory services.

Gujarat and Andhra Pradesh (in PPP) have a robust laboratory information management system (LIMS) in all their laboratories for laboratory operations and data analytics. Rajasthan has leveraged e-Aushadhi system for data collection (of service utilisation) from all health facilities.

5. Recruitment and training of human resources

Recruitment of adequate number of human resources to run the laboratories could be achieved through various measures, as mentioned below:

i. Hire technicians on permanent basis preferably, else for contractual positions.

ii. Conduct recruitment drives where adequate days are dedicated for interviewing technicians at various places in the state.

iii. Hire a placement agency for recruitment of human resources.

iv. If diagnosticians/laboratory technicians are not available for full-time jobs, manage their acute shortage by getting them on a visiting basis and paying visiting charges for the fixed hours of visit. Approval for visiting doctors/technicians should be taken from the state-level diagnostics team. The per visit rates may be fixed by the state-level diagnostics team. These would be indicative rates and may vary depending on the supply and demand in the district. In case of any variation within 10% of the visiting fees, the district collectors can be authorized to increase rates of the human resources engaged to fill up the service gap. However, these would be stop-gap arrangements and the department of health should fill up these gaps as and when suitable human resources become available.

v. Integrate work for laboratory technicians across various programmes and levels of health facilities. During integration of work, the technicians should preferably be assigned work based on their preference. This will enable better efficiency in their work.

Gujarat succeeded in filling majority of its in-house positions of laboratory technicians through recruitment drives. Rajasthan has engaged diagnosticians and technicians on a per-day basis as a stop-gap arrangement for health facilities/laboratories where the in-house positions were vacant. The service provider in Andhra Pradesh recruited all its laboratory technicians and phlebotomists within a period of 3 months through recruitment drives.

Orientation trainings should be conducted for all laboratory technicians of hub laboratories at the district hospital. The training should be conducted by diagnosticians (MD/DNB/Diploma Biochemistry/

Pathology/Microbiology/Laboratory medicine) or PhDs in Biochemistry/Microbiology. The duration of orientation training should be 15 days for each technician posted in the hub laboratories. For laboratory technicians and ANMs of non-hub laboratories, orientation training should be conducted for 5 days at the district hospital. The training should focus on hands-on learning. The trainings should be conducted under direct supervision of the diagnosticians from medical colleges.

Telangana provided 15 days of orientation training to all its laboratory technicians at its district hospital prior to rolling out the diagnostic services. This was followed by another round of training at the time of roll out in their respective laboratories. Gujarat and Rajasthan leveraged diagnosticians of medical colleges and district hospitals for conducting training of diagnosticians, medical officers and laboratory technicians on the laboratory processes.

6. Procurement of equipment and reagents and consumables

- Based on the gap analysis for equipment, requisite equipment should be procured. The equipment should meet the technical specifications including the technology, sensitivity and specificity criteria of test results etc. The equipment should be preferably closed system and the rates of reagents should be negotiated with the vendors at the time of procurement of the equipment. The rates of reagents should include free supply of controls and calibrators without specifying the quantity of the of controls and calibrators. However, the States may go for open system, in which case they shall assure QA and QC of the reagents provided by the vendors . The procurement details of equipment including the equipment type, brand, price as well as the basis of selection of the brand should be shared with NHM. The equipment purchased should be uniform for all laboratories of the same level.

- The procurement of equipment and reagents should be done through tender documents specific to diagnostics. These documents should be prepared by the state-level diagnostics team. The specifications of equipment and reagents for procurement should also be decided by this team. In Gujarat, the state laboratory coordination cell is the decision making body for procurement of equipment, reagents and consumables through the state corporation.

  States may use MoHFW specifications for equipment procurement.

- The procurement of equipment should only be carried out by the state-level procurement agency. States should set up a central corporation for managing all the procurement. No large equipment should be purchased locally by the health facility. Rate contracts should be established by the procurement agency for equipment and reagents and consumables on an annual basis. If health facilities urgently require any small equipment or reagents and consumables which are not included in the list of rate contract of state procurement agency, then the facility in-charge should invite bids for procurement of the same. At the same time, it should inform the state procurement agency for inclusion of the same in its rate contract. The state procurement agency should establish rate contracts for these items within one month of intimation from the health facility. The facility-in-charge should ensure timely supply and installation of the equipment/reagents and consumables.

  Gujarat, Rajasthan, Telangana and Andhra Pradesh have a central procurement agency (state medical corporation) which procures equipment for all health facilities. The state corporations procure all reagents and consumables in Gujarat and Telangana and in Andhra Pradesh, only rapid kits. In Andhra Pradesh (PPP), the service provider procures reagents and consumables for its laboratories through a centralized system.

  Gujarat and Rajasthan establish annual rate contracts for equipment, and reagents and consumables.

- At the time of procurement, the state government should ensure that the equipment vendor provides the following as complimentary services with procurement of the equipment: 3-5 years of AMC and CMC; annual calibration of equipment; training of laboratory technicians and diagnosticians on the equipment, software, biomedical waste management as well as training of technicians on phlebotomy; and annual refresher training of technicians and diagnosticians on the same.
- The list of equipment procured for each facility and the expected date of installation should be informed to the health facility. Copies of orders should be made available on the website of procurement agency. The facility in-charge should be provided the list of pre-installation requirements and should be instructed to make all the arrangements. For any advice, the health facility in-charge should be able to contact biomedical engineering division. The steps for equipment receiving and installation are as follows:

    i. Receive the consignment

    ii. Get the installation done at the prepared site

    iii. Verify all attachments and accessories as per purchase order and mark the same entries in inventory register

    iv. Check functionality of the equipment and have demonstration as well as training of Pathologist

    v. Register equipment entry in the inventory software (e-Aushadhi/any other)

    vi. After finishing with this, start tests

A suggestive checklist for equipment receipt used by Rajasthan is given in Annexure 3.

- Whenever, a new equipment is installed, the district health officer should inspect and physically verify the supplied equipment within 3 months of installation.
- The vendor should also carry out the equipment qualification testing including IQ (Installation Qualification), OQ (Operational Qualification), PQ (Performance Qualification), calibration and precision testing.
- The orders for reagents and consumables should be placed by the state-level procurement agency to the vendor (s) on a yearly basis. The delivery by the vendor (s) of these reagents and consumables should be done on a quarterly basis to the district central drug store. The state government should ensure accountability for stock-outs at the district stores and health facilities. Root cause analysis should be carried out for each episode of stock-out. For local purchase, vendors should already be identified for each district and random checks on the quality of supplied reagents should be done. Local purchase should not be allowed for rapid diagnostic test (RDT) kits and glucometer strips. Glucometer should be used at PHCs and higher facilities only for emergencies or during breakdown of analyser or reagent stock-out. There should be proper mechanisms in place for reporting stock-outs.
- The indent for equipment should be sent to the state level procurement agency. E-Aushadhi or a similar module in the laboratory information management system should be used for placing orders for reagents and consumables. The state-level diagnostics team should act as a liaison between health facilities and state-level procurement agency for approval of demand for equipment and reagents and consumables. The orders for equipment and reagents and consumables should route through this team before issuance by the state-level procurement agency.

- In Andhra Pradesh and Gujarat, the health facilities use e-Aushadhi software for placing orders for reagents and consumables for their in-house laboratories. For PPP services in Andhra Pradesh, the service provider uses a robust inventory management system for online orders and stock management. In Gujarat, the laboratory management information system has a feature for inventory management.
- During procurement of reagents, requisite standards should be ensured.
- Pre-dispatch testing of each batch should be carried out before supply of reagents (third party testing). The vendors who have supplied poor quality reagents more than once should be blacklisted.
- The States should establish testing laboratories for quality check of reagents. Till that time they should tie up with other States which have testing laboratories.

7. Establishment of a centralised supply chain

- The state should put in place a robust supply chain with online inventory management system.
- All reagents should be procured by the centralised state level agency
- The reagents should preferably be closed system for all analysers. Open system reagents could be used with robust QA/QC. Telangana and Andhra Pradesh (PPP) are using closed system reagents for majority of the equipment.
- The reagents and consumables should meet the technical specifications including the technology, sensitivity and specificity criteria etc. In Gujarat, the state technical committee is responsible for formulation of standards and specifications for procurement of equipment and reagents.
- The vendors or authorized channel partner (s) of the vendors should deliver the reagents and consumables directly to the districts. But the billing should be done by the primary vendors and the payments should be made to their accounts only.
- It should be ensured that the central district stores have the requisite infrastructure for receiving the supply from the vendors.
- Local purchase should not exceed more than 10 percent of the total inventory and should be made online with identified vendors. In Gujarat and Andhra Pradesh (in-house), local procurement is allowed only when state corporation has not been able to procure the reagents. In Andhra Pradesh (PPP), the service provider supplies reagents and consumables to its laboratories through a centralized mechanism with minimum local purchase by these laboratories.
- When the state launches the free diagnostics initiative, the estimate for quantity of reagents required at each facility could be based on patient footfall in the last year and with the assumption that 10 percent of the total footfall would require testing. The approximate percentage of each test required (data from Gujarat) is given in Annexure 4.

8. Institution of monitoring mechanisms

- State and district level diagnostics teams and the district officer-in-charge will be responsible for monitoring the free diagnostics service initiative.
- District diagnostics teams, district officers in-charge, district health officers and block CMOs should visit their respective districts and closely monitor the preparatory work for

implementation of the diagnostic services. They should visit all health facilities to check if adequate preparations have been done for launching the diagnostic services at these facilities. The visits and inspections should not merely be a fault-finding exercise, but officer in-charge should ensure that any discrepancies/lacunae are corrected at the district level. It has to be continuously followed up by the officer in-charge, till the gaps are filled. Non-compliance by any facility should be brought to the notice of the state-level diagnostics team by the officer-in-charge. Rajasthan assigned districts in-charge for close supervision of implementation of diagnostic services.

- A checklist for completion of preparatory work should be prepared and filled under supervision of officer in-charge as well as facility in-charge. In case external experts are engaged for handholding the laboratories, the checklist should be filled by them with supervision of facility in-charge. The filled checklist should be submitted to the state diagnostics team. The checklist should comprise of – civil works, furniture, IT network and laboratory information system, IEC, manpower, equipment, reagents and consumables, and record keeping. A suggestive checklist prepared by Rajasthan is given in Annexure 2.
- Monitoring indicators should be developed by the state government. A suggestive list of monitoring indicators is given in Annexure 5. Requisite infrastructure, tracking systems and details of processes to be tracked should be in place for monitoring as per monitoring indicators so that requisite monitoring could be initiated as soon as the services become operational. Andhra Pradesh (in PPP) used key performance indicators (KPIs) to closely monitor the service provider's services.
- The data capture of laboratory services should be IT enabled through a Laboratory Information Management System and be readily available real time to State and to NHM. This should specifically include –
  - Data on availability of equipment; procurement of new equipment (through centralized procurement); cost of new equipment; bidding costs should be made available. Case load of the laboratory for which equipment is being purchased and case load of laboratory for which equipment is already available to be displayed.
  - Availability of HR and gap in HR at various laboratories with list of tests and case load of each laboratory (basic laboratory/hub laboratory/mother laboratory).
  - Cost of reagent of each test parameter (centralized procurement) and bidding costs .
  - At each laboratory: Number of tests performed to be matched with reagents consumed and purchased. Equipment utilization rate (number of tests performed by each equipment)to be monitored.
  - At each Government health facility –Total patient load (OPD+IPD), Number of patients tested, types of tests conducted (conducted at health facility or sent to the hub laboratory)
  - Total money spent – State and Central for in-house and PPP
  - Turn around time of each type of test - at each Government health facility
  - Duration of breakdown in services at each Government health facility - tests not available
  - Names and contact details of State Nodal officer, State procurement officer, State technical team managing laboratory services
- States should build capacity for monitoring of services at all levels including facility level. Adequate capacity for data management and validation should be in place.

- The state government should prepare test requisition forms and provide stamps to each doctor for putting on the requisition forms. The stamp should have name, designation, facility name and employee ID of the doctor. This will enable tracking test prescriptions of doctors.
- Guidelines on clinical pathways and use of diagnostics in patient management should be available to all doctors and should be enforced especially at Primary health centres. Clinicians should receive training on use and interpretation of tests for more effective patient management.

9. Setting up of biomedical maintenance management programme (BMMP) team

A biomedical maintenance team comprising of central and district teams of biomedical engineers should be set up (in-house/PPP) for managing the equipment across the state. Also, a call centre and email facility should be set up for registering requirements/complaints for calibration, maintenance and breakdown of equipment.

Based on the gap analysis for equipment dysfunctionality, the equipment should be rectified by the BMMP team and made operational. The equipment to be condemned should be noted and new equipment should be procured for that facility in the next PIP.

Rajasthan and Andhra Pradesh have dedicated state biomedical maintenance management programmes. Rajasthan was the first state to implement this programme (e-Upkaran). In both the states, the programme has been outsourced to a single service provider and in-house biomedical engineers are monitoring the services.

10. Institution of an effective biomedical waste management programme

Although guidelines regarding universal precautions and other bio-safety practices are available since long, strict implementation is not in practice in health care setting. There is a definite need that the health care personnel take bio-safety practices seriously. For effective compliance, the facility in-charge should ensure adequate supply of personal protective equipment, availability of materials for hand washing, disinfectants etc. and set up an effective waste disposal programme for disposal of biomedical wastes.

As per BMW (Management & Handling) Rules, 1998 & the amendments thereof, a health care establishment should either set up requisite biomedical waste treatment techniques such as autoclave, microwave, hydroclave, shredder or any other technology as approved by Central Pollution Control Board/Ministry of Environment, Forest and Climate Change for treatment of bio-medical waste generated in the facility premises as a part of onsite treatment by the health facility. Prior to commencement of the onsite BMW treatment, requisite treatment of BMW at an approved common waste treatment facility (CTF) should be ensured. Health facilities in-charge should ensure final disposal of BMW by applying for CTF enrolment of their facilities.

11. Preparation of a list of frequently asked questions

A list of frequently asked questions and their responses should be prepared and circulated in all health facilities. These FAQs should address the basic concept of services. A suggestive FAQ list used in Rajasthan is mentioned in Annexure 6.

12. Development of IEC

The state government should have the information, education and communication (IEC) plan ready (materials for TV, radio, newspaper advertisements, banners, handouts etc.) for launching the services

and on an ongoing basis. Also, standardised display boards/signage for health facilities mentioning list of tests, timings of services etc. should be designed. For boards to be displayed within health facilities, the state could release budget to the health facilities or ask the facilities to use their individual budgets.

Andhra Pradesh (in PPP) conducted extensive IEC campaigns for creating awareness among the people about the free diagnostics services.

B. 2 MONTHS BEFORE THE ROLLOUT

Inspections of new/upgraded laboratories prior to commencement of operations

Laboratories should be inspected by the state and district diagnostic teams along with the team of technical experts (if engaged for setting up/upgradation of laboratories). The equipment, quality of reagents, infrastructure for cold chain (where applicable), standard operating procedures etc. should be assessed. Following activities should be completed:

i. Adequate testing of equipment, ice boxes, needle destroyers, and reagents should be complete, and results of testing should have been assessed.

ii. The state government should install small refrigerators at each health facility for storage of samples.

iii. Power back-up for the laboratory should be ensured.

iv. The state government should ensure that standard operating procedures for sample collection, transportation, storage, testing and reporting processes are sent to all health facilities.

v. For transport of samples as part of a hub and spoke model, districts (district health societies) should be asked to prepare and submit a detailed logistics plan to the state government.

vi. The training structure and curriculum for laboratory staff and diagnosticians should be in place.

vii. Quality control systems should be instituted in the preparatory phase

V. ROLLOUT PLAN

i. The diagnostics services should be rolled out in a phased manner. Services should be started in two districts in the initial two months before rolling out in the entire state. In these two districts, laboratories should start full-fledged services in 1% of facilities (each type) for the first two weeks. In parallel, a dry-run should be done for two weeks at all government health facilities in these two districts. After full-fledged implementation in these two districts for two months, the services should be extended to all the remaining districts. In these districts, the services should be first set up in the district hospitals in the first three months and then extended to sub-district hospitals in the fourth month and to CHCs and PHCs in the sixth month.

   The phased roll out would give enough time for setting up robust processes to deliver quality services right at the outset. Also, if quality and availability of services is satisfactory from the beginning, the services are likely to gain popularity among doctors at the government health facilities and will in turn foster adequate utilisation of services.

   Rajasthan, Telangana and Andhra Pradesh (in PPP) rolled out the services over a period of 3-6 months in a phased manner. Telangana also carried out a dry run of services prior to the rollout.

ii. Following should be ensured immediately after the rollout:

   a. The monitoring indicators should be used from beginning of the rollout. The states should closely monitor all aspects of services including availability of sampling services and tests at the government health facilities, cold chain, transportation (where applicable), quality assurance at laboratories, including processing of samples, testing, quality control, verification of results and training of staff.

      The state government should commence inspections of its laboratories and sampling areas at the health facilities. Government of Andhra Pradesh started inspection of laboratories and sampling stations of the service provider after few months of rollout and found gaps in certain areas. The gaps could have been plugged at the time of commencement of the services through timely inspection by the government.

   b. Audits of test prescription patterns should be enforced right from the beginning of implementation of services.

VI. OPERATIONS

1. SAMPLE COLLECTION

i. Sampling of patients should be done by laboratory technicians at all types of facilities. At PHCs with vacant positions, ANMs could be trained for conducting phlebotomy and conducting rapid diagnostic tests.

ii The OPD sampling should start at 6 am to cater to the fasting patients especially for Blood sugar samples. The maximum hours of overnight fasting beyond which the Blood sugar readings are not acceptable and will affect the glycemic control are 10-12 fasting hours. So, it is recommended to measure fasting plasma glucose after overnight fasting of 8 to 12 hours to reach the target goals for good glycemic control, and to avoid diabetic complications.

iii. In SDHs and DHs, the sampling timings for OPD should be from 6 am - 4 pm. However, laboratory technicians should be stationed round-the-clock on all days including Sundays and public holidays for sampling and testing. The sampling services for IPD and emergency should be available round the clock. In DHs, 3 laboratory technicians and in SDHs, 2 laboratory technicians should be stationed in the morning shift in the facilities with large OPD load. In the night shift and on Sundays and public holidays, 1 laboratory technician could be stationed as the patient load is less. For registration and report dispatch, separate data entry personnel should be deputed (1-3 in number depending on the workload). The human resources should be in sync with the revised guidelines of IPHS.

iv. In CHCs, FRUs and 24*7 PHCs sampling timings for OPD should be from 6 am - 3 pm. The laboratory technician should be available on call after working hours for emergency tests. 2 laboratory technicians should be stationed. For registration and report dispatch, separate personnel should be deputed at large CHCs.

v. In day care PHCs, sampling timings for OPD should be from 6 am - 12 pm. 1 laboratory technician/ ANM should be stationed in the morning shift. He/she could be incentivised to start the shift earlier at 6 am.

vi. Attendance records of laboratory technicians should be maintained by all health facilities including timings.

vii. In case no laboratory technician is available at a health facility on a particular day, a laboratory technician should be deputed from the nearby health facility which has more than one laboratory technician. It should be determined which all health facilities will be provided a laboratory technician by a particular health facility in case of absence of the technician in those facilities.

viii Trained ANMs could be deployed for phlebotomy at PHCs and CHCs on PMSMA days to support the laboratory technicians. This will help in ensuring that ANC women are not denied services or do not have to undergo long waiting times as a result of which they may opt to go to private laboratories.

ix. The laboratory technicians/trained ANMs should carry out registration, collection, labelling, and storage of samples and dispatch of the samples to the hub laboratories.

x. Data for services (number of patients/tests) should be uploaded daily on the state portal. Data should be updated only after sample dispatch so that patients are not denied services because data for that day has been uploaded.

Rajasthan has leveraged e-Aushadhi software for updation of data by the health facilities on a daily basis. In Andhra Pradesh (PPP), the service provider updates the data in the dashboard available in public domain on a real-time basis.

xi. Laboratory technicians/ANMs should be especially trained on sampling of small children and infants, as it needs more expertise than in case of sampling of adults.

xii. Sampling methodology of the laboratory technicians/ANMs should be monitored at regular intervals by the district diagnostics team.

xiii. Sample collection facilities should have and maintain appropriate first aid materials for both patient and staff needs.

Work process flow during patient registration and sample collection

i. A requisition form should be provided to the doctors with a printed list of tests. The tests should be mentioned as individual tests and not as profiles (e.g. liver function tests, anaemia profile) or group of tests (sodium/potassium/chloride).

ii. The requisition form should have an acknowledgement slip which could be teared and given to the patient after sampling.

iii. The treating doctor should fill the patient's name and put a tick mark against the tests prescribed.

iv. The patient should reach with the requisition form to the registration counter for laboratory services. In PHCs and small CHCs, the registration should be carried out by the laboratory technician/ANM.

v. However, in large CHCs and all SDHs and DHs, there should be a dedicated registration counter manned by a data entry person. The registration of patients at all facilities should be electronic and the electronic data should reach directly to the hub laboratory either online or offline (where the internet connectivity is poor).

vi. A UHID (unique health identification) number of the patient for enrolment for laboratory services should be generated. The UHID could be the Aadhaar number/registration number provided by the government health facility or the laboratory. The unique ID along with the phone number should be filled on the requisition form as well as fed electronically at the registration counter.

vii. The LIMS should have the facility to register existing patients using mobile number. The system should have a field to capture clinical diagnosis of the patient. The system should be able to bifurcate the investigations that are to be transferred to the hub laboratory from the ones to be done at the facility and generate separate acknowledgement prints for the two varieties. For samples that have to be transported to the hub laboratories, the prescription of the doctor should be scanned at the time of registration and the soft copy should be sent to the hub laboratory along with the patient registration details.

viii. In addition to UHID, barcodes should be used for sample identification. The UHID and barcode will be different numbers. All samples of a patient should be labelled with the same barcode number. Barcodes could be printed at the time of registration. Else, pre-printed barcodes could be used. In case the barcode is printed at the time of registration, the barcodes should have a prefix of facility ID (PH, CH, SD, DH) as well as OP and IP. The barcode should be put on the sampling tubes/containers after registration and before collecting the sample. Barcodes should also be put on the patient's requisition form, registration register (if entry is done manually in the register) and batch sheet (sheet prepared for the ILD personnel) for proper identification of samples. One barcode should also be put on the acknowledgement slip to be given to the patients for report collection.

ix. The laboratory technician/ANM should clearly explain to the patient about the day and time for report collection.

x. Blood samples should be collected in vacutainers. There should be no leakages of samples from the containers. The laboratory technician/ANM should ensure that all consumables for sampling including blood culture bottles (especially paediatric), PT tubes etc. are adequate in number and of good quality.

xi. For emergency samples, there should be instructions for the receipt, labelling, processing and reporting of these samples. The instructions should include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

xii. The request by doctors at government health facilities for repeat orders (testing of the same sample or re-sampling), due to unsatisfactory test report should not be communicated verbally to the hub laboratory. A repeat order form should be filled by the laboratory technician/ANM in case of re-sampling, and by the laboratory technician in case of re-testing of the same sample. For identification of repeat samples, the laboratory technician/ANM should put a sticker on the requisition form as well as on the sample containers.

xiii. Biomedical waste guidelines and universal precautions should be followed by the laboratory technicians/ANMs including presence of fully functional needle-cutter, colour-coded waste bags and personal protective gear.

Andhra Pradesh (in PPP) and Telangana (in-house) are following most of these best practices including use of UHID for registration, vacutainers for sample collection and barcodes for labelling.

2. SAMPLE TRANSPORTATION

i. The spokes should be set up in a manner that cumulative sample transportation time from multiple health facilities to the primary receiving hub laboratory should not exceed 2 hours (starting from where pick-up has started). An additional time could be factored in for transportation of advanced tests from hub laboratories to mother laboratory.

ii. Samples should be picked up from the health facilities on the same day and transported to the hub laboratory/mother laboratory for testing.

iii. Samples should be picked up once a day from PHCs, twice from CHCs//FRUs and every 1–1.5 hours from SDHs and DHs. Pick-up of emergency samples should be done within 15 minutes from SDHs and DHs and within 1 hour from CHCs. For CHCs, the reason for emergency sample pick up should be provided by the health facility in a form, which will ensure that

the service provider sends a transportation person out of turn for only those samples which actually require urgent report.

iv. The samples should be picked up from PHCs essentially not before 12 pm. In CHCs, FRUs and 24*7 PHCs, the first round of sample pick up should be at 11 am and second round of sample pick up should be at 4 pm. The sample dispatch time should be recorded electronically.

iii. Samples reaching hub laboratory from PHCs/CHCs and from the facility where hub laboratory is located, will need to be segregated into routine and advanced tests. All advanced tests from the hub laboratories will be transported to the mother laboratory of DH where advanced tests facility has been created. Samples for advanced tests should be picked up twice-at 2 pm and 6 pm from hub laboratories for transportation to the mother laboratory.

iv. The sample dispatch time should be recorded electronically by in-house laboratory technician/ ANM. Sample dispatch time at individual health facilities should be carefully decided by administrators at the health facilities to ensure that no patients are denied services because sample dispatch has already happened. At the same time, it would be important to ensure that sample transportation time is not compromised. The government health facilities should keep a record of delays in sample dispatch and also of samples which are dispatched earlier than the scheduled time.

v. A dedicated ILD person should be assigned for transportation of samples from government health facility to the hub laboratory. One ILD person could manage 2–4 PHCs, depending on the distance from the nearest hub laboratory. In addition, one ILD person each will be required for transportation of samples for advanced tests from each hub laboratory to the mother laboratory.

vi. The cold chain should be monitored throughout transportation. Data of the entire transportation should be analysed on a daily basis by the ILD person and monitored on a weekly basis by the laboratory technician of the hub laboratory.

vii. During high season and epidemics, the number of ILD persons should be increased for more frequent sample pick-up from health facilities. This will ensure that turnaround time and quality of testing are not compromised despite high test load.

viii. Requisite regulations should be followed for the transport of infectious and other diagnostic specimens so that in the event of an accident, courier staff and the general public may not be exposed to blood and body fluids. The parcel of infectious substances should be attached with a plastic envelope containing document — bio-hazardous diagnostic specimens.

ix **Cold chain**

a. Cold chain is a crucial component for maintaining sample integrity during transportation.

b. The cold chain for sample storage should be robust at all steps:

- Storage of samples at the health facilities prior to dispatch
- Transportation from PHCs/small CHCs to hub laboratories
- Transportation from hub laboratories to mother laboratories

c. In all government health facilities, the state government should provide a small refrigerator with power back-up for storage of samples awaiting dispatch and for storage of reagents.

d. For monitoring cold chain at the government health facilities, the laboratory technicians/ ANMs should be trained. Periodic surprise visits should be made at the government health

facilities by the state/district diagnostics team. In addition to other aspects, the team should check if the samples awaiting dispatch are refrigerated.

e. To ensure adequate cold chain during transportation of samples to the testing laboratories, cool boxes equipped with temperature monitoring device and containing sufficient quantity of ice packs at requisite temperature should be made available. The temperature monitoring device should monitor the temperature from sample pick up till receipt of sample at the hub/mother laboratory. The data of temperature monitoring device should be downloaded at the hub/mother laboratory.

f. For transportation to mother laboratories of different districts, couriers could be used with no compromise on cold chain maintenance.

3. REPORT DISPATCH

i. Test reports should be given as printed reports to the patients/doctors for all tests done within the health facility (including rapid tests/point-of-care tests) and at hub/mother laboratories.

   Doctors mostly do not access reports on email. However, reports should still be e-mailed to the health facilities by the hub/mother laboratories to respective doctors' individual email ids as soon as the reports are generated at the laboratories. The reports should be printed at the health facility itself from where the test was ordered. The hub/mother laboratories need not deliver the reports to the health facility.

ii. Printing stations should be made available by the state government at all facilities to enable printing of reports within the health facility, as and when the reports are ready. This will avoid delays in report dispatch as well as save on transportation of reports from hub/mother laboratory to the health facility. In the health facilities, the reports should be printed as soon as these are received and not when patients come to collect the reports which leads to increased waiting time.

iii. For non-emergency OPD samples, the report dispatch time should be from 8 am till 4 pm at DHs, SDHs, CHCs and 24*7 PHCs and from 8 am till 2 pm at day care PHCs. For IPD and emergency samples, test reports should be dispatched round the clock.

iv. The report dispatch at DHs and SDHs should be handled by a dedicated person. The report dispatch counter should be separate from the registration counter. In large CHCs, report dispatch and registration of patients should be managed by a dedicated person at a common registration and report dispatch counter.

v. At PHCs and small CHCs, report dispatch should be managed by the laboratory technician/ ANM. Patient registration for tests at PHCs could be carried out by OPD registration staff or the laboratory technician/ANM.

vi. Printed reports should be dispatched to patients or doctors by laboratory technicians/ ANMs. Handwritten reports should not be given to the patients even for rapid tests and manual tests.

   Time of printing reports at the government health facilities should be defined, recorded and closely monitored for each type of facility by the state government.

   Telangana and Andhra Pradesh (in PPP) are providing printed reports to the patients. There is also a facility for electronic report receipt at the health facilities from the hub laboratories.

4. TURNAROUND TIME

Timely results of diagnostic tests are key in timely and comprehensive management of patients. The state government should measure and monitor turnaround time of test reports.

i. Components of turnaround time

For an accurate analysis of the turnaround time for laboratory services, the starting point should be time of sample collection at the government health facility where the tests are prescribed, and the end point should be printing of reports at the health facility or receipt of electronic report at the health facility (if printing facility not available at the health facility).

For assessing efficiency of processes at different stages of the sample cycle in terms of turnaround time, the state government should monitor pre-analytical, analytical and post-analytical turnaround times separately. It would also be useful to further divide these parameters into specific components and monitor each component separately to identify areas requiring strengthening.

- Pre-analytical turnaround time could be broken into 2 components: a) for routine tests, time from sample collection to time of registration of the sample at the hub laboratory b) For advanced tests, time from sample collection to time of registration of sample at the mother laboratory.
- Analytical turnaround time could be divided as: a) time for testing b) time from testing to report verification
- Post-analytical turnaround time could be divided as: a) time from verification of report to electronic report dispatch to the health facilities b) time from electronic report dispatch of report to printing of report at the health facility.

ii. Prescribed turnaround time

- The pre-analytical time (time from sample collection for laboratory tests at the government health facility to time of registration of the sample at the testing laboratory) for routine tests should not exceed 1 hour for facilities where hub laboratory is situated within the premises of that health facility. For samples transported from distant facilities (PHCs and small CHCs), the maximum permitted pre-analytical time should be 7 hours.

For advanced tests such as cultures etc. for which samples need to be transported to mother laboratories in the same district, the preanalytical time should not be more than 2 hours for DHs and 10 hours for other facilities. For few other advanced tests including histopathology, FNAC, pap smear, HbA1C, haemoglobin electrophoresis for which samples might require transportation to another district, pre-analytical time should not be more than 20 hours.

Table 1 : Recommended Preanalytical turnaround time

Preanalytical time (Time from registration of patient for laboratory tests at the government health facility to time of registration of sample at the testing laboratory)	**PHCs, small CHCs (with basic laboratory)**	**Large CHCs, SDHs, DHs (hub laboratory located within the facility)**
Rapid diagnostic tests/point of care tests done within the health facility	1 hour	
Routine tests sent to hub laboratory at CHC/SDH/DH	7 hours	1 hour
Advanced tests sent to mother laboratory in the same district (cultures etc.)	2 hours for DH, SDH and 10 hours for other facilities	
Advanced tests sent to mother laboratory in a different district (such as histopathology, cytology, pap smear, electrophoresis)	Upto 27 hours	Upto 20 hours

- The analytical time is different for each test and is mentioned in the table in Annexure 7.
- Verification of test results should not exceed 1 hour and time from verification to electronic report dispatch should not exceed 1 hour.
- The reports received from hub laboratories should be printed within 1 hour of electronic receipt of test results. For rapid tests/point-of-care tests carried out within the health facility, the reports should be printed within 1 hour of testing.
- The test results which fall in critical range and test results for samples labelled as 'emergency' should be automatically recorded and sent through automated messaging system to the concerned doctors within 30 minutes of verification of the reports. The turnaround time for automated messaging of test results in critical range and emergency samples should be closely monitored by the state government.
- The patients should be informed about the day of collection of printed reports based on the turnaround time of the tests. For the reports which would be received on the next day of sample collection, the patient should be called to collect those reports next day and not after 2-3 days. The registration slip given to the patient at the time of registration for tests should clearly mention report collection day in the local language.
- For OPD cases, printed reports should be made available to the patients by 9 am next working day from sample collection day (for tests with analytical time upto 8 hours). For tests with analytical time of more than 8 hours, the printed reports should be made available at the health facility by 9 am on the next day of validation of test reports (as per the stipulated analytical time).
- For IPD and emergency cases, the reports should be printed as soon as these are received from the laboratory and provided to the concerned department.
- The total turnaround time (preanalytical + analytical + postanalytical) is mentioned in the table in Annexure 7.

iii. Monitoring of turnaround time

- It is recommended that the state government keeps a close watch on the turnaround time for each kind of test at each type of facility (PHCs, CHCs, SDHs, DHs) and for OPD/IPD/emergency and for routine, advanced, emergency and critical tests. The state government should also ensure that a root cause analysis for delays in test results for each kind of test and for individual government health facilities is done and monthly reports are provided by health facilities on gaps identified and actions taken to plug those gaps.
- Monitoring of the turnaround time will require a robust IT system (LIMS), which tracks the sample status almost instantaneously. This IT system should be integrated between health facilities, hub laboratories and mother laboratories; and each case should be closed only after generation of the report and its final receipt by the patient.
- For overcoming delays in the turnaround time, the state government should ensure that the facilities continually work on improving operational efficiency and monitor turnaround time at every level.
- The diagnostics teams at state and district levels need to be engaged in supervising turnaround time on a periodic basis for each facility.
- The laboratory technicians should be instructed to work towards achieving stipulated turnaround time.

- The number of ILD personnel should be sufficient.
- The number of diagnosticians (including part-time) should be adequate for quick verification of test results.
- Machines with faster processing speeds should be installed in the laboratories, for example, for TSH, fully automated analyser should be used instead of semi-automated.
- Blood and urine cultures should be available in all districts.
- The integrity of samples which are transported to the mother laboratories should be addressed. For example, in case of fluid examination, cell count and biochemistry should be done in the primary receiving hub laboratory and smear for cytological examination could be sent to the mother laboratory. Similarly, in case of peripheral blood smear, the first smear should be prepared at the time of sampling and second at the time of receipt of sample at hub laboratory instead of when the samples reach the mother laboratory. These stained smears should be sent to the mother laboratory. For urine cultures, urine samples should be plated by the laboratory technicians/ANMs at the health facility itself and the plate instead of urine sample should be transported to the mother laboratory for reporting.

  Government of Andhra Pradesh closely monitors the turnaround time of tests conducted by the service provider and levies penalties on the service provider for exceeding the prescribed turnaround time.

5. LABORATORIES

The state government should establish high quality hub laboratories at DHs, SDHs and large CHCs and basic laboratories at PHCs and small CHCs for providing requisite services under the Free Diagnostics Initiative. The infrastructure, equipment, reagents, processes, supply chain and software should be standardised across all laboratories.

Majority of in-house laboratories in Gujarat and service provider's laboratories in Andhra Pradesh (in PPP) have been set up in a standardised manner.

i. Equipment

a. All laboratories should have appropriate and adequate equipment for all designated routine and advanced tests. Annexure 1b provides the list of equipment recommended for each type of laboratory.

   Majority of equipment in the newly set up hub laboratory in Telangana and in service provider's laboratories in Andhra Pradesh (in PPP) is state-of-the-art, fully automated with interfacing.

b. The existing equipment should be utilised as suggested below:

   - Haematology analysers which are available at PHCs, CHCs, SDHs and DHs could continue to be used if they are less than 8 years old.
   - Small equipment like autoclave, weighing scale, centrifuge should continue to be used if less than 10 years old and are in/can be brought to a proper functional state.
   - Pipettes if more than 5 years old should be replaced.
   - Other large equipment, if any at DHs such as histopathology equipment should be assessed for functionality and if required be replaced.

Rajasthan and Gujarat utilised their existing equipment effectively by ensuring requisite repair and used these for provision of services under the newly launched free diagnostics scheme. Repair and maintenance workshops were conducted at zonal levels. In addition to this, new equipment was also procured.

c. The health facilities should have easy access to biomedical maintenance team. The guidelines of biomedical maintenance programme should be followed for the procedure and maximum permitted duration of breakdown. The health facilities should contact the biomedical maintenance team/vendor on the same day of breakdown of equipment. If the engineer does not visit the health facility to repair the equipment, in spite of the reminder by the health facility, the health facility in-charge should register a complaint on phone or email to the BMMP central control room. Electronic records of equipment breakdown should be maintained by the facilities as well as by the biomedical maintenance team. During breakdown, the facility should use the back-up equipment. In case of absence of back-up equipment, the health facility in-charge should ensure that the services are not denied to the patients and the samples are sent for testing to the nearest hub laboratory. The transportation of samples in such cases could be done by the laboratory technician/other staff of the health facility.

d. All laboratories should maintain electronic records for equipment calibration. All equipment should be calibrated at requisite intervals:

   - For policy on calibration and traceability of measurements, NABL 142 should be followed. The equipment should be calibrated from NPL India or NABL accredited calibration laboratory or accredited by its MRA partners having accreditation for the specific scope. In case of analytical systems such as automated analysers, the frequency of calibration should refer to the manufacturer's guidelines. Many types of equipment may be calibrated in-house by using reference materials or comparative techniques. In such cases, reference materials should demonstrate traceability to SI units or the appropriate measurement standards.
   - Equipment like centrifuge, pipettes and culture hood should also be calibrated.
   - The equipment maintenance plan should be prepared and followed.
   - Calibration of equipment should be closely monitored by the state government.
   - The health facilities should contact the vendor if timely calibrations have not been carried out. If calibrations are not carried out despite reminder by the health facility, the health facility in-charge should register a complaint on phone or email to the BMMP central control room. The biomedical maintenance programme guidelines should be followed for acceptable duration of delays in calibration by the vendor.

e. The health facilities should update the inventory of equipment and instruments including guarantee and maintenance contracts and calibration status in the online inventory management system and biomedical management system software every six months.

   Rajasthan is using its e-Upkaran software for updating inventory status of the equipment along with information on new installation, breakdown, maintenance, calibration and usage of equipment.

f. It is advised that all hub laboratories have a laboratory information system (LIS)/laboratory information management system (LIMS).

   - At least haematology analyser, biochemistry analyser, electrolyte analyser and urine analyser should be interfaced with the LIS. It is also desirable to interface coagulation analyser.

Interfacing of the equipment with the LIS will reduce pre- and post-analytical errors resulting due to manual entries. Interfacing should be monitored by the state government.

- LIMS data should be linked with GIS system to strengthen implementation, monitoring and actions required for diagnostic services.
- All laboratory based programmes such as RNTCP, HIV, NVBDCP, IDSP, NCD, RCH should be integrated in one common portal of Free Diagnostics. LIMS software should be capable to prepare L form data for IDSP, MF 2&4 for NVBDCP, MCH related laboratory data, RNTCP and HIV data in the respective formats to enable availability of integrated data and formats in the LIMS software.
- Laboratory based surveillance of communicable and non-communicable diseases should be established to detect outbreaks as well as disease patterns.

  Gujarat is using an advanced LIMS software which has most of the features mentioned above (point f).

g. Power back-up should be present in all laboratories.

ii. Reagents and consumables

a. Only quality assured reagents and closed system reagents should be procured. Consumables such as urine plates and paediatric culture bottles should be made available.

b. An inventory management system should be implemented in all laboratories:

- The facility in-charge should be accountable for inventory management for the respective facility. A senior laboratory technician should manage the inventory and provide monthly reports to the facility in-charge and laboratory director (one laboratory director will supervise multiple laboratories) on reagents consumed, indents and stock-outs. The facility in-charge/laboratory director should match reagents consumed with number of tests conducted.
- Orders should be placed online using inventory management software after every 2 months for a stock of 3 months which means that the health facilities should always have sufficient stock for 3 months.
- All laboratories should place electronic orders to the district central drug store (CDS); CDS should in turn place the orders to the central warehouse. The central warehouse should purchase the reagents and consumables from fixed vendors. The manufacturer should supply the equipment to the facilities and reagents and consumables to CDS. From CDS, the reagents and consumables should be transported to the health facilities.
- The reagents should be received at the laboratories within 1 month from the time of ordering.
- The reagents and consumables should be supplied of the latest date of manufacturing.
- During stock-outs, the facilities could borrow from their nearby facilities. Local purchase should be discouraged.
- Local purchase should be restricted to emergency situations and not exceed 10 percent of the total reagent and consumable consumption. The local purchase could be done using health facility funds. For local purchase, the central inventory management system should have a feature where database of vendors identified by the state is formed and the health facilities could do an online purchase from these vendors. Details of the purchase

(amount, reagent/consumable type and quantity, brand) therefore will be automatically fed into the centralised inventory management software of the state and local purchase could be closely monitored.

iii. Human resources

An MD/DNB/Diploma (post MBBS) in Pathology/Biochemistry/Microbiology should be designated as the nodal officer and will be responsible for at least 5 hub laboratories at DH/SDHs/CHCs. In case of shortage of diagnosticians, PhDs could be appointed as laboratory Nodal officers. The non-hub laboratories should be managed by PhDs. One PhD should be designated as the laboratory director for at least 20 non-hub basic laboratories at PHCs/small CHCs.

The laboratory nodal officer should remotely manage the laboratories and supervise them on a daily basis. The specific roles and responsibilities of the laboratory director are as follows:

a. Verify test results of hub laboratories (applicable for MD/DNB/diploma post MBBS diagnosticians only). For non-hub laboratories at PHCs and small CHCs, result verification of basic tests could be carried out by MBBS doctor at the health facility.

b. Carry out periodic inspections of their respective hub laboratories and support the state diagnostics team for annual internal audit of these laboratories.

c. Provide effective leadership of the laboratory services, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.

d. Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements when required.

e. Ensure that there are appropriate numbers of staff with the required education, training and competence to provide laboratory services that meet the needs and requirements of the users.

f. Ensure the implementation of the quality policy.

g. Implement a safe laboratory environment in compliance with good practice and applicable requirements.

h. Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results.

i. Monitor laboratory suppliers.

j. Supervise inventory of the laboratories.

k. Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations.

l. Define, implement and monitor standards of performance and quality improvement of the laboratory services.

m. Monitor all work performed in the laboratory to determine that clinically relevant information is being generated.

n. Address any complaint, request or suggestion from staff and/or users of laboratory services.

o. Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.

- All mother laboratories and hub laboratories of DHs should have a MD/DNB/Diploma (post MBBS) pathologist and a biochemist and microbiologist (MD/DNB/Diploma/ post MBBS).
- In every district, one diagnostician should act as a liaison between the mother laboratory and all the hub laboratories in that district (from where the samples for advanced tests are sent to the mother laboratory for testing).
- Each hub laboratory should have a laboratory manager who is a senior laboratory technician. The laboratory managers should report to their respective laboratory Nodal officers in addition to their facility in-charge. The manager should supervise laboratory operations, inventory, quality control, attendance of staff; carry out validation of service data; and handle technical complaints.
- Rationalisation of laboratory staff should be done. The hub laboratories at DHs, SDHs and large CHCs could have senior laboratory technicians and small CHCs and PHCs could have junior laboratory technicians. ANMs could be trained if there is a shortage of laboratory technicians at small CHCs and PHCs. The laboratory technicians from vertical programmes such as RNTCP, NACP and NVBDCP should be trained for conducting all types of tests. An integrated approach is suggested for work allocation for different kinds of laboratory technicians. This will be instrumental in providing comprehensive laboratory services to patients at all levels of facilities.
- Each hub laboratory at DH should have at least 4 technicians (at least 2 senior technicians with more than 5 years of experience) in the morning shift. Mother laboratories should have 7 technicians (at least 4 senior technicians with more than 5 years of experience) in the morning shift. In the night shift, there could be fewer technicians in the laboratories–2 in hub and 3 in mother laboratories. During high season and epidemics, the state government should arrange for extra laboratory technicians on visiting basis at its laboratories to manage the extra test load during such times (this is a common practice in private laboratories).

Gujarat carried out rationalization and multi-skilling of its existing laboratory technicians.

p. Laboratory technicians should be adequately trained on conducting tests; running controls and corrective and preventive actions required for managing out-of-range quality control results; identifying and managing erroneous results due to technical problems in equipment or testing methodology; and maintenance of records. The quality control (IQC and EQAS) should be run by senior laboratory technicians.

q. An enabling and encouraging environment should be provided to the laboratory staff to acquire new skills. The laboratory staff and those supervising the laboratories should be provided an extra allowance for making work related calls. The state government should institute mechanisms for motivating laboratory technicians -- workshops at DHs, employee of the month awards etc.

Table 2 : Number of Human Resources recommended at each level of Health facility in hub and spoke model

Type of laboratory	Estimated daily total patient load for tests & estimated laboratory tests/day in hub lab	No. of Lab Assistants (E)	No. of Junior technicians (E)	No. of Senior technicians (E)	Total no. of Lab technicians (including senior and junior lab technicians)	No. of Pathologists	No. of Biochemists	No. of Microbiologists
Mother lab at DH conducting advanced tests (Histopathology, Cytology, Electrophoresis, Cultures etc.)	150 patients; 200 tests	3 = 1 morning shift + 1 evening shift + 1 night shift	3	4	**7** Note:Maximum case load for LTs: 30 bacterial cultures and antimicrobial sensitivities/or 15 cases of Histopathology/ or 40 cases of Cytology/ or 50 cases of Electrophoresis or a mix of these. Beyond average daily case load of addition of 1 LT for additional 30 cultures, 1 LT for additional 15 cases of Histopathology, 1 LT for additional 40 cases of Cytology, 1 LT for additional 50 cases of Electrophoresis.	**2** Recommended average daily case load per Pathologist – Maximum of 25 cases of Histopathology or 30 cases of Cytology or 50 cases of Electrophoresis or a mix of these. The recommended limits will depend on the availability of Pathologists.	**0**	**1** Recommended average daily case load per Microbiologist – Maximum of 75 cultures and 100 serological tests. The recommended limits will depend on the availability of Microbiologists.
a. Hub lab at DH conducting routine tests (Clinical hematology, Clinical Biochemistry including immunoassays, Clinical	750 patients; 3000 tests	3 = 1 morning shift + 1 evening shift + 1 night shift	12 = 7 for testing (2 morning shift + 2 evening shift + 1 night shift) and 5 for sampling for DH (3 morning shift + 1 evening shift + 1 night shift).	13 (9 in main lab = 4 morning shift + 3 evening shift + 2 night shift; 4 in Blood bank = 2 morning shift + 1 evening shift +	**25** Note: Maximum case load for LTs: 400 routine tests/ or 30 bacterial cultures and antimicrobial sensitivities/or 15 cases of Histopathology/ or 40 cases of Cytology/ or 50 cases of Electrophoresis. Beyond average daily case load of 2000 routine	**3** (1 morning shift and 2 evening shift). Recommended average daily case load per Patholgist – Maximum of 200 cases of	**2** (1 morning shift and 1 evening shift). Recommended average daily case load per Biochemist – maximum of 2000 clinical	**1** Recommended average daily case load per Microbiologist – Maximum of 75 cultures and 100 serology cases

Type of laboratory	Estimated daily total patient load for tests & estimated laboratory tests/day in hub lab	No. of Lab Assistants (E)	No. of Junior technicians (E)	No. of Senior technicians (E)	Total no. of Lab technicians (including senior and junior lab technicians)	No. of Pathologists	No. of Biochemists	No. of Microbiologists
Pathology, Clinical Microbiology) b. Blood bank at DH			Night shift LT should take early morning OPD/IPD samples and take help of senior LT of night shift if patient load is high. Patient registration and report dispatch should be managed by Data entry operators.	1 night shift. For requirement of HR in blood banks conducting component separation, Drugs and cosmetics act needs to be referred to)	and advanced tests, addition of 1 LT for every 400 routine tests, 1 LT for additional 30 cultures, 1 LT for additional 15 cases of Histopathology, 1 LT for additional 40 cases of Cytology, 1 LT for additional 50 cases of Electrophoresis.	Clinical Hematology including smear microscopy and Clinical Pathology or 350 cases of Clinical Hematology/ Clinical Pathology for remote verification	biochemistry/ immunoassays/ clinical pathology . The recommended limits will depend on the availability of Biochemists. Also, in case of non availability of Biochemists, Pathologits could be recruited.	(including remote verification of serology) or a mix of these. The recommended limits will depend on the availability of Microbiologists.
a. Hub lab at SDHs conducting routine tests (Clinical hematology, Clinical Biochemistry, Clinical Pathology, Clinical Microbiology) b. Blood storage unit at SDH	250 patients; 1200 tests	2 = 1 morning shift + 1 evening shift	5 = 2 for testing (1 morning shift + 1 evening shift) and 2 for sampling of patients of SDH (2 Morning shift + 1 night shift). Night shift LT should take early morning OPD/IPD samples and take help	11 = 8 in Main lab (4 morning shift + 3 evening shift + 1 night shift) and 3 in Blood storage unit (one in each shift).	**16** Note: Maximum case load for LTs: 300 routine tests/ or 30 bacterial cultures and antimicrobial sensitivities/or 15 cases of Histopathology/ or 40 cases of Cytology/ or 50 cases of Electrophoresis. Beyond average daily case load of 2000 routine and advanced tests, addition of 1 LT for every 400 routine tests, 1 LT for additional 30 cultures, 1 LT for additional	**0**	**0**	**0**

Type of laboratory	Estimated daily total patient load for tests & estimated laboratory tests/day in hub lab	No. of Lab Assistants (E)	No. of Junior technicians (E)	No. of Senior technicians (E)	Total no. of Lab technicians (including senior and junior lab technicians)	No. of Pathologists	No. of Biochemists	No. of Microbiologists
			of senior LT of night shift if patient load is high. Patient registration and report dispatch should be managed by Data entry operators.		15 cases of Histopathology, 1 LT for additional 40 cases of Cytology, 1 LT for additional 50 cases of Electrophoresis.			
a) Hub lab at large CHCs conducting routine tests (Clinical hematology, Clinical Biochemistry, Clinical Pathology, Clinical Microbiology) b) Blood Storage unit	250 patients; 1000 tests	2 = 1 morning shift + 1 evening shift	4 = 2 for testing (1 morning shift + 1 evening shift) and 2 for sampling of patients of that CHC (Both morning shift). Patient registration and report dispatch should be managed by Data entry operators.	10 = 7 in Main lab: 3 morning shift + 3 evening shift + 1 night shift and 3 in Blood storage unit (one in each shift). Night shift LT of hub lab should take early morning OPD/IPD samples.	**14** Note: Maximum case load for LTs: 300 routine tests/or 30 bacterial cultures and antimicrobial sensitivities/or 15 cases of Histopathology/ or 40 cases of Cytology/ or 50 cases of Electrophoresis. Beyond average daily case load of 2000 routine and advanced tests, addition of 1 LT for every 400 routine tests, 1 LT for additional 30 cultures, 1 LT for additional 15 cases of Histopathology, 1 LT for additional 40 cases of Cytology, 1 LT for additional 50 cases of Electrophoresis.	**0**	**0**	**0**

Type of laboratory	Estimated daily total patient load for tests & estimated laboratory tests/day in hub lab	No. of Lab Assistants (E)	No. of Junior technicians (E)	No. of Senior technicians (E)	Total no. of Lab technicians (including senior and junior lab technicians)	No. of Pathologists	No. of Biochemists	No. of Microbiologists
Secondary care CHCs and SDHs 31-50 beds a) Basic laboratory (samples of these facilities will be sent to hub lab) b) Blood storage units		0	4 (2 morning shift +1 evening shift+1 night shift). Night shift LT should take early morning OPD/IPD samples.	3 for Blood storage unit (1 morning shift+1 evening shift+1 night shift).	**7**	**0**	**0**	**0**
Primary care CHCs and 24*7 PHCs -- Basic laboratory (samples of these facilities will be sent to hub lab)		0	3 = 1 morning shift + 1+evening shift+ 1 night shift. Night shift LT should take early morning OPD/IPD samples.	0	**3**	**0**	**0**	**0**
Basic laboratories at Day care PHCs (samples of these facilities will be sent to hub lab)		0	**1** Morning shift LT should also take early morning OPD samples. Incentive can be given for taking early morning OPD samples.	0	**1** Note: Incentive could be provided to morning shift LT to start its shift from 6 am.	**0**	**0**	**0**

iv. Training of human resources

The state government should make focused and concerted efforts for building capacity across various categories of staff, as most of the laboratories will function without direct supervision of a diagnostician. Following are some specific recommendations for capacity building:

- The state government should ensure that a training structure and curriculum is in place. Dedicated resources including a MD/DNB/Diploma Pathologist and Biochemist of government or external experts (if engaged for training) should design the trainings. The trainings should cover the following aspects:
  - Test-wise standard operating procedures which outline testing methodologies and key performance/quality requirements
  - All kinds of error-prone areas of the laboratory processes (pre-analytical, analytical and post-analytical) along with corrective and preventive actions for these
  - Errors which have already happened in the past and corrective actions taken (if any) to share learnings and to avoid similar errors by others
  - NABL standards
  - Quality management system
  - Assigned work processes and procedures
  - Documentation processes
  - Patient preparation, sample collection procedure, sample packing and transportation
  - Sample receipt and accession
  - Sample rejection criteria
  - Applicable laboratory information system
  - Health and safety, including the prevention or containment of the effects of adverse incidents, personal protective equipment
  - Biomedical waste management
  - Ethics
  - Confidentiality of patient information
- The trainings including induction trainings, orientation trainings and refresher trainings could be conducted by the government or external experts.
  - Induction/orientation trainings for laboratory technicians/laboratory managers should be conducted by a diagnostician (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/ laboratory medicine) or PhD Biochemistry/Microbiology. Duration of each training should be 15 days.
  - Refresher trainings for all laboratory technicians/laboratory managers of mother laboratories and hub laboratories should be conducted on a half yearly basis at DHs. The training should cover laboratory processes, quality control, NABL etc. The duration of each training should be 5 full days.
  - The laboratory technicians/ANMs of PHCs and small CHCs should receive refresher training on a yearly basis at DHs. Training at DHs should be conducted by a diagnostician (MD/DNB/

Diploma Biochemistry/Pathology/Microbiology/Laboratory medicine) or PhD Biochemistry/Microbiology. The duration of each training should be 2 full days.

- The laboratory technicians should also receive on-job training from district diagnostics team every month.
- For ILD personnel, refresher trainings should be conducted on a yearly basis. The duration of each training should be 1 full day.
- Diagnosticians and PhDs from the state diagnostics team; and laboratory Nodal officers and 2 senior laboratory technicians from each district diagnostics team should receive a formal 1 month induction training. They should also be given yearly training on ISO certification and NABL accreditation. In addition, the senior laboratory technicians who are part of the district diagnostics team should receive quarterly training at the DH. Training at DHs should be conducted by a diagnostician (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/Laboratory medicine) or PhD Biochemistry/Microbiology. The duration of each training at DH should be 5 full days.

- Induction trainings and refresher trainings should be followed by competency assessment of the staff. Those failing the competency assessment should be further trained before they re-join work.
- It is also important to build capacity of diagnosticians and assess quality of their work and supervision of laboratories by them. It is suggested that the diagnosticians should receive yearly training.

Gujarat has prepared laboratory training manuals and SoPs for all levels of health facilities. Laboratory technicians are being trained on quality management system, calibration etc.

v. Records

a. The quality and technical records that need to be maintained by each laboratory are mentioned below. The laboratory information system should have the provision to store and retrieve these records:

- Supplier selection and performance, and changes to the approved supplier list
- Staff qualifications, training and competency records
- Request for examination
- Records of receipt of samples (including emergency samples, samples rejected and repeat orders) in the laboratory and samples which are sent to mother laboratories or outsourced to other laboratories.
- Information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts)
- Laboratory work books or work sheets
- Instrument printouts and retained data and information
- Examination results and reports (including critical test results)
- Instrument maintenance records, including internal and external calibration records
- Calibration functions and conversion factors
- Quality control records

- Incident records and action taken
- Accident records and action taken
- Risk management records
- Non-conformities identified, and immediate or corrective action taken
- Preventive action taken
- Complaints and action taken
- Records of internal and external audits
- Inter-laboratory comparisons of examination results
- Records of quality improvement activities
- Minutes of meetings that record decisions made about the laboratory's quality management activities

b. All documents that are associated with the performance of examinations should be subject to document control. Various aspects that need to be maintained for all examination procedures are as below.

- Purpose of the examination
- Principle and method of the procedure used for examinations
- Performance characteristics (performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity)
- Type of sample (e.g. plasma, serum, urine)
- Patient preparation
- Type of container and additives
- Required equipment and reagents
- Environmental and safety controls
- Calibration procedures (metrological traceability)
- Procedural steps
- Quality control procedures
- Interferences (e.g. lipemia, haemolysis, bilirubinaemia, drugs) and cross reactions
- Principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values
- Biological reference intervals or clinical decision values
- Reportable interval of examination results
- Instructions for determining quantitative results when a result is not within the measurement interval

- Alert/critical values, where appropriate
- Laboratory clinical interpretation
- Potential sources of variation
- References

vi. Quality assurance

The state government should continually work towards improving quality of the laboratory services.

a. All laboratories should be certified under ISO 9001 expeditiously.

b. The diagnostics teams at state and district levels will be responsible for quality assurance. The teams should undergo training on ISO certification and NABL accreditation. The roles and responsibilities of the diagnostics teams with respect to quality assurance are as follows:

State diagnostics team

- Oversee quality assurance in diagnostic services for the entire state and prepare budget for requisite quality control, reagents and equipment.
- Organise trainings at district levels; prepare test-wise standard operating procedures for training of laboratory technicians.
- Assess monthly reports of quality control, turnaround time, erroneous results etc.
- Facilitate NABL accreditation of laboratories.
- Carry out internal audits of hub laboratories.

Laboratory Nodal Officers

- Inspect (physically) hub laboratories assigned to them – DHs on a monthly basis, SDHs on a quarterly basis and large CHCs on a 6-monthly basis and small CHCs and PHCs on a yearly basis.
- Support the state-level diagnostics team for conducting yearly internal audit of hub laboratories.
- Carry out internal audits of basic laboratories and sampling facilities.
- Supervise quality control and quality of pre-analytical, analytical and post-analytical processes in their laboratories.
- Carry out verification of quality control results.
- Supervise root-cause analysis of erroneous test results and corrective and preventive actions for all 'out-of-control' situations including out of reference IQC and EQAS.

Senior laboratory technicians

- Provide onsite support/troubleshooting for any breakdown of equipment and processes.
- Monitor turnaround time and transportation of samples to hub laboratories.
- Provide on-job training whenever required.
- Support the laboratory Nodal officers in inspection of the laboratories, if required.

The diagnostics teams should receive a formal 1 month training on all aspects of diagnostic services including quality control, and refresher trainings on a quarterly basis. An agency could be hired for training them.

c. Effective quality control – IQC and inter-laboratory comparison programme (EQAS/proficiency testing) should be established

NABL standards on quality control should be adhered to even if the laboratories are not NABL accredited. The quality control – IQC and EQAS/Inter-lab comparison should be established for all designated tests. For rapid tests, traceability of kits should be ensured. For cytology, histopathology, and peripheral smear examination, the diagnosticians should participate in an inter-diagnostician comparison. Inter-laboratory proficiency should be carried out for tests like prothrombin time, fluid cell count etc.

Internal quality control

- The laboratory should include a minimum of one-level QC at least once a day. However, where the number of patient samples analysed for any parameter exceeds 25 per day, the laboratory should employ 2 levels of QC at least once a day for such parameters. Further, if the number of patient samples analysed for any parameter exceeds 75 per day, the laboratory should employ 2 levels of QC at least twice a day at appropriate intervals.
- The daily QC values should be documented along with the calculation of % CV from the monthly QC data. The laboratory should maintain control charts to demonstrate stability of the analytical measuring systems.
- For haematology, the data of internal control should be plotted on control charts (L.J. charts or Cusum charts). In a small laboratory, stable controls may not be available. In these situations, precision of routine work can be monitored by performing duplicate tests on some patient samples.
- Control strains of known susceptibility should be used along with the test sample while performing drug susceptibility testing.

Inter-laboratory comparison programme

- The laboratory should participate in external quality assessment scheme (EQAS)/inter-laboratory comparison as defined in NABL 163. For those analytes where a formal EQAS is not available, the laboratory should exchange samples with other NABL accredited laboratories.
- The performance in inter-laboratory comparisons should be reviewed and discussed with relevant staff. When pre-determined performance criteria are not fulfilled (i.e. non-conformities are present), staff should participate in the implementation and recording of corrective action. The effectiveness of corrective action should be monitored. The returned results should be evaluated for trends that indicate potential non-conformities and preventive action should be taken.
- An ongoing association should be established with agencies such as CMC Vellore and AIIMS for EQAS.
- Gujarat has set up EQAS for its in-house laboratories in district hospitals and medical college hospitals. Andhra Pradesh has established EQAS and IQC for all laboratories of service provider.

QC data

- The laboratory should incorporate in the procedure, the multi-control QC rules used to detect systematic (trends or shifts) and random errors.
- Quality control data should be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions should be taken and recorded.
- The verification of IQC data should be real-time. The diagnosticians and PhDs (laboratory nodal officers) should be responsible for reporting IQC and EQAS data, managing out-of-range IQC and EQAS and guiding corrective and preventive actions.
- The laboratories should maintain electronic records for out-of-range IQC and EQAS. The corrective and preventive actions for out-of-range IQC and EQAS should be defined in MIS and records of these actions should be maintained. These records should be submitted to the state diagnostics team on a monthly basis.
- The state government should have adequate resources to monitor quality.
- The state government should build capacity of its diagnosticians, PhDs and laboratory technicians for identification of out-of-range IQC and EQAS and for its management through appropriate corrective and preventive actions. The training curriculum should incorporate training on corrective and preventive actions.

Release of test reports

- The laboratory should have a procedure to prevent the release of patient results in the event of quality control failure.
- When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results should be rejected, and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory should also evaluate the results from patient samples that were examined after the last successful quality control event.

Comparability of examination results

- There should be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these. The laboratory should document, record and, as appropriate, expeditiously act upon results from the comparisons performed.

d. The laboratories must establish and document procedures for monitoring and evaluating analysis of testing processes including procedures for resolving out-of-control situations.

e. The laboratory should employ suitable reference material traceable to international standards for calibration of measuring systems and methods. Traceability certificates for calibrators should be obtained from kit suppliers and appropriately documented.

   Prothrombin time results should contain the time taken by the patient specimen to clot and mean normal prothrombin time (MNPT) and the International Normalized Ratio (INR). MNPT (geometric/arithmetic mean of prothrombin time of 20 normal healthy individuals) should be determined for every new lot of reagent, type of reagent and the instrument used. The INR must be appropriately adjusted for every new lot of prothrombin time reagent, types of reagent, technique and instrument used.

f. Adequate number of laboratories should be set up by the state government for testing of reagents; the laboratories should achieve NABL accreditation over a period of time. Till the laboratories are set up, the state government could empanel NABL accredited private laboratories or send samples to government laboratories in other states.

Gujarat conducts third party pre-dispatch testing of each batch before supply of reagents.

vii. NABL accreditation and audits

- It is suggested that all hub laboratories should be NABL accredited for all designated tests. NABL consultants should be hired for preparatory work for NABL accreditation.
- The state government should prepare an action plan for achieving NABL accreditation.
- The state government should prepare and implement a schedule of periodic internal and external audits of all its laboratories, using robust protocols.
- Laboratories should conduct internal audit of each of its collection centre (including transportation processes from collection centre to testing laboratory) at least once a year.
- The state government should get all its laboratories audited by a third party NABL accredited laboratory.
- Audits should be conducted by the state and district diagnostics teams.
- The highlights of internal and external audits should be shared with the state government.

Andhra Pradesh (in PPP) is in the process of NABL accreditation of some of its laboratories.

viii. Assuring quality of test results

a. **Verification of test results**

- All test results should be verified by qualified MD/Diploma (post MBBS)/DNB pathologists/ biochemists/microbiologists Haematology and clinical pathology results should be validated by pathologists; biochemistry and immunoassay test results by pathologists or biochemists; and serology and microbiology test results by pathologists or microbiologists. However, rapid/point of care diagnostic tests can be validated by an MBBS doctor.
- The diagnosticians can remotely validate results of tests conducted by laboratory technicians in hub laboratories. To ensure quality in reporting, the state government should decide the maximum number of tests which can be validated by a diagnostician per day.
- In case the laboratory implements a structure of automated selection and reporting of test results within biological reference interval, then it should establish a documented procedure to ensure the following:
  - The criteria for automated selection and reporting should be defined, approved, readily available and understood by the staff. Items for consideration when implementing automated selection and reporting include algorithms for assessing validity of normal test results by matching the normal test results with results of other relevant tests of that patient, IQC results of that day for those tests, changes from previous patient values that require review.
  - The criteria should be validated for proper functioning before use and verified after changes to the system that might affect their functioning.

- There should be a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipemia) that may alter the results of the examination.
- There should be a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate.
- There should be provision for adding diagnostician's comments and for ordering re-run or re-check of samples which should reflect in the laboratory information system of the respective laboratories. For example, the software should enable the diagnostician to order preparation of blood smear in case of low platelet count and order for dilution of sample in case of abnormally high value of serum creatinine. The laboratory technician can then perform the requisite procedure as ordered by the diagnostician.
- Results selected for automated reporting should be identifiable at the time of review before release and include date and time of selection.

- Precision testing should be carried out on a daily basis for all routine test types to check accuracy of results of tests conducted by laboratory technicians who work without any direct supervision of diagnosticians.

b. Erroneous results

- Root-cause analysis should be carried out by the state diagnostics team for various aspects of inaccuracies in test results such as erroneous results, too many or too less test results outside biological reference interval, too many repeat tests requested by clinicians and out-of-range IQC and EQAS.
  - Equipment calibration, IQC and EQAS and use of good quality reagents do not guarantee that there will be no erroneous results.
  - Inaccuracies resulting due to loss of sample integrity as a result of long sample transportation times, low quality anticoagulant used in vacutainers, inadequate cold chain could also lead to erroneous results.
  - Absence of certain gold standard pre-analytical processes such as preparation of blood smear at the time of sample collection compromise the quality of reporting of platelet count test and peripheral blood smear examination.
  - Lack of relevant clinical history and specimen description in the requisition forms for cytology and histopathology specimens compromise the quality of reporting.
  - Errors arising out of manual labelling of secondary tubes and manual entry of results should also be taken into consideration.
  - Pipettes are mostly not calibrated resulting in pipetting errors.
  - Media for blood culture and urine culture needs to be of high quality.
  - Reagents for few tests have very short shelf lives and those should be monitored.
  - Erroneous results could arise when the tests are conducted without adequate corrective actions for a failed IQC.
- The state government should give clear instructions to the laboratory technicians not to conduct tests on erroneous equipment or when results are erroneous due to unknown causes.
  - Till the equipment is rectified or the root cause analysis is carried out for other technical faults, the samples for those tests should be sent to the laboratory at a nearby facility.

- Diagnosticians who validate the test results should be made responsible for monitoring erroneous results and their requisite and timely correction.
- Facilities in-charge should ensure that all events of erroneous results are recorded at health facilities and the report is sent to the state government.
- The state government should engage its diagnostics team/external experts (if engaged for monitoring quality) at state and district levels for close monitoring of significant deviations in test result values for each test and for individual facilities (separately for outpatients and inpatients) and carry out a root cause analysis on the same day with help from the doctor of that government health facility and the testing laboratory.
- The state government should keep a close watch on test result values for any significant deviations. Analytical monitoring reports should be assessed by the state government every month.
- The records of repeat orders should be maintained electronically at the laboratories and monitored for tests which are repeated most frequently. This would enable the laboratories to identify and correct the errors which are causing discrepancies in the test results.
- The health facilities should send 1 percent of samples tested at hub laboratories at CHCs and SDHs for testing to the hub laboratories at DHs for verification of test results at regular interval of 6 months.
- Doctors prescribing the tests should write detailed clinical history and specimen details especially for advanced tests like histopathology and cytology for improving accuracy of results for these tests. A copy of case summary sheet or OPD sheet of the patient could be sent to the laboratory with the specimens of histopathology, cytology and fluid. Standard templates for clinical history could be created for ease of use and legibility.

c. Sample rejection rates

- The criteria for sample rejection should be defined in the MIS and laboratory technicians should be trained on identification of criteria for sample rejection.
- Each event of sample rejection should be recorded electronically and monitored by the state diagnostics team for sample rejection rates of individual laboratories.
- The laboratories should also record the source of rejected samples – facility type, OPD/IPD etc. At the same time, laboratory technicians/ANMs should be trained for minimising sample rejection.

VII. SUPERVISION AND MONITORING

1. KEY AREAS FOR MONITORING

For continual supervision and monitoring of the services, key areas which require focus are:

a. **Access to laboratory services**

- Total number of government health facilities (DHs, SDHs, CHCs and PHCs) serviced
- Total number of patients who availed diagnostic services and total number of tests conducted, test mix, patient to test ratio, percentage of patients who were tested out of the total patients visiting the health facilities.
- Availability of services of the laboratories – number of days on which sampling services are available and number of tests that are available each day.
- Change in OOPE after rollout of the initiative:
  - Savings on diagnostics can be calculated as money saved by patients on tests which were conducted for patients at government health facilities. The assumption is that the patients would have otherwise got these tests done from private laboratories in absence of availability of these tests at the government health facilities.
  - Surveys on reduction in OOPE can be carried out.
- Change in total number of OPD and IPD patients after roll out of the free diagnostics initiative

b. **Quality of laboratory services**

- *Quality assurance at laboratories:*
  - Equipment (adequacy and availability)
  - Human resources
  - Training
  - Standard operating procedures
  - Quality of processes
  - Supply chain management
  - Internal quality control (IQC)
  - External quality assurance system (EQAS)

- Readiness of laboratories for NABL accreditation etc.

- *Test results:*
  - Incidence of erroneous results
  - Repeat sampling
  - Results outside biological reference interval
  - Relay of information to clinicians about critical results
- *Clinician satisfaction:*
  - Quality and turnaround time of test reports
  - Change in availability of tests
  - Accuracy of diagnosis
  - Clinical outcomes etc.
- *Patient satisfaction:*
  - Out-of-pocket expenditure
  - Waiting time
  - Turnaround time for receiving test reports etc.

c. **Monitoring of services**

- *Monitoring by the state government:*
  - Data validation
  - Feedback/grievance mechanism
  - Periodic reviews/audits
  - Surprise visits to government health facilities and laboratories
  - Tests which are not being done despite in-house capacity
- *Third party monitoring*

d. **Cost efficiency of the initiative**

- Per patient cost and per test cost to the government - Total budget spent and number of patients tested and number of tests conducted.
- Variety of tests conducted – cheap and expensive in cost, routine and advanced.
- Cost spent on various aspects of services – Equipment, HR, reagents and consumables, trainings, transportation, monitoring.

The local procurement of reagents, consumables, etc. should reflect on the dashboard.

2. MONITORING BY THE STATE GOVERNMENT

The state government should set up stringent monitoring mechanisms right at the outset for monitoring rollout of services under the free diagnostics initiative. Following are the key monitoring structures which can be set-up by the state government:

At the state level

a. **Dashboard**: A dashboard should be created and made available in the public domain in the initial stages of the rollout. Following features are recommended for the dashboard:

- The dashboard should be interfaced with the laboratory information system. Patient registration data from sample collection sites at the government health facilities should get automatically fed into the dashboard on a real-time basis.
- The dashboard should reflect facility-wise data on total number of patients tested, total number of tests done, total number of each type of test conducted, percentage of patients tested (out of total number of patients) and percentage of tests complying with the stipulated turnaround time.
- The dashboard should provide separate analyses for PHCs, CHCs, SDHs, DHs and OPD/IPD for indicators like total number of patients tested, total number of tests conducted, types of tests conducted and turnaround time.
- Real-time, to-date and monthly figures should be made available -- facility-wise, doctor-wise and test-wise.
- There should be provision for generating weekly and monthly MIS data analytics and reports (in the form of statistical reports, charts and data summary visuals) for better monitoring and supervision.

b. **State-level diagnostics team**: The role of the state-level diagnostics team with respect to implementation/monitoring of the free diagnostics initiative would be as follows:

- Assessing capacities for and cost-efficiency of implementing the free diagnostic initiative through their in-house laboratories.
- Selection of external experts (if applicable).
- Ongoing monitoring of in-house services based on WHO's list of monitoring indicators (Annexure 5).
- Monitoring the dashboard data daily for important indicators like facility-wise total number of patients tested and total number of tests conducted as well as state-wide turnaround time. Some important pointers for monitoring data are as follows:
  - The percentage of patients tested (out of total number of patients) should be highest in hospitals and lowest in PHCs. The patient profile at DHs is comparatively more morbid and a higher percentage of patients require tests, whereas PHCs and CHCs cater to less severe disease profiles and therefore lesser percentage of patients require tests.
  - The percentage of inpatients tested (out of total number of inpatients) should be significantly higher than the percentage of outpatients tested (out of total number of outpatients) corroborating with the fact that inpatient department caters to more severe morbidities.
  - Patient-to-test ratio should be highest in DHs followed by SDHs, CHCs and PHCs corroborating with the profile of patients at the respective facilities. The patient-to-test ratio should be significantly higher for inpatients compared to outpatients in line with the morbidity profile of inpatients.
  - Monthly and yearly trends in uptake of services (number of patients tested, number of tests conducted) should match with seasonal trends of diseases and with patient load in health facilities. This assessment should be done for individual tests at each level of

facility and for OPD and IPD. Any abnormal fluctuations in usage of services should be investigated. A steep increase in uptake would be seen in the first few months as the doctors start using the expanded basket of services.

- Inter-district comparison should be carried out for total number of patients tested, tests conducted, percentage of patients tested (out of total patients) and patient-to-test ratio. Data should be compared for each month across all kinds of facilities. The data should be analysed separately for DHs, SDHs, CHCs and PHCs.

- MIS data should be combined with periodic surveys/inspection reports of the laboratories to enable the state government to maintain a more vigilant supervision of the initiative.
- Reports from analytics of laboratory services should be integrated with data on medicines prescribed, pharmacy usage and other relevant parameters. This will not only enable closer monitoring of the initiative, but also help in tracking morbidity conditions, appropriateness of medicines prescribed, supplies needed in a facility and other decision support information for the state officials. To achieve this, integration of IT systems in the public health system at all levels will be required. The state can build technical capacity for such analytics, interpretation of reports and taking corrective measures.
- Zero samples in any facility should be investigated on a daily basis by the state-level diagnostics team. In facilities with zero samples for a long period or on multiple occasions in a month, difficulty in recruiting laboratory technicians (mainly in remote locations) and absence of government doctors at health facilities could be the reason (s).
- The health facilities which do not report data of laboratory tests should be reminded through automated SMS on a daily basis to send their data.
- Besides dashboard data, the state-level diagnostics team should carry out analysis of more detailed data on turnaround time of individual tests on a weekly basis and EQAS results on a monthly basis. The data should be examined for any deviations.
- It should facilitate linking of the LIS data with GIS system to strengthen implementation, monitoring and actions required for diagnostic services.
- It should establish laboratory based surveillance of communicable and non-communicable diseases to detect outbreaks as well as disease patterns.

  It should collect and analyse regular and formal feedback from:

  State and district officials of the Department of Health and Family Welfare

  At health facilities

  - Doctors (including administrators)
  - Laboratory technicians/ANMs and Inter-Laboratory Delivery (ILD) personnel
  - Patients

  At the laboratories

  - Diagnosticians
  - Laboratory managers
  - Laboratory technicians and other staff
- The state-level diagnostics team should assess test prescription patterns of doctors. For the assessment, doctors' data should be defined in the MIS and captured against each

patient in the MIS. A unique ID will be required for proper identification of the doctor. Also, the name and unique ID of the prescribing doctor will be required on the requisition form for tests. To this end, the state government should create a database of doctors which includes name, specialty, phone number and employee code/Aadhaar number (unique identifier). The state government should also make it mandatory for doctors to put a seal on the requisition forms; the seal should contain name and unique ID.

In the initial stages of rollout, there is a strong possibility of resistance among doctors for ordering tests due to their existing practice of referring patients to local private laboratories. The state-level diagnostics team and other senior state officials should undertake stringent measures to increase the uptake of services such as weekly video conferences with doctors and district officers as well as monitoring utilization of services with a close watch on facilities where services are underutilized. The state government should also send a circular to all the government facilities and doctors that they should refrain from prescribing tests to the private laboratories for those tests that are available at the facilities under the free diagnostics initiative. Information should be displayed in the health facilities that if any patients are asked to get their tests done from private laboratories, they can drop a complaint in the complaint box. The state government may consider not allowing any private laboratories within 5 km radius of the government health facilities.

The state-level diagnostics team should keep a close watch on the utilization of services by the doctors in terms of number of patients prescribed tests, number of each type of tests conducted, percentage of patients tested out of total patients, patient-to-test ratio. The monitoring should be for each level of facility and preferably individual facilities. An intra- specialty comparison for prescription patterns of doctors should be done monthly for prescription of each type of test. If EHR is in place, percentage of patients who were prescribed tests by each doctor (out of the total patients who consulted that doctor) could be tracked.

Fluctuations in uptake of services by doctors over a period of time should be identified and a root-cause analysis should be done. The percentage of tests (of each type) with results outside biological reference interval should be closely monitored, whether most of the test results are within the reference interval.

One of the correlations to be made is if there is any change in uptake of any particular type of test by the doctors and change in satisfaction levels of clinicians with quality and turnaround time for those tests.

Periodic and random prescription audits should be done. It would be useful to make unit heads accountable for rational prescriptions in their respective departments in hospitals. This would also enable direct supervision of junior doctors.

The state-level diagnostics team with support from state government should introduce evidence-based prescription practices to determine the upper limit to the number of tests prescribed or combination of tests in groups. The government can develop standard treatment guidelines (if not available) coupled with laboratory test prescription guidelines/test panels to ensure standardization and develop evidence based medicine (EBM) protocols specially at lower levels of the health system. Once MIS is in place for prescription of laboratory tests and pharmacy, these guidelines would be useful for standardizing care.

- The expert committee consisting of government pathologists/biochemists/microbiologists/ other reputed experts and relevant stakeholders should monitor the technical aspects of laboratories periodically. Surprise visits at the laboratories will help in spot checks on quality of reagents being used, type of laboratory technicians working in the laboratory, absenteeism

of staff, work process flow, compliance with biomedical waste management guidelines etc. If required, the government could use independent professionals/professional bodies for this monitoring.

- It should organise periodic patient and clinician satisfaction surveys for assessing patients' and clinicians' experiences with services under the free diagnostics initiative. In these surveys, it would also be important to investigate if any fee was paid by patients for getting tests done at the government health facilities.
- The government should conduct periodic security audit of its IT systems for data security and confidentiality.

c. **Monthly state-level review meetings:** These should be conducted by senior-most government officials. District health officials; and state and district diagnostics team should provide feedback in these meetings on the progress of the initiative. The teams should present progress on initiative as well as actions taken on concerns raised in the previous meetings.

d. **Availability of doctors**: The government should monitor the availability of doctors at the government health facilities.

At the district level

a. The district diagnostics team should conduct inspections of laboratories. Each hub and mother laboratory should be inspected every 6 months. The team should check: a) equipment: availability and usage status of equipment, calibration certificates of the equipment; b) availability of laboratory staff c) list of facilities catered by the laboratory and list of tests provided by the laboratory to these facilities; d) reagents and consumables: quality, inventory, purchase bills; the quantity of reagents and consumables received should be tallied with number of tests conducted in that period; e) other processes of the laboratory should be examined and records, log books, certificates of laboratory registration, biomedical waste management, pollution clearance also checked; f) log in and log out times in the main computer where reports were entered should be monitored and matched with the time of report generation on the patients' reports; g) patients should be called on the phone numbers provided in the records for whether they received their test reports.

b. During their monthly visits to the government health facilities, district health officials should inspect availability of sampling services, report dispatch services, maintenance of records, biomedical waste management, training of laboratory technicians/ANMs, their attendance records etc. Many of these visits should be surprise visits. Feedback should also be taken from doctors on various aspects of laboratory services, such as quality and turnaround time. In addition, the district officials should also inspect laboratories. District health officials should also assess monthly analytical reports on availability and utilisation of laboratory services at individual government health facilities; and quality assurance at laboratories. The district officials should provide feedback to the state officials based on an in-depth and closer monitoring of the services and their uptake. All information from the health facilities and laboratories should be validated before it is presented.

c. The district collector should conduct review meetings with district health officials; and administrators and doctors of the government health facilities once in two months to discuss progress of the initiative (other programmes/schemes could also be reviewed in this meeting).

At the health facility level

a. The laboratory director and the laboratory manager should oversee diagnostic services of their respective facilities.

b. Administrators/facilities' in-charge should take up a larger role in monitoring of services at the health facility level. They should seek feedback from the clinicians on quality and availability of tests. If required, concerns of the doctors should be escalated to the district officials. Administrators should also regularly check attendance records of laboratory technicians/ ANMs/ILD persons at the facilities. The facility administrator should be responsible for adequate uptake of call centre services (if available).

c. It is imperative to use a single patient identity (registration number) for patients availing laboratory services to maintain uniformity in identification of new and repeat patients. This would enable capturing of repeat orders by clinicians in case of inaccuracies in test results and follow-ups. This would also help in analysing the disease patterns and trends among populations. Option of using Aadhaar data with thumb impression identification of patients can be explored. To ensure that patients using laboratory services furnish their unique ID, it is suggested that a message in local language be displayed prominently in the health facility and printed on the acknowledgement slip given to patients for report collection.

d. Patients' profile – BPL/APL, tribal, ANC, gender, age group etc. should be captured to facilitate analysis of uptake of services among these segments of population.

e. Data of patients availing laboratory services should to be captured electronically at the point of sample collection for seamless flow and data integration. Also, the time of patient registration for sampling should be recorded to track the pre-analytical turnaround time. The records of all patients availing laboratory services should be captured electronically in MIS at the government health facility itself. In those states where electronic health record application is being implemented, it could be leveraged for the same.

f. Data validation at the health facility level should be robust. The facility in-charge should be given the responsibility for data validation.

   - Validation should be done for number of patients prescribed tests, number of tests prescribed etc.
   - S/he should put his/her signature on the sample dispatch register maintained by the laboratory technicians at the health facility.
   - S/he should also check whether all reports have been received from the hub/mother laboratories and whether the received reports have been printed.
   - Once the MIS/EHR is in place, data recorded by technicians/data entry operator in the MIS of the government health facilities should be validated as mentioned above. The software should have a feature to reflect completion of the process of validation.

g. In addition to daily validation, the laboratory Nodal officer and facility in-charge should also match the monthly figures on the dashboard (total number of patients tested and total number of tests conducted) with the data available at the health facility in the sample dispatch-cum-report receipt register.

h. All government health facilities should maintain attendance register/biometric attendance (at facilities which have this provision) for laboratory technicians, ANMs and ILD persons.

VIII. INFORMATION, EDUCATION AND COMMUNICATION (IEC) & GRIEVANCE REDRESSAL

IEC

i. The state government should actively promote the services available under the free diagnostics initiative to ensure wide acceptance among doctors and general public. The government should launch massive campaigns (even prior to rollout of the services) for creating awareness about the free diagnostics initiative through multiple channels including:

   a. Posters, pamphlets, banners and inserts (with OPD card and reports).

   b. Local newspapers and TV.

   c. 104 services.

   d. ANMs and ASHAs should be sensitised about the services in their regular review meetings and they should disseminate information at sub-centre and village level respectively.

   e. Medical officers should talk about the services at community meetings with people's representatives.

   f. Information should be disseminated at meetings of Gram Sabha with the government officials and public.

   g. Doctors should talk about the initiative to their patients.

ii. The list of available tests should be displayed at a prominent location at the government health facilities.

iii. A banner should be displayed at the health facilities, guiding patients to reach out to the facility in-charge in case of unavailability of tests.

iv. There should be a clear display of laboratory timings at the health facilities (in OPD, outside laboratory and at registration counter for laboratory).

GRIEVANCE REDRESSAL

i. The laboratory should have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff and other stakeholders.

ii. A call centre could be established for grievance redressal.

iii. Records should be maintained for all complaints and their investigation and the action taken.

SECTION B

Guidelines for States for implementing laboratory services under the Free Diagnostics Initiative in Public Private Partnership mode

I. SCOPE OF SERVICES UNDER FREE DIAGNOSTICS INITIATIVE

A range of complementary laboratory tests should be provided at the government health facilities through the service provider and in-house laboratories.

The state should assess its in-house capacities for extent/status of availability of the laboratory services. A gap analysis tool should be used for this purpose (Annexure 2). It should be assessed that which all tests can be offered through in-house laboratories, at various levels of facilities, using the existing in-house capacities. The capacity of the state to further strengthen its in-house services should then be assessed. The state government should then assign tests to in-house laboratories and to the service provider.

Some facilities might not require outsourcing testing services at all, and in others a mixed approach could be more suitable. The states should not preferably outsource all facilities for the entire gamut of tests. Routine tests from screening camps should not be outsourced to service provider.

The services of the private provider should be procured using a transparent competitive bidding process. Robust technical and financial criteria should be used for selection of the private provider. The state government should issue a Request for proposal (RFP) in the public domain. This will be followed by a transparent pre-bidding and bidding process under the oversight of the state-level diagnostics team–the core team responsible for managing the Free Diagnostics Initiative in the state. The state could follow a cluster approach for outsourcing the laboratory services, where different service providers could provide these services in different sets of districts (clusters). A particular service provider could be selected for more than one cluster.

Prior to advertising the RFP, the state should carry out an in-depth assessment of tests that are required at each level of facility for comprehensive care and require outsourcing. Addition of tests after signing the Agreement with the service provider might pose challenges such as denial by the service provider to provide these extra services, extra costs incurred etc.

II. OPERATIONAL MODEL

i. It is suggested that the service provider uses a hub and spoke model for providing laboratory services under the free diagnostics initiative. This will ensure availability of maximum possible number of tests at different levels of facilities in a cost-efficient way. The availability of comprehensive diagnostic services at all levels will improve patient care and minimise referral of patients. This will also curtail patients' out-of-pocket expenditure on laboratory tests.

ii. Under the hub and spoke model, laboratories of service provider should essentially be set up within/ in close proximity to all district and sub-district hospitals and preferably within/in close proximity to large CHCs. Locating laboratories inside government health facilities will reduce turnaround time for test reports; build confidence of clinicians and administrators in the services of service provider; facilitate better interaction between government doctors and diagnosticians of service provider for discussing test reports, patient history etc.; and enable easier and more effective monitoring of laboratories by hospital administrators and district health officials.

iii. The services made available by the service provider at the government health facilities should be availed only by patients prescribed tests at the government health facilities. Depending on which tests are prescribed, patients should avail services of in-house laboratories or through the service provider or both. All designated tests should be provided by the service provider on all working days.

iv. The service provider's laboratories should be categorized as L1 (Mother laboratories) and L2. Mother laboratories (L1 laboratories) should provide all designated routine and advanced tests (cultures, TSH, Histopathology etc.). L2 laboratories should provide all designated routine tests. Mother laboratories (L1 laboratories) should be set up within/in close proximity to the district hospital. The mother laboratories should cater to the facility in which it is located and to nearby PHCs and CHCs (spokes), for routine and advanced tests as well as cater to remaining health facilities in the district for their advanced tests. Few of the advanced tests (such as histopathology) could be made available at mother laboratories of only select districts in case of shortage of resources. L2 laboratories should essentially be set up inside/in close proximity to sub-district hospitals and preferably inside/in close proximity to large CHCs. The L2 laboratories should cater to the facility in which it is located and to nearby PHCs and CHCs (spokes) for routine tests. The samples for advanced tests coming from spoke facilities to L2 laboratories should be aggregated at the respective L2 laboratory and from there transported to the mother laboratory. The samples for advanced tests that need to be transported from L2 to mother laboratory should be registered first at the L2 laboratory.

v. The spokes should be set up in a manner that cumulative sample transportation time from multiple health facilities to the primary receiving laboratory should not exceed 2 hours (starting from where pick-up started). An additional time could be factored in for transportation of advanced tests from L2 laboratories to mother laboratory.

Also, each laboratory of the service provider should be mapped to its nearest laboratory for sending samples for testing during breakdown.

vi. Each mother (L1) laboratory should have diagnosticians stationed at the laboratories -- MD/DNB/ Diploma (post MBBS) in Biochemistry, Pathology and Microbiology; and laboratory medicine (optional). L2 laboratories could be managed by PhD or M.Sc. (Microbiology/Biochemistry/Laboratory medicine). The diagnosticians in the mother laboratories should remotely carry out verification of results of all routine tests and of IQC and EQAS of all L2 laboratories of that district and should sign the reports. The advanced tests conducted at mother laboratory however should be physically verified by these diagnosticians for reporting. In case of proven shortage of diagnosticians in the state, the state government could allow the service provider to use services of the government diagnosticians for verification of results of tests conducted at service provider's laboratories under the free diagnostics initiative.

   Government of Andhra Pradesh has made it mandatory for the service provider (PPP) to gets all pathology tests verified by Pathologists, biochemistry tests by Biochemists and microbiology tests by Microbiologists. Most of the tests are validated remotely by these diagnosticians.

III. PRE-ROLLOUT PLAN

The service provider should be given 90 days from the date of signing of the Agreement for preparation of rollout of services.

In the pre-rollout/preparatory phase, following measures would enable a smooth implementation:

i. The state should build capacity for monitoring of the services at all levels including facility level. A state-level diagnostics team should be formed under the leadership of a Joint Director. Members should include a Nodal officer with good administrative experience, senior laboratory staff deputed from Government medical colleges including a senior Pathologist (MD), a senior Biochemist (MD), a senior Microbiologist (MD) and 2 senior laboratory technicians; an accounts person; a senior IT person; and a data entry person. This team should be responsible for overall designing and monitoring of diagnostic services in the state. At district level, the district health officer and at the facility-level, the facility in-charge should be responsible for monitoring the implementation of the services and for ongoing supervision. State-level diagnostics team, district health officers, facility in-charges should receive training for this purpose. In addition, the nodal officer of the state-level diagnostics team should receive training on payment administration.

ii. The service provider should map the health facilities for setting up hub laboratories and spokes and prepare a detailed logistics plan and submit to the state diagnostics team.

iii. The state government should allocate requisite space within health facilities (essentially in DHs and SDHs and preferably in large CHCs) for setting up of laboratories of service provider. In case space cannot be provided within these health facilities, the service provider should identify space for setting up laboratories outside. For DHs and SDHs the laboratories should not be situated more than 10 kilometres away from the hospital. *The sample collection though should be done inside the premises of the health facilities.*

iv. Before setting up the laboratories, the service provider should send its team to study best practices of reputed institutes like CMC and AIIMS for laboratory processes (pre-analytical, analytical and post-analytical).

v. The service provider should prepare and submit standard operating procedures for sample collection, transportation, storage, testing and reporting processes to the state government.

vi. The service provider should declare its human resources and equipment at each laboratory.

vii. The service provider should design training structure and curriculum for diagnosticians and laboratory technicians and it should be duly assessed by the state diagnostics team.

Induction trainings should be conducted for all laboratory technicians. The training should be conducted by diagnosticians (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/ Laboratory medicine) or PhDs in Biochemistry/Microbiology. The duration of induction training should be 15 days for each diagnostician and technician.

viii. The service provider should put in place a robust centralised supply chain with online inventory management system and it should be duly assessed by the state diagnostics team.

ix. The state government and the service provider should put in place requisite infrastructure, tracking systems and details of processes to be tracked for monitoring as per monitoring indicators so that requisite monitoring could be initiated as soon as the services become operational.

x. The state government and the service provider should put in place adequate capacity for data management and data validation (of services).

xi. The service provider should set up the transportation system (cold chain) for transportation of samples and the system should be duly assessed by the state diagnostics team.

xii. The service provider should set up the Laboratory information system and dashboard and the system should be duly assessed by the state diagnostics team. *In case the state has a LIS for its in-house laboratories, the service provider should integrate its systems with this LIS.*

xiii. The service provider should ensure procurement and adequate testing of equipment including analysers, ice boxes, needle destroyers, and reagents. The results of the testing should be assessed.

xiv. After the service provider sets up the laboratories, these should be inspected by the service provider and the state diagnostics team before these laboratories start providing services to the government health facilities. The equipment, quality of reagents, qualification and experience of laboratory technicians, infrastructure for cold chain, standard operating procedures, laboratory information system used in the laboratories etc. should be assessed. Quality control systems should be instituted in the preparatory phase itself. The State-level diagnostics team and the drug control administration (DCA) officers could carry out these inspections. The quality teams of service provider should carry out independent inspections of its laboratories.

xv. The state government should sensitize doctors about introduction of services of a private provider to curtail any potential resistance among them.

xvi. The state government should have the information, education and communication (IEC) plan ready (materials for TV, radio, newspaper advertisements, banners, handouts etc.) for launching the services and on an ongoing basis.

xvii. The service provider should prepare test requisition forms and the state government should provide stamps to each doctor for putting on the requisition forms. The stamp should have name, designation, facility name and employee ID of the doctor.

xviii. The service provider should declare the list of empanelled laboratories to the state government (if service provider needs to outsource few advanced tests to another laboratory with due approval from state government). The empanelled laboratories should be NABL accredited for the outsourced tests. The service provider should not outsource more than 10 percent of the designated tests.

xix. The state government should install small refrigerators at each health facility for storage of samples awaiting dispatch from the health facilities. Where the refrigerator cannot be made available, the service provider should ensure availability of ice boxes with adequate number of ice packs for storing the samples.

xx. A list of frequently asked questions and their responses should be prepared and circulated in all health facilities. These FAQs should address the basic concept of services.

IV. ROLLOUT PLAN

i. After 90 days of preparatory work, the service provider should roll out its services in the state. The services should be rolled out in a phased manner. In the initial two months of roll out, only two districts should be covered. In these two districts, laboratories should start full-fledged services in 1% of facilities (each type) for the first two weeks. In parallel, the service provider should do a dry-run for two weeks at all government health facilities in these two districts. After two weeks, the services should be extended to all the facilities in the two districts.

   After full-fledged implementation in these two districts over a period of two months, the services should be extended to all the remaining districts. In these districts, the services should be first set up in DHs in the first month and then extended to SDHs in the second month and to CHCs and PHCs in the third month.

   The phased roll out would give enough time to the service provider to set up robust processes to deliver quality services right at the outset. If quality and availability of services is satisfactory from the beginning, the services are likely to gain popularity among doctors at the government health facilities and will in turn foster adequate utilisation of services at the health facilities.

ii. The state government should work closely and synergistically with the service provider for ironing out the teething issues. The state government should also provide adequate autonomy to the service provider in its day-to-day operations.

iii. Following should be ensured immediately after the rollout:

   a. The monitoring indicators should be used from beginning of the rollout. The state should closely monitor all aspects of services including availability of sampling services and tests at the government health facilities, cold chain, transportation, quality assurance at laboratories, including processing of samples, testing, quality control, verification of results and training of staff of service provider.

   b. The service provider should commence inspections of its laboratories and sampling areas at the government health facilities and these should be in turn supervised by the government through periodic inspections.

   c. Audits of test prescription patterns should be enforced right from the beginning of implementation of the initiative.

V. OPERATIONS

There should be no tests which are available to patients only on specific days. No patient should be denied any designated test by the service provider unless that test has been reported to the government as unavailable for a specified period of time.

SAMPLE COLLECTION

i. Sampling of patients should be done inside the government health facilities by the phlebotomists of the service provider. The service provider should set up sampling stations at all health facilities for sampling and report dispatch carried out by its phlebotomists.

ii. In DHs and SDHs, the sampling facility should be available round-the-clock. In CHCs and FRUs, from 6 am - 4 pm and in PHCs 6 am - 12 pm. The maximum hours of overnight fasting beyond which the Blood sugar readings are not acceptable and will affect the glycemic control are 10-12 fasting hours. So, it is recommended to measure fasting plasma glucose after overnight fasting of 8 to 12 hours to reach the target goals for good glycemic control, and to avoid diabetic complications.

iii. The service provider's phlebotomists should be stationed round-the-clock at DHs and SDHs on all days including Sundays and public holidays. In CHCs and FRUs, the phlebotomist should be available on call after working hours for emergency samples

iv. In DHs, 6-8 phlebotomists and in SDHs, 3-5 phlebotomists should be stationed in the morning shift. In the night shift and on Sundays and public holidays, the number could be less as the patient load is less. In CHCs and FRUs, 2-3 phlebotomists should be stationed from 6 am - 4 pm and in PHCs 1 phlebotomist from 6 am - 12 pm.

v. The availability of sampling services should not be hampered by long distances of health facilities from the laboratories.

vi. Attendance records of phlebotomists of service provider should be maintained by all health facilities including timings.

vii. If phlebotomist of service provider is on leave, replacement should be provided.

viii. The service provider should be flexible in deployment of its staff. For instance, more phlebotomists should be provided at PHCs and CHCs on PMSMA days to ensure that ANC mothers are not denied services or do not have to undergo long waiting times as a result of which they may opt to go to private laboratories.

ix. The service provider should not be required to station extra phlebotomists at health facilities exclusively for conducting tests of in-house laboratories. If in-house technicians are present, the phlebotomists of service provider should not conduct any in-house tests.

x. The phlebotomists of service provider should carry out registration, collection, labelling, and storage of samples and dispatch of the samples to the service provider's laboratories.

The state should ensure that the phlebotomists of service provider are given adequate space for setting up the sampling station and for seating. Adequate access should be provided for the phlebotomists to washrooms, drinking water, resting (during night shifts) and for storage of personal protective equipment and clothing.

xi. The state should ensure that patient sample collection facilities should have separate waiting and collection areas as well as a toilet facility.

xii. Service provider's phlebotomists should be especially trained on sampling of small children and infants, as it needs more expertise than in case of sampling of adults.

xiii. Sampling methodology of the service provider's phlebotomists should be monitored at regular intervals by expert committee of the state government.

xiv. The percentage of samples which are unfit for testing (haemolysed/clotted/insufficient quantity) should be monitored through data provided by service provider on rejected samples as well as by the technical committee of the government during inspection of sampling stations at health facilities and inspection of service provider's laboratories.

xv. The facility for primary sample collection should comply with the relevant requirements of ISO 15189.

WORK PROCESS FLOW

i. A requisition form should be provided to the doctors with a printed list of tests. The doctor should fill the patient's name. The phone number and unique ID should be filled by the phlebotomist. The tests should be mentioned as individual tests and not as profiles (e.g. liver function tests, anaemia profile) or group of tests (sodium/potassium/chloride).

ii. The patient should reach with the requisition form to the registration counter for laboratory services. In PHCs and small CHCs, the registration should be carried out by the phlebotomist. However, in large CHCs and all SDHs and DHs, there should be a dedicated registration counter manned by a data entry person. The registration of patients at all facilities should be electronic and data should reach directly to the service provider's laboratory either online or offline (where the internet connectivity is poor).

iii. The UHID (unique health identification) number of the patient for enrolment for laboratory services should be the Aadhaar number/registration number provided by the government health facility/ unique number provided by the laboratory. In addition, for sample identification, barcodes should be used. The UHID and barcode could be different numbers. All samples of a patient should be labelled with the same barcode number. Barcodes could be printed at the time of registration. Else, pre-printed barcodes could be used. In case the barcode is printed at the time of registration, the barcodes should have a prefix of facility ID (PH, CH, SD, DH) as well as OP and IP. The barcode should be put on the sampling tubes/containers after registration and before collecting the sample. Barcodes should also be put on the patient's requisition form, registration register (if entry is done manually in the register) and batch sheet (sheet prepared for the transportation personnel) for proper identification of samples. An acknowledgement slip should be given to the patients for report collection. One barcode should also be put on the acknowledgement slip.

iv. The prescription of the doctor should be scanned at the time of registration and the soft copy should be sent to the service provider's laboratory along with the patient registration details.

v. The phlebotomist should clearly explain to the patient about the day and time for report collection.

vi. Blood samples should be collected in vacutainers. There should be no leakages of samples from the containers. The phlebotomist should ensure that all consumables for sampling including blood culture bottles (especially paediatric), PT tubes etc. are adequate in number and of good quality.

vii. For emergency samples, there should be instructions for the receipt, labelling, processing and reporting of these samples. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

viii. The request by doctors at Government health facilities for repeat orders (testing of the same sample or re-sampling), due to unsatisfactory test report should not be communicated verbally to the service provider's laboratory. A repeat order form should be filled by the phlebotomist in case of re-sampling, and by the laboratory technician in case of re-testing of the same sample. For identification of repeat samples, the phlebotomist should put a sticker on the requisition form as well as on the sample containers.

ix. Biomedical waste guidelines and universal precautions should be followed by the phlebotomists including presence of fully functional needle-cutter, colour-coded waste bags and personal protective gear. The service provider shall follow guidelines of the independent occupier and shall follow BME waste management rule 2016 and any other amendments as applicable.

x. The service provider should have and maintain appropriate first aid materials for both patient and staff needs at sample collection facilities.

SAMPLE TRANSPORTATION

i. The spokes should be set up in a manner that cumulative sample transportation time from multiple health facilities to the primary receiving laboratory should not exceed 2 hours (starting from where pick-up has started). An additional time could be factored in for transportation of advanced tests from L2 laboratories to mother laboratory.

ii. Samples should be picked up from the health facilities on the same day and transported by the service provider to its laboratories for testing.

iii. Samples should be picked up once a day from PHCs and twice from large CHCs/FRUs and every 1–1.5 hours from SDHs and DHs. Pick-up of emergency samples should be done within 15 minutes from SDHs and DHs and within 1 hour from CHCs. For CHCs, the reason for emergency sample pick up should be provided by the health facility in a form, which will ensure that the service provider sends a transportation person out of turn for only those samples which actually require urgent report.

iv. The samples should be picked up from PHCs essentially not before 12 pm. In CHCs/FRUs/24*7PHCs the first round of sample pick up should be at 11 am and the second round of sample pick up should be at 4 pm. The sample dispatch time should be recorded electronically by service provider's phlebotomist under supervision of in-house laboratory technician. The service provider should consult with administrators at the health facilities and the state government to decide sample dispatch time at individual health facilities to ensure that no patients are denied services because sample dispatch has already happened. At the same time, it would be important to ensure that sample transportation time is not compromised. The government health facilities should keep a record of delays in sample dispatch and also of samples which are dispatched earlier than the scheduled time.

v. A dedicated pick-up/ILD person should be assigned for transportation of samples from and delivery of reports to a particular government health facility. One ILD person each should

be assigned for DHs, SDHs and large CHCs. For PHCs and remaining CHCs, each delivery personnel could manage 2–4 facilities depending on the distance from the nearest laboratory. In remote areas, the phlebotomist and the inter-laboratory delivery (ILD) person could meet halfway for sample transportation.

vi. During high season and epidemics, the service provider should increase the workforce of transportation staff for more frequent sample pick-up from health facilities. This will ensure that turnaround time and quality of testing are not compromised despite high test load.

vii. National/international regulations should be followed for the transport of infectious and other diagnostic specimens so that in the event of an accident, courier staff and the general public may not be exposed to blood and body fluids. The parcel of infectious substances should be attached with a plastic envelope containing document — Bio-hazardous diagnostic specimens.

viii. **Cold chain**

a. Cold chain is a crucial component for maintaining sample integrity during transportation.

b. The cold chain for sample storage should be robust at all steps:

- Storage of samples at the government health facilities prior to dispatch
- Transportation from health facilities to primary receiving laboratories
- Transportation from L2 to mother (L1) laboratories

c. In all government health facilities, the state government should provide a small refrigerator with power back-up for storage of samples awaiting dispatch and reagents.

d. To ensure adequate cold chain during transportation of samples to the testing laboratories, cool boxes equipped with temperature monitoring device and containing sufficient quantity of ice packs at requisite temperature should be made available. The temperature monitoring device should monitor the temperature from sample pick up till receipt of sample at the testing laboratory. The data of temperature monitoring device should be downloaded at the testing laboratory.

e. For monitoring cold chain at the government health facilities, the service provider should train the phlebotomists and conduct surprise visits at the government health facilities to ensure that the samples are refrigerated.

f. For transportation to mother laboratories of different districts, couriers could be used with no compromise on cold chain maintenance.

REPORT DISPATCH

i. Test reports should be given by the service provider as printed reports to the government health facilities. The doctors mostly do not access reports on email. However, reports should still be e-mailed to the health facilities and to respective doctors' individual email ids by the service provider's laboratories as soon as the reports are generated at the laboratories.

ii. Reports should be dispatched to patients or doctors by phlebotomists of the service provider.

iii. In SDHs and DHs, the report dispatch counter should be separate from the registration counter.

TURNAROUND TIME

Timely results of diagnostic tests are key in timely and comprehensive management of patients. The state government should measure and monitor turnaround time of test reports.

Components of turnaround time

For an accurate analysis of the turnaround time for laboratory services, the starting point should be time of sample collection at the government health facility where the tests are prescribed and the end point should be printing of reports at the health facility or receipt of electronic report at the health facility (if printing facility not available at the health facility).

For assessing efficiency of processes at different stages of the sample cycle in terms of turnaround time, the state government should monitor pre-analytical, analytical and post-analytical turnaround times separately. It would also be useful to further divide these parameters into specific components and monitor each component separately to identify areas requiring strengthening.

- Pre-analytical turnaround time could be broken into 2 components: a) for routine tests, time from sample collection to time of registration of the sample at the service provider's laboratory b) For advanced tests, time from sample collection to time of registration of sample at the mother laboratory.
- Analytical turnaround time could be divided as: a) time for testing; b) time from testing to report verification.
- Post-analytical turnaround time could be divided as: a) time from verification of report to electronic report dispatch to the health facilities. b) time from electronic report dispatch of report to printing of report at the health facility.

Prescribed turnaround time

Recommended Pre-analytical turnaround time

- The pre-analytical time (time from sample collection for laboratory tests at the government health facility to time of registration of the sample at the testing laboratory) for routine tests should not exceed 2 hours for facilities where service provider's laboratory is situated within/in close proximity of the premises of that health facility. For samples transported from distant facilities (PHCs and Primary Care CHCs), the maximum permitted pre-analytical time should be 7 hours.
- For advanced tests such as cultures etc. for which samples need to be transported to mother laboratories in the same district, the preanalytical time should not be more than 2 hours for DHs and 10 hours for other facilities. For few other advanced tests including histopathology, FNAC, pap smear, Haemoglobin electrophoresis for which samples might require transportation to another district, the pre-analytical time could be 20 hours for DHs and SDHs and 27 hours for CHCs and PHCs.

Table 1 : Recommended Preanalytical turnaround time

Preanalytical time (Time from sample collection at the government health facility to time of registration of sample at the testing laboratory)	PHCs, Primary Care CHCs	Secondary Care CHCs, SDHs, DHs (hub laboratory located within/in close proximity to the facility)
Routine tests	7 hours	2 hours for DH and SDH and preferably for large CHCs and FRUs
Advanced tests sent to mother laboratory in the same district (cultures etc.)	10 hours	2 hours for DH, SDH and 10 hours for other facilities
Advanced tests sent to mother laboratory in a different district (such as histopathology, cytology, pap smear, electrophoresis)	Up to 27 hours	Up to 20 hours

Recommended analytical turnaround time:

a. The analytical time is different for each test and is mentioned in the table in Annexure 7.

b. Analytical turnaround time for verification of test results

- Verification of test results should not exceed 1 hour.

Recommended Post analytical turnaround time

- **Electronic report dispatch**
  - The turnaround time from verification to electronic report dispatch should not exceed 5 minutes
  - The test results which fall in critical range and test results for samples labelled as 'emergency' should be automatically recorded and sent through automated messaging system to the concerned doctors within 30 minutes of verification of the reports. The turnaround time for automated messaging of test results in critical range and emergency samples will be closely monitored by the state government.
- **Printed Report**
  - The patients should be informed about the day of collection of printed reports based on the turnaround time of the tests. For the reports which would be received on the next day of sample collection, the patient should be called to collect those reports next day and not after 2-3 days. The registration slip given to the patient at the time of registration for tests should clearly mention report collection day in the local language.
  - For OPD cases, printed reports should be made available to the patients by 9 am next working day from sample collection day (for tests with analytical time upto 8 hours). For tests with analytical time of more than 8 hours, the printed reports should be made available at the health facility by 9 am on the next day of validation of test reports (as per the stipulated analytical time).
  - For IPD and emergency cases, the reports should be printed as soon as these are received from the laboratory and provided to the concerned department.

The total turnaround time (preanalytical + analytical + postanalytical) is mentioned in the table in Annexure 7.

It is recommended that the state government keeps a close watch on the turnaround time for each kind of test at each type of facility (PHCs, CHCs, SDHs, DHs) and for OPD/IPD/emergency and for routine, advanced, emergency and critical tests. The state government should also ensure that the service provider carries out a root cause analysis for delays in test results for each kind of test and for individual government health facilities and provides monthly reports on gaps identified and actions taken to plug those gaps.

Monitoring of the turnaround time

Monitoring of the turnaround time will require a robust IT system, which tracks the sample status almost instantaneously. This IT system should be integrated between health facilities, L2 laboratories and

mother laboratories; and each case is closed only after generation of the report and its final receipt by the patient:

- The state government should levy penalties on the service provider, for not meeting turnaround time, from the beginning of roll out of the services. The state government should not relax the prescribed limit of turnaround time even if requested by the service provider. For levying penalty on unmet turnaround time in per-test payment model, 50% amount should be deducted for tests that did not meet the prescribed turnaround time, when the percentage of tests not meeting turnaround time is more than 5% of total tests. If percentage of tests not meeting turnaround time is less than 5% of total tests, then 25% amount should be deducted for these tests. In per-patient payment model, the delay in turnaround time for even a single test of a patient should be counted as delayed turnaround time for the patient. If the turnaround time is delayed for more than 25% of patients, 50% amount should be deducted for all patients whose tests did not meet the prescribed turnaround time. For critical tests (Fluids, Troponin, Culture, CRP, Platelet count, Bilirubin and other tests decided by the State), 100% amount should be deducted for all patients whose tests did not meet the prescribed turnaround time. For non critical tests, if percentage of patients is less than 5% (in one month) from his invoice, then 25% amount should be deducted for all patients whose tests did not meet the prescribed turnaround time.
    - During periods of high patient load for tests, such as rainy season or during epidemics, the service provider is likely to find it difficult to manage the turnaround time. The State Government should ensure that the service provider plans in advance for such times.
    - For overcoming delays in the turnaround time, the state government should ensure that the service provider continually works on improving operational efficiency and monitor turnaround time at every level.
- All levels of service provider's team (district teams, central team) need to be engaged in supervising turnaround time on a daily basis for each facility.
- The laboratory technicians should also be instructed to work towards achieving stipulated turnaround time.
- The number of transportation/ILD personnel should be sufficient, pick up of samples should be increased to twice a day at select CHCs.
- The number of diagnosticians (including part-time) should be adequate for quick verification of test results.
- Machines with faster processing speeds should be installed in the laboratories, for example, for biochemistry tests, immunoassays etc., fully automated analysers should be used instead of semi-automated.
- Blood and urine cultures should be available in all districts.
- The work flow in laboratories should be smooth, for example, samples with different turnaround time could be segregated in colour-coded racks.
- The long pre-analytical time in case of advanced tests, samples for which are transported to the mother laboratories should be addressed. In case of fluid examination, cell count and biochemistry should be done in the primary receiving laboratory (L2) and smear for cytological examination sent to the mother laboratory. Similarly, in case of peripheral blood smear, the first smear should be prepared at the time of sampling and second at the time of receipt of sample at L2 laboratory instead of when the samples reach the mother laboratory.

These stained smears should be sent to the mother laboratory or district reporting centre for reporting. For urine cultures, urine samples should be plated by the phlebotomist at the health facility itself and the plate instead of urine sample should be transported to the mother laboratory for reporting.

PRINTED REPORTS

a. In case the service provider's laboratories are not set up within health facilities, the printing stations should be made available by the service provider at all facilities to enable printing of reports, as and when the reports are ready. This will avoid delays in report dispatch, especially for IPD and emergency patients. Also, the reports received electronically should be printed as soon as these are received (within 1 hour) and not when patients come to collect the reports which leads to increased waiting time. The state government should provide a safe place for installing printing station at the health facilities which could also be used for phlebotomy.

b. In exceptional cases, where printing facility cannot be made available, the reason (s) for the same should be documented. In such cases, the reports should be printed at service provider's laboratory. These reports should reach PHCs and CHCs by 9 am next day even for samples dispatched from the health facility after 4 pm. This applies to tests with analytical time up to 8 hours. For tests with analytical time more than 8 hours, the printed reports should reach the facility at 9 am on the next day of verification of test reports (as per the stipulated analytical time). At SDHs and DHs, the printed reports should reach the facility within 1 hour of report verification. The printed reports for emergency samples and of tests with critical results should reach these facilities within half an hour of report verification.

c. Time of printing/receipt of printed reports at the government health facilities should be defined, recorded and closely monitored for each type of facility by the service provider as well as by the state government.

PATIENTS' RECORDS

i. Records of the test reports should be maintained in the service provider's laboratory information system. However, the state government should be the sole owner of all patients' records.

ii. If the service provider outsources its IT systems, there must be a tri-partite IPR Agreement signed for all systems developed for the project among outsourced partner, service provider and the state government.

VI. SYNERGIES WITH SERVICES OF IN-HOUSE LABORATORIES

i. The patients requiring tests from in-house and service provider's laboratories should be pricked only once and the sample should be shared between service provider and in-house laboratory. The sample should not be transferred from one tube to another as it leads to over-concentration of the anticoagulant. Instead, the sample should be divided in two tubes from the sampling syringe itself. Also, the in-house laboratory technicians should not simply borrow some quantity of sample from service provider's tube at the time of testing but put the sample in a separate tube which could be saved for later if repeat testing is required. A standard operating procedure document stipulating all these details should be formulated and circulated among the staff.

ii. Adequate oversight is required for tests which are being done in-house and through the service provider at individual facilities.

iii. Monthly trends in the number of tests conducted under the PPP scheme and the number of tests conducted by in-house laboratories should be monitored separately for all levels of facilities by the state government.

iv The state government should do a regular comparison between the uptake of in-house tests and service provider's tests separately for all levels of facilities. The uptake is calculated as ratio of total number of tests conducted to total number of patients who visited the health facilities.

VII. LABORATORIES OF THE SERVICE PROVIDER

The service provider should establish high quality laboratories for providing requisite services under the Free Diagnostics Initiative. Setting up new laboratories will enable standardisation of infrastructure and processes across these laboratories. At the same time, the large scale of purchase of equipment and reagents for all laboratories will enable the service provider to negotiate good rates with the equipment and reagent vendors. On the other hand, laboratories which are existing and taken over by the service provider can face challenges in terms of availability of equipment for the requisite tests, alignment of existing software with the new centralised software, differences in work process flow etc. Therefore, the service provider should be discouraged for taking over existing laboratories.

EQUIPMENT

a. All laboratories of the service provider should have appropriate and adequate equipment for all designated routine and advanced tests. The state government should define the technology and product for each test and identify the equipment manufacturers and service provider should only procure the recommended equipment. The table below provides the list of major equipment recommended for each type of laboratory:

Table 2 : List of equipment for hub laboratories (non-Mother lab) catering to routine tests of PHCs, CHCs, SDHs

S. No.	Equipment for hub laboratories (non-Mother lab) catering to routine tests of PHCs, CHCs, SDHs,	Number of units required
Hematology		
1	3-part Haematology cell counter (analyser)	1 analyser for a maximum of 150 Hematology samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 40-60 samples per hour.
2	ESR analyser	1 analyser for a maximum of 100 ESR samples per day
3	Automated Coagulation analyser (atleast 4 channel)	1 analyser for 200 coagulation study samples per day
4	Binocular Microscope LED	
5	Centrifuge (8 tube/16 tube)	
6	Refrigerator	

S. No.	Equipment for hub laboratories (non-Mother lab) catering to routine tests of PHCs, CHCs, SDHs,	Number of units required
Biochemistry		
7	Fully automated Biochemistry analyser	1 analyser for a maximum of 400 Biochemistry samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 400 tests per hour. Permissible daily sample load for analysers with lesser or more higher throughput can be calculated accordingly.
8	Electrolyte analyser with indirect ion selective electrode	1 analyser for a maximum of 200 tests of electrolytes per day
9	Centrifuge (8 tube/16 tube)	
10	Refrigerator	
Clinical Pathology		
11	Urine analyser	1 analyser for a maximum of 150 urine samples per day
12	Binocular Microscope LED	
13	Improved neubauer chamber/Haemocytometer	
Immunology and Serology		
14	Turbidometer	1 analyser per 200 tests of turbidometry per day
15	Rotor/Shaker	
16	Centrifuge (8 tube/16 tube)	
17	Refrigerator	
Microbiology		
18	Binocular Microscope LED	

Table 3 : List of equipment for Mother laboratory at District hospital (Catering to advanced tests of DH and all health facilities in the District and routine tests of DH and the nearby spoke health facilities)

S.No.	Equipment for laboratory	Number of units required
Hematology		
1	Improved neubauer chamber/Haemocytometer	
2	5-part Haematology cell counter (analyser)	1 analyser for a maximum of 150 Hematology samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 40-60 samples per hour.
3	ESR analyser	1 analyser for a maximum of 100 ESR samples per day
4	Automated Coagulation analyser (atleast 4 channel)	1 analyser for 200 coagulation study samples per day
5	Binocular Microscope LED	
6	Electrophoresis machine	1 if required
7	High pressure liquid chromatography (HPLC)	1 machine for 100 samples of Hemoglobinopathies/ HbA1C

S.No.	Equipment for laboratory	Number of units required
8	Centrifuge (8 tube/16 tube)	1-2 depending on requirement
9	Refrigerator	
Biochemistry		
10	Fully automated Biochemistry analyser	1 analyser for a maximum of 400 Biochemistry samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 400 tests per hour. Permissible daily sample load for analysers with lesser or more higher throughput can be calculated accordingly.
11	Electrolyte analyser with indirect ion selective electrode	1 analyser for a maximum of 200 tests of electrolytes per day
12	Blood gas analyser	1 machine per 30 ICU beds
13	Centrifuge (8 tube/16 tube)	
14	Refrigerator	2-4 depending on requirement
Clinical Pathology		
15	Urine analyser	1 analyser for a maximum of 150 urine samples per day
16	Binocular Microscope LED	
17	Improved neubauer chamber/Haemocytometer	
Immunology and Serology		
18	Fully automated Chemiluminescence immunoassay	1 analyser for a maximum of 400 immunoassay and serology samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 400 tests per hour. Permissible daily sample load for analysers with lesser or more higher throughput can be calculated accordingly.
19	Fully automated ELISA reader and washer	1 analyser for a maximum of 180 samples of ELISA per day
20	Turbidometer	1 analyser per 200 tests of turbidometry per day
21	Rotor/Shaker	
22	Centrifuge (8 tube/16 tube)	
23	Refrigerator	
Microbiology equipment		
24	Binocular Microscope LED	
25	Automated Blood Culture/Liquid Media System with Smart Rapid detection	1 machine for a maximum of 50 blood culture samples per day
26	Automated Organism Identification and Antimicrobial sensitivity system	1 machine for a maximum of 200 culture samples per day
27	Culture hood/Class 1 Biosafety cabinet	
28	Incubator	
29	Laminar flow	
Histopathology equipment		
30	Binocular Microscope LED	

S.No.	Equipment for laboratory	Number of units required
31	Rotary microtome	
32	Knife sharpner	
33	Block wax trimmer	
34	Paraffin dispenser	
35	Automated tissue processor	
36	Slide staining racks	
37	Tissue floatation Bath with Digital Temperature Controller and display	
38	Antigen retrieval unit	
39	Hot Plate with Digital Temperature Controller	
40	Cryostat Instrument for Frozen Section	
41	Embedding Station	
42	Wax embel bath	
43	Bone cutter with saw	
44	Immunohistochemistry stainer	
Cytology equipment		
45	Improved neubauer chamber/Haemocytometer	
46	Binocular Microscope LED	
47	Cytocentrifuge	
48	Liquid Based Cytology System	
49	Refrigerator	
Other equipment		
50	**Flurometer**	

b. All laboratories should maintain electronic records for equipment calibration. All equipment should be calibrated on requisite intervals. Equipment like centrifuge, pipettes and culture hood should also be calibrated. The equipment maintenance plan should be prepared and followed. Calibration of equipment should be closely monitored by the state government.

c. For policy on calibration and traceability of measurements NABL 142 shall be followed. The equipment should be calibrated from NPL India or NABL accredited calibration laboratory or accredited by its MRA partners having accreditation for the specific scope. In the case of analytical systems such as automated analysers the frequency of calibration should refer to the manufacturer's guidelines. Many types of equipment may be calibrated in-house by using reference materials or comparative techniques. In such cases, reference materials should demonstrate traceability to SI units or the appropriate measurement standards.

d. Electronic records of equipment breakdown should be maintained by the service provider.

e. During breakdown, the facility should use the back-up equipment. In case of absence of back-up equipment, the service provider should ensure that the services are not denied to the patients and the samples are sent for testing to the nearest laboratory of the service provider.

f. All equipment should be interfaced with the laboratory information system including automated coagulation analyser, urine analyser, electrolyte analyser to reduce pre- and post-analytical errors resulting due to manual entries. Interfacing should be monitored by the state government.

g. Power back-up should be present in all laboratories.

REAGENTS AND CONSUMABLES

a. The service provider should declare the list of brands and vendors of reagents and consumables, which will be used in all its laboratories.

b. Only quality assured and closed system reagents should be procured.

c. A stock of at least 45 days should always be available in the laboratories.

d. A centralised inventory management system should be implemented in all laboratories.

- All laboratories should place electronic orders for reagents and consumables to mother laboratories; the mother laboratories should in turn place the orders to service provider's head office. The head office should purchase the reagents and consumables from fixed vendors.
- Local purchase should not exceed more than 1 percent of the total inventory. Local purchase should also be done online from the list of vendors declared to the state government.

HUMAN RESOURCES

a. All mother laboratories should have a MD/DNB/Diploma (post MBBS) pathologist and a biochemist and if possible a microbiologist.

b. Each L2 laboratory should be headed by a PhD or M.Sc. (Biochemistry/Microbiology/other medical laboratory fields).

c. The minimum qualifications of laboratory technicians stationed in laboratories should be DMLT. Those with B.Sc., M.Sc. degrees should be given preference at the time of recruitment. Each mother laboratory should have minimum 7 technicians (at least 4 senior technicians with more than 5 years of experience) in the morning shift. In the night shift, there could be fewer technicians. L2 laboratories should have at least 4 technicians (at least 2 senior technicians with more than 5 years of experience) in the morning shift. During high season and epidemics, the service provider should arrange for extra laboratory technicians at its laboratories to manage the extra test load during such times (this is a common practice in private laboratories).

d. Laboratory technicians should be adequately trained on conducting tests; running controls and corrective and preventive actions required for managing out-of-range quality control results; identifying and managing erroneous results due to technical problems in equipment or testing methodology; and maintenance of records. The quality control (IQC and EQAS) should be run and managed by senior laboratory technicians.

e. For phlebotomy, DMLT technicians fresh pass outs or with experience or ANMs with at least 2 years of experience could be employed.

f. The service provider should have a dedicated central quality team and a team of diagnosticians in each district which should:

- Oversee quality control and quality of pre-analytical, analytical and post-analytical processes in the laboratories.
- Carry out validation of quality control results (diagnosticians stationed in the districts) and monitor the validation (central team).

- Supervise root-cause analysis of erroneous test results and corrective and preventive actions for IQC and EQAS.
- Prepare test-wise standard operating procedures for training of laboratory technicians.
- Carry out inspection of laboratories.
- Provide technical support for NABL accreditation.
- Organise trainings for diagnosticians, technicians, phlebotomists, ILD staff and other laboratory staff.

g. District level quality assurance teams and operational teams should also be instituted. These teams should:

- Make weekly visits to the laboratories to oversee the processes and to conduct on-job training of technicians.
- Carry out minor repairs of equipment.
- Support laboratory technicians in troubleshooting for quality control and erroneous results due to technical problems
- Visit the doctors to take feedback from doctors on quality and turnaround time of tests.
- Closely supervise turnaround times and sample transportation.
- Monitor attendance of laboratory staff
- Supervise inventory in each laboratory
- Manage other requirements of or breakdowns in the laboratory, with support from district and central teams.

TRAINING

The service provider should make focused and concerted efforts for building capacity across various categories of staff, as most of the laboratories will function without direct supervision of a medical doctor (diagnostician). Following are some specific recommendations for capacity building:

a. The service provider should put in place a training structure and curriculum and dedicate at least one qualified resource (MD/PhD Biochemistry) to design and implement the trainings. The trainings should cover the following aspects:

- Test-wise standard operating procedures which outline testing methodologies and key performance/quality requirements.
- All kinds of error-prone areas of the laboratory processes (pre-analytical, analytical and post-analytical) along with corrective d preventive actions for these.
- Errors which have already happened in the past and corrective actions taken (if any) to share learnings and to avoid similar errors by others.
- NABL standards
- Quality management system
- Assigned work processes and procedures
- Documentation processes
- Patient preparation, sample collection procedure, sample packing and transportation

- Sample receipt and accession
- Sample rejection criteria
- Applicable laboratory information system
- Health and safety, including the prevention or containment of the effects of adverse incidents, personal protective equipment
- Biomedical waste management
- Ethics
- Confidentiality of patient information

b. The laboratory staff should receive induction, refresher and on-job trainings.

- Induction trainings should be conducted by a diagnostician (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/Laboratory medicine) or PhD Biochemistry/Microbiology. The training should be conducted for 15 days.
- Refresher trainings should be conducted every 6 months by a diagnostician (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/Laboratory medicine) or PhD Biochemistry/Microbiology. Each training should be conducted for 5 days.
- The laboratory technicians should also receive on-job training from quality assurance managers every month.
- For phlebotomists and transportation staff, refresher trainings should be conducted on a yearly basis. The duration of each training should be 1 full day.
- Since quality assurance managers are trainers in the training cascade and are involved in supervision of quality and troubleshooting in laboratories, they should receive rigorous quarterly training from a diagnostician at the mother laboratory. The duration of each training should be 2 full days.
- Training should focus on hands-on learning.

c. Induction trainings and refresher trainings should be followed by competency assessment of the staff. Those failing the competency assessment should be further trained before they re-join work.

d. It is also important to build capacity of diagnosticians and assess quality of their work and supervision of laboratories by them. It is suggested that the diagnosticians should receive yearly training.

RECORDS

a. The quality and technical records that need to be maintained by each laboratory are mentioned below. The Laboratory Information System should have the provision to store and retrieve these records.

- Supplier selection and performance, and changes to the approved supplier list
- Staff qualifications, training and competency records
- Request for examination
- Records of receipt of samples (including emergency samples, samples rejected and repeat orders) in the laboratory and samples which are sent to mother laboratories or outsourced to other laboratories.

- Information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts)
- Laboratory work books or work sheets
- Instrument printouts and retained data and information
- Examination results and reports (including critical test results)
- Instrument maintenance records, including internal and external calibration records
- Calibration functions and conversion factors
- Quality control records
- Incident records and action taken
- Accident records and action taken
- Risk management records
- Nonconformities identified, and immediate or corrective action taken
- Preventive action taken
- Complaints and action taken
- Records of internal and external audits
- Interlaboratory comparisons of examination results
- Records of quality improvement activities
- Minutes of meetings that record decisions made about the laboratory's quality management activities

b. All documents that are associated with the performance of examinations should be subject to document control. Various aspects that need to be maintained for all examination procedures are as below:

- Purpose of the examination
- Principle and method of the procedure used for examinations
- Performance characteristics (Performance characteristics of an examination procedure should Include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity)
- Type of sample (e.g. plasma, serum, urine)
- Patient preparation
- Type of container and additives
- Required equipment and reagents
- Environmental and safety controls
- Calibration procedures (metrological traceability)
- Procedural steps

- Quality control procedures
- Interferences (e.g. lipemia, haemolysis, bilirubinaemia, drugs) and cross reactions
- Principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values
- Biological reference intervals or clinical decision values
- Reportable interval of examination results
- Instructions for determining quantitative results when a result is not within the measurement interval
- Alert/critical values, where appropriate
- Laboratory clinical interpretation
- Potential sources of variation
- References

QUALITY ASSURANCE

The service provider should continually work towards improving quality of its services. The Agreement should clearly specify the technology of equipment to be used for each kind of test, quality of reagents to be used for testing and for internal control, mechanisms of IQC and EQAS, agencies for EQAS, cold chain monitoring and transportation of samples. Minimum qualifications and training structure for the service provider's staff should also be outlined.

a. All laboratories should be certified under ISO 9001 within 1 year of rollout.

b. **Effective quality control – IQC and Proficiency testing (EQAS/inter-laboratory comparison programme) should be established.**

NABL standards on quality control should be adhered to even if the laboratories are not NABL accredited. The quality control – IQC and EQAS/Inter-lab comparison should be established for all designated tests. For rapid tests, traceability of kits should be ensured. For cytology, histopathology, and peripheral smear examination, the diagnosticians should participate in an inter-diagnostician comparison. Inter-laboratory proficiency should be carried out for tests like prothrombin time, fluid cell count etc.

Internal Quality Control

- The laboratory should include a minimum of one-level QC at least once a day. However, where the number of patient samples analysed for any parameter exceeds 25 per day, the laboratory should employ 2 levels of QC at least once a day for such parameters. Further, if the number of patient samples analysed for any parameter exceeds 75 per day, the laboratory should employ 2 levels of QC at least twice a day at appropriate intervals.
- The daily QC values should be documented along with the calculation of %CV from the monthly QC data. The laboratory should maintain control charts to demonstrate stability of the analytical measuring systems.
- For haematology, the data of internal control should be plotted on Control Charts (L.J. Charts or Cusum Charts). In a small laboratory, stable controls may not be available. In these situations, precision of routine work can be monitored by performing duplicate tests on 10 patient samples.

- Control strains of known susceptibility should be used along with the test sample while performing drug susceptibility testing.

Proficiency testing

- The laboratory should participate in External Quality Assessment Scheme (EQAS)/Inter-laboratory comparison as defined in NABL 163. For those analytes where a formal EQAS is not available, the laboratory should exchange samples with other NABL accredited laboratories.
- The performance in inter-laboratory comparisons should be reviewed and discussed with relevant staff. When pre-determined performance criteria are not fulfilled (i.e. non-conformities are present), staff should participate in the implementation and recording of corrective action. The effectiveness of corrective action should be monitored. The returned results should be evaluated for trends that indicate potential non-conformities and preventive action should be taken.
- An ongoing association should be established with agencies such as CMC Vellore, National Institute of Biologicals, AIIMS etc. for EQAS.

QC data

- The laboratory should incorporate in the procedure, the multi-control QC rules used to detect systematic (trends or shifts) and random errors.
- Quality control data should be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions should be taken and recorded.
- The validation of IQC data should be real-time. The diagnosticians should be responsible for reporting IQC and EQAS data, managing out-of-range IQC and EQAS and guiding corrective and preventive actions.
- The laboratories should maintain electronic records for out-of-range IQC and EQAS. The corrective and preventive actions for out-of-range IQC and EQAS should be defined in MIS and records of these actions should be maintained. These records should be submitted to the state diagnostics team on a quaterly basis.

Release of test reports

- The laboratory should have a procedure to prevent the release of patient results in the event of quality control failure.
- When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results should be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory should also evaluate the results from patient samples that were examined after the last successful quality control event.

Comparability of examination results

- There should be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these. The laboratory should document, record and, as appropriate, expeditiously act upon results from the comparisons performed.

- The laboratories must establish and document procedures for monitoring and evaluating analysis of testing processes including procedures for resolving out-of-control situations.
- The laboratory should employ suitable reference material traceable to international standards for calibration of measuring systems and methods. Traceability certificates for calibrators should be obtained from kit suppliers and appropriately documented. For example, Prothrombin Time results should contain the time taken by the patient specimen to clot and mean normal prothrombin time (MNPT) and the International Normalized Ratio (INR). MNPT (geometric/arithmetic mean of prothrombin time of 20 normal healthy individuals) should be determined for every new lot of reagent, type of reagent and the instrument used. The INR must be appropriately adjusted for every new lot of prothrombin time reagent, types of reagent, technique and instrument used.
- The service provider should have adequate resources to monitor quality.
- The service provider should build capacity of its diagnosticians, technicians and quality team for identification of out-of-range IQC and EQAS and for its management through appropriate corrective and preventive actions. The training curriculum should incorporate training on corrective and preventive actions.
- An independent body should review the appropriateness of corrective and preventive actions for quality control.
- An ongoing association should be established with agencies such as CMC Vellore and AIIMS for EQAS.

NABL accreditation and audits

- The service provider should initiate the accreditation process of all the laboratories within 6 months of operationalization of the laboratories.
- All Mother laboratories of service provider should be NABL accredited for all designated tests within 2 years of signing the Agreement. All remaining laboratories of service provider should be NABL accredited for all designated tests within 3 years of signing the Agreement. 5 % incentive shall be given on per tests cost to NABL accredited Labs for the tests defined in scope of work. The Service provider shall renew the NABL accreditation for all these laboratories for all tests every two years
- The service provider should submit an action plan to the state government for achieving NABL accreditation.
- The service provider should outsource tests to only those private laboratories which are NABL accredited for those tests. The outsourcing should be restricted and be carried out only for select advanced tests and after taking approval from state authority.
- The service provider should prepare and implement a schedule of periodic internal and external audits of all its laboratories, using robust protocols.
- The service provider should get all its laboratories audited by a third party NABL accredited laboratory.
- Diagnosticians of service provider in each district should conduct half-yearly inspections and yearly internal audits of the laboratories of their respective districts. The service provider should also conduct internal audit of each of its sample collection sites at government health facilities (including transportation processes from sample collection sites to testing laboratory) at least once a year.
- The central quality team of the service provider should oversee all audits.

- The highlights of internal and external audits should be shared with the state government on an annual basis.

Assuring quality of test results

Verification of test results

- All test results should be verified by qualified MD/Diploma (post MBBS)/DNB post MBBS pathologists/biochemists/microbiologists/laboratory medicine. Haematology and clinical pathology results should be validated by pathologists; biochemistry and immunoassay test results by biochemists/pathologists/laboratory medicine; and serology and microbiology test results by microbiologists.
- In case the laboratory implements a structure of automated selection and reporting of test results within biological reference interval, then it should establish a documented procedure to ensure the following:
  - The criteria for automated selection and reporting should be defined, approved, readily available and understood by the staff. Items for consideration when implementing automated selection and reporting include algorithms for assessing validity of normal test results by matching the normal test results with results of other relevant tests of that patient, IQC results of that day for those tests, changes from previous patient values that require review.
  - The criteria should be validated for proper functioning before use and verified after changes to the system that might affect their functioning.
  - There should be a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipemia) that may alter the results of the examination.
  - There should be a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate.
  - There should be provision for adding diagnostician's comments and for ordering re-run or re-check of samples which should reflect in the laboratory information system of the respective laboratories. For example, the software should enable the diagnostician to order preparation of blood smear in case of low platelet count and order for dilution of sample in case of abnormally high value of serum creatinine. The laboratory technician can then perform the requisite procedure as ordered by the diagnostician.
  - Results selected for automated reporting should be identifiable at the time of review before release and include date and time of selection.
- Precision testing should be carried out on a daily basis for all routine test types to check accuracy of results of tests conducted by laboratory technicians who work without any direct supervision of diagnosticians.

Erroneous results and 'out-of-control situations'

- Root-cause analysis should be carried out by the service provider's quality team for various aspects of inaccuracies in test results such as erroneous results, too many or too less test results outside biological reference interval, too many repeat tests requested by clinicians and out-of-range IQC and EQAS. Some of the common reasons for inaccuracies in tests results are:
  - Lack of proper equipment calibration, IQC and EQAS and use of poor quality reagents.

- Loss of sample integrity as a result of long sample transportation times, low quality anticoagulant used in vacutainers, inadequate cold chain etc.
- Absence of certain gold standard pre-analytical processes such as preparation of blood smear at the time of sample collection (these compromise the quality of reporting of platelet count test and peripheral blood smear examination).
- Lack of relevant clinical history and specimen description in the requisition forms for cytology and histopathology specimens.
- Manual labelling of secondary tubes and manual entry of results.
- Lack of caliberation of pipettes.
- Poor quality media for blood culture and urine culture.
- Short shelf lives of reagents for few tests and lack of monitoring of this.
- Tests being conducted without adequate corrective actions for a failed IQC.

- The service provider should give clear instructions to the laboratory technicians not to conduct tests on erroneous equipment or when results are erroneous due to unknown causes.
  - Till the equipment is rectified or the root cause analysis is carried out for other technical faults, the samples for those tests should be sent to the nearby laboratories of the service provider.
  - In case re-routing of samples is not possible, the service provider should stop accepting samples for those tests and inform the health facilities about unavailability of those tests for the specified period.
  - Once the tests become available, the facilities should again be informed.
- Diagnosticians of the service provider who validate the test results should be made responsible for monitoring erroneous results and their requisite and timely correction.
- Administrators of the government health facilities should ensure that all events of erroneous results are recorded at health facilities and the report is sent to the state government.
- The service provider should engage its quality team at all levels – head of quality, district managers, diagnosticians and quality assurance managers for close monitoring of significant deviations in test result values for each test and for individual facilities (separately for outpatients and inpatients) and carry out a root cause analysis on the same day with help from the doctor of that government health facility and the testing laboratory.
- The state government should keep a close watch on test result values for any significant deviations. Analytical monitoring reports should be assessed by the state government every month.
- The records of repeat orders should be maintained electronically at the service provider's laboratories and monitored for tests which are repeated most frequently. This would enable the laboratories to identify and correct the errors which are causing discrepancies in the test results.
- For the initial 6 months, the service provider should send 1 percent of samples tested at L2 laboratories for testing to the mother laboratories for verification of test results of its L2 laboratories.
- The service provider should engage an independent body to review the appropriateness of corrective and preventive actions for erroneous results etc.

- Doctors prescribing the tests should write detailed clinical history and specimen details especially for advanced tests like histopathology and cytology for improving accuracy of results for these tests. A copy of case summary sheet or OPD sheet of the patient could be sent to the laboratory with the specimens of histopathology, cytology and fluid. Standard templates for clinical history could be created for ease of use and legibility.
- A regular and structured inter-laboratory comparison of in-house laboratories and service provider's laboratories should be instituted for relevant tests to allay any quality-related concerns of the doctors. These comparisons would also enable identification of discrepancies in test outcomes of the two laboratories.

SAMPLE REJECTION RATES

- The criteria for sample rejection should be defined in the MIS of the service provider and laboratory technicians should be trained on identification of criteria for sample rejection.
- Each event of sample rejection should be recorded electronically and monitored by service provider's central quality team for sample rejection rates of individual laboratories.
- The laboratories should also record the source of rejected samples – facility type, OPD/ IPD etc. At the same time, the service provider should train its phlebotomists for minimising sample rejection.

VIII. SUPERVISION AND MONITORING

A dashboard should be created and made available in the public domain by the service provider in the initial stages of the rollout. Key performance indicators shall be provided to Service provider by the Contracting authority prior to project implementation.

1. For continual supervision and monitoring of the services, key areas requiring focus are

a. **Access to laboratory services –** service provider's and in-house

- Total number of government health facilities (DHs, SDHs, CHCs and PHCs) serviced by the service provider and turnaround time for commencement of its services.
- Total number of patients who availed diagnostic services through service provider's and in-house laboratories and total number of tests conducted, test mix, patient to test ratio, percentage of patients who were tested out of the total patients visiting the health facilities
- Availability of services of the service provider and in-house laboratories – number of days on which sampling services are available and number of tests that are available each day.
- Change in OOPE after rollout of the initiative:
  - Savings on diagnostics can be calculated as money saved by patients on tests which were provided through the service provider at government health facilities. The assumption is that if these tests were not provided at the government health facility, the patients would have gone to the private laboratories for these tests and incurred out-of-pocket expenditure.
  - Surveys on reduction in OOPE can be carried out.
- Change in total number of OPD and IPD patients after roll out of the free diagnostics initiative

b. **Quality of laboratory services** – service provider's and in-house

- *Quality assurance at laboratories:*
  - Equipment (adequacy and availability)
  - Human resources
  - Training
  - Standard operating procedures

- Quality of processes
- Supply chain management
- Internal quality control (IQC)
- Proficiency testing (External quality assurance system/Interlaboratory comparison)
- Readiness of service provider for NABL accreditation etc.

- *Test results:*
  - Incidence of erroneous results
  - Repeat sampling
  - Test results outside biological reference interval
  - Relay of information to clinicians about critical results
- *Clinician satisfaction:*
  - Quality and turnaround time of test reports
  - Change in availability of tests
  - Accuracy of diagnosis
  - Change in clinical outcomes etc.
- *Patient satisfaction:*
  - Out-of-pocket expenditure
  - Waiting time
  - Turnaround time for receiving test reports etc.

c. **Monitoring of services**

- *Monitoring by the state government:*
  - Data validation
  - Feedback/grievance mechanism
  - Periodic reviews/audits
  - Surprise visits to government health facilities and laboratories
  - Tests which are being outsourced despite in-house capacity
  - Penalties to private providers etc.
- *Monitoring by the service provider:*
  - Allocation of resources for monitoring
  - Feedback
  - Surprise visits
  - Audits etc.
- *Third party monitoring*

d. **Adherence of service provider to Agreement clauses**

e. **Satisfaction of service provider**

- Payments: Procedure for submitting bills for reimbursement, periodicity and mode of payments, challenges (if any) in receiving payments etc. *as per the approved implementation manual.*
- Support from government for rollout of services: Provision of requisite infrastructure etc.*as per the approved implementation manual.*

f. **Cost efficiency of the initiative**

2. MONITORING BY THE STATE GOVERNMENT

The state government should set up stringent monitoring mechanisms right at the outset for monitoring rollout of services under the Free Diagnostics Initiative. Following are the key monitoring structures which can be set-up by the state government:

A. At the state level

a. A dashboard should be created and made available in the public domain by the service provider in the initial stages of the rollout. Following features are recommended for the dashboard:

- The dashboard should be interfaced with the laboratory information system. Patient registration data from sample collection sites at the government health facilities should get automatically fed into the dashboard on a real-time basis.
- The dashboard should reflect facility-wise data on total number of patients tested, total number of tests done, total number of each type of test conducted, percentage of patients tested (out of total number of patients) and percentage of tests complying with the stipulated turnaround time. The state government should provide data on total number of patients (outpatients and inpatients) at individual facilities to the service provider at least on a monthly basis to enable calculation of percentage of patients tested.
- The dashboard should provide separate analyses for PHCs, CHCs, SDHs, DHs and OPD/IPD for indicators like total number of patients tested, total number of tests conducted, types of tests conducted and turnaround time. Monthly trends of all these parameters should be studied for monitoring utilisation of services. The state government should also monitor facility-wise and doctor-wise utilisation of each kind of test.
- Real-time, to-date and monthly figures should be made available.
- There should be provision for generating weekly and monthly MIS data analytics and reports (in the form of statistical reports, charts and data summary visuals) for better monitoring and supervision.

b. **Role of the state-level diagnostics team**

The role of State-level diagnostics team with respect to implementation/monitoring of the free diagnostics initiative would be as follows:

- Assessing capacities for and cost-efficiency of implementing the free diagnostic initiative through their in-house laboratories.
- Institution of a cross-functional team for assessment of bids and selection of service provider(s).
- Ongoing monitoring of PPP servces based on list of KPIs and monitoring indicators (Annexure 8).

- Monitoring the dashboard data daily for important indicators like facility-wise total number of patients tested and total number of tests conducted as well as state-wide turnaround time. Some important pointers for monitoring data are as follows:
    - The percentage of patients tested (out of total number of patients) should be highest in hospitals and lowest in PHCs. The patient profile at DHs is comparatively more morbid and a higher percentage of patients require tests, whereas PHCs and CHCs cater to less severe disease profiles and therefore lesser percentage of patients require tests.
    - The percentage of inpatients tested (out of total number of inpatients) should be significantly higher than the percentage of outpatients tested (out of total number of outpatients) corroborating with the fact that inpatient department caters to more severe morbidities.
    - Patient-to-test ratio should be highest in DHs followed by SDHs, CHCs and PHCs corroborating with the profile of patients at the respective facilities. The patient-to-test ratio should be significantly higher for inpatients compared to outpatients in line with the morbidity profile of inpatients.
    - Monthly and yearly trends in uptake of services (number of patients tested, number of tests conducted) should match with seasonal trends of diseases and with patient load in health facilities. This assessment should be done for individual tests at each level of facility and for OPD and IPD. Any abnormal fluctuations in usage of services of service provider should be investigated. A steep increase in uptake would be seen in the first few months as the doctors start using the services of service provider.
- Inter-district comparison should be carried out for total number of patients tested, tests conducted, percentage of patients tested (out of total patients) and patient-to-test ratio. Data should be compared for each month across all kinds of facilities. The data should be analysed separately for DHs, SDHs, CHCs and PHCs.
- MIS data should be combined with periodic surveys/inspection reports of the government health facilities and service provider's laboratories to enable the state government to maintain a more vigilant supervision of the initiative.
- Reports from analytics of laboratory services should be integrated with data on medicines prescribed, pharmacy usage and other relevant parameters. This will not only enable closer monitoring of the initiative, but also help in tracking morbidity conditions, appropriateness of medicines prescribed, supplies needed in a facility and other decision support information for the state officials. To achieve this, integration of IT systems between the service provider and the public health system at all levels will be required. The state can build technical capacity for such analytics, interpretation of reports and taking corrective measures.
- Zero samples in any facility should be investigated on a daily basis by the state-level diagnostics team. In facilities with zero samples for a long period or on multiple occasions in a month, difficulty in recruiting phlebotomists (mainly in remote locations) and absence of government doctors at health facilities could be the reason (s).
- The health facilities which do not report data of laboratory tests should be reminded through automated SMS on a daily basis to send their data.
- Besides dashboard data, the state-level diagnostics team should carry out analysis of more detailed data on turnaround time of individual tests on a weekly basis and EQAS results

on a monthly basis. The data should be examined for any deviations. Penalties should be levied and payments should be made to the service provider accordingly.

- It should facilitate linking of the LIS data with GIS system to strengthen implementation, monitoring and actions required for diagnostic services.
- It should establish laboratory based surveillance of communicable and non-communicable diseases to detect outbreaks as well as disease patterns.
- It should feed the data on SLAs, metrics, monies spent etc. in the central portal.
- It should participate in all meetings of state officials with the service provider.
- It should collect and analyse regular and formal feedback from:
  - State and district officials of the Department of Health and Family Welfare
  - Senior management and district teams of the service provider
- *At health facilities*
  - Doctors (including administrators)
  - Laboratory technicians of in-house laboratories
  - Phlebotomists and Inter-Laboratory Delivery (ILD) personnel of service provider
  - Patients
- *At the service provider's laboratories*
  - Diagnosticians
  - Laboratory managers
  - Laboratory technicians and other staff
- The state-level diagnostics team should take the following measures to monitor whether service provider is actually conducting the tests:
  - Monitor the percentage of tests outside biological reference interval for each kind of test and investigate too low or too high percentage of abnormal results.
  - Periodically ask for archive print-outs of test reports directly from the equipment for randomly selected dates.
  - Obtain access to view real-time laboratory information system of all its laboratories. A dedicated resource assigned by the government can randomly check in the system whether the tests were actually conducted at the service provider's laboratories and the test reports are genuine.
  - Get 0.5-1 percent of samples tested at another laboratory on a weekly basis and match test results with service provider's results. This will also enable monitoring of erroneous results of service provider.
- Prescription patterns: The state-level diagnostics team should assess test prescription patterns of doctors. For the assessment, doctors' data should be defined in the MIS of service provider and captured against each patient in the MIS. A unique ID will be required for proper identification of the doctor. Also, the name and unique ID of the prescribing doctor will be required on the requisition form for tests. To this end, the state government should provide database of doctors to the service provider which includes name, specialty, phone

number and employee code/Aadhaar number (unique identifier). The state government should also make it mandatory for doctors to put a seal on the requisition forms; the seal should contain name and unique ID.

In the initial stages of rollout, there is a strong possibility of resistance among doctors for ordering tests through the service provider due to their existing practice of referring patients to local private laboratories. The state-level diagnostics team and other senior state officials should undertake stringent measures to increase the uptake of services such as weekly video conferences with doctors and district officers as well as monitoring utilization of services with a close watch on facilities where services are underutilized. The state government should also send a circular to all the government facilities and doctors that they should refrain from prescribing tests to the private laboratories for those tests that are available at the facilities under the free diagnostics initiative. Information should be displayed in the health facilities that if any patients are asked to get their tests done from private laboratories, they can drop a complaint in the complaint box.

The state-level diagnostics team should keep a close watch on the utilization of services by the doctors in terms of number of patients prescribed tests, number of each type of tests conducted, percentage of patients tested out of total patients, patient-to-test ratio, single test prescriptions, percentage of cheaper and more expensive tests ordered etc. The monitoring should be for each level of facility and preferably individual facilities. An intra- specialty comparison for prescription patterns of doctors should be done monthly for prescription of each type of test.

Fluctuations in uptake of services by doctors over a period of time should be identified and a root-cause analysis should be done. In the per-patient rate model, a close watch should be kept if the increase in total number of patients tested is significantly more than the increase in total number of tests conducted. The percentage of tests (of each type) with results outside biological reference interval should be closely monitored, whether most of the test results are within the reference interval.

One of the correlations to be made is if there is any change in uptake of any particular type of test by the doctors and change in satisfaction levels of clinicians with quality and turnaround time for those tests.

Periodic and random prescription audits should be done. It would be useful to make unit heads accountable for rational prescriptions in their respective departments in hospitals. This would also enable direct supervision of junior doctors.

The state-level diagnostics team with support from state government should introduce evidence-based prescription practices to determine the upper limit to the number of tests prescribed or combination of tests in groups. The government can develop standard treatment guidelines (if not available) coupled with laboratory test prescription guidelines/test panels to ensure standardization and develop evidence based medicine (EBM) protocols specially at lower levels of the health system. Once MIS is in place for prescription of laboratory tests and pharmacy, these guidelines would be useful for standardizing care.

- It should constitute an expert committee consisting of government pathologists/ biochemists/microbiologists/other reputed experts and relevant stakeholders to monitor the technical aspects of service provider's laboratories periodically. Surprise visits at the service provider's laboratories will help in spot checks on quality of reagents being used, type of laboratory technicians working in the laboratory, absenteeism of staff,

work process flow, compliance with biomedical waste management guidelines etc. If required, the government could use independent professionals/professional bodies for this monitoring.

- It should formulate protocols for making payments to the service provider.
- It should conduct annual review of performance of service provider.
- It should organise periodic patient and clinician satisfaction surveys for assessing patients' and clinicians' experiences with services under the free diagnostics initiative. In these surveys, it would also be important to investigate if any fee was paid by patients for getting tests done at the government health facilities.
- It should conduct periodic security audit of the service provider's IT systems for data security and confidentiality.

c. **Role of Drug Control Administration (DCA)**

The state government could leverage the Drug Control Administration (DCA) for inspection of laboratories of the service provider. Each laboratory should be inspected at regular intervals by the drug inspectors. The drug inspectors should check: a) equipment: availability and usage status of equipment, calibration certificates of the equipment; b) laboratory staff: availability of laboratory staff and their qualification certificates; c) list of facilities catered by the laboratory and list of tests provided by the laboratory to these facilities; d) reagents and consumables: quality, inventory, purchase bills; the quantity of reagents and consumables in purchase bills should be tallied with number of tests conducted in that period; e) other processes of the laboratory should be examined and records, log books, certificates of laboratory registration, biomedical waste management, pollution clearance also checked; f) log in and log out times in the main computer where reports were entered should be monitored and matched with the time of report generation on the patients' reports; g) patients should be called on the phone numbers provided in the records for verifying if those are real patients and whether they received their test reports.

d. **Monthly state-level review meetings:** These should be conducted *by a committee formed by the State Government*. District health officials, DCA and State Program Managment Unit should provide feedback in these meetings on the progress of the initiative. The service provider should present progress on the initiative as well as actions taken on concerns raised in the previous meetings.

e. The government should monitor the availability of doctors at the government health facilities.

f. All decisions related to provision of services under the free diagnostics initiative, for example conducting screening camps should be taken after approval from the state government.

B. At the district level

a. District health officers should make monthly visits to the government health facilities to inspect availability of sampling services, report dispatch services, maintenance of records, biomedical waste management, qualifications and training of phlebotomists, attendance records of phlebotomists etc. Many of these visits should be surprise visits. Feedback should also be taken from doctors on various aspects of service provider's services, such as quality and turnaround time. In addition, they should inspect laboratories of the service provider on a monthly basis. District health officials should also assess monthly analytical reports on availability and utilisation of service provider's services at individual government health facilities; and quality assurance at service provider's laboratories.

b. Based on an in-depth and close monitoring of the services, the district health officers should provide feedback to the state-level diagnostics team and other state officials. All information from the health facilities and laboratories should be validated before it is presented.

c. The district collector/or his/her nominated representative should conduct review meetings with district health officers; and administrators and doctors of the government health facilities once in two months to discuss progress of the initiative (other programmes/schemes could also be reviewed in this meeting). The district representatives of the service provider should also be invited to these meetings, when required to address concerns regarding the initiative.

C. At the health facility level

a. A resource should be appointed by each health facility to oversee services under the initiative. This resource (nodal officer) should carry out validation of patient data for the initiative; supervise availability and quality of services; and handle grievances related to the services under the initiative.

b. Facility in-charges should take up a larger role in monitoring of services at the health facility level. She/he should closely supervise the data on services of the service provider (number of patients tested, number of tests conducted). She/he should monitor prescriptions of each doctor. She/he should seek feedback from the clinicians on quality and availability of tests provided by the service provider. Concerns of the doctors should be escalated to the district officials/service provider. She/he should also regularly check attendance records of the service provider's staff (phlebotomists etc.) at the facilities. She/he should be responsible for adequate uptake of call centre services.

c. It is imperative to use a single patient identity (registration number) for patients availing laboratory services to maintain uniformity in identification of new and repeat patients. This would enable capturing of repeat orders by clinicians in case of inaccuracies in test results and follow-ups. This would also help in analysing the disease patterns and trend among populations. Option of using Aadhaar data with thumb impression identification of patients can be explored. To ensure that patients using laboratory services furnish their unique ID, it is suggested that a message in local language be displayed prominently in the health facility and printed on the acknowledgement slip given to patients for report collection.

d. Patients' profile – BPL/APL, tribal, ANC, gender, age group etc. should be captured to facilitate analysis of uptake of services among these segments of population.

e. Data of patients availing laboratory services should to be captured electronically at the point of sample collection for seamless flow and data integration. Also, the time of sample collection should be recorded to track the pre-analytical turnaround time. The records of all patients availing laboratory services both at the in-house laboratory and through service provider need to be captured electronically in one single integrated MIS at the government health facility itself. In those states where electronic health record application is being implemented, it could be leveraged for the same.

f. Data validation at the health facility level should be robust. Following are some recommendations for the same:

- Validation should be done for number of patients prescribed tests, number of tests prescribed and percentage of patients for which printed reports are provided by the service provider for all the prescribed tests.

- The designated nodal officer at the health facility under supervision of the administrator should be given the responsibility for data validation.
    - The nodal officer should check whether the requisition forms were filled by the doctors, any tests have been removed from the prescribed list of tests on the forms and the number of samples matches the tests prescribed on the requisition forms.
    - She/he should put his/her signature on the sample dispatch register maintained by the phlebotomist(s) at the health facility.
    - She/he should also check whether all printed reports have reached the health facility by matching the printed reports received with the report receipt register maintained by the phlebotomist(s) at the health facility.
    - Once the MIS/EHR is in place, data recorded by phlebotomists of the service provider in the MIS of the government health facilities should be validated as mentioned in point b. The software should have a feature to reflect completion of the process of validation. Receipt of printed reports should also be validated in patient's EHR.
    - In addition to daily validation, the nodal officer along with the administrator should also match the monthly figures on the dashboard (total number of patients tested and total number of tests conducted) with the data available at the health facility in the sample dispatch-cum-report receipt register.

g. The health facilities should carefully monitor that data of service provider's tests does not spill into that of in-house tests leading to over-projection of number of in- house tests.

h. All government health facilities should maintain attendance register/biometric attendance (at facilities which have this provision) for service providers' staff (phlebotomists etc.).

3. MONITORING BY THE SERVICE PROVIDER

The service provider should institute mechanisms for monitoring services under the free diagnostics initiative.

i. The service provider should put in place a dedicated monitoring team.

   a. The team should comprise of state-level and district-level teams.

   b. The state-level teams should have dedicated resources for operations, total quality management and quality assurance in the laboratories. The central quality team should carry out periodic inspection of the laboratories.

   c. In each district, there should be a team of diagnosticians who carry out test results' verification, reporting and monitoring of IQC and EQAS.

   d. Each district team should have dedicated resources for operations, quality assurance, IT management, inventory management and accounts management.
       - The quality assurance managers should be senior laboratory technicians with at least 5 years of experience. These managers are responsible for supervising quality assurance in laboratories, troubleshooting for analytical processes, training of laboratory technicians, addressing concerns of clinicians about accuracy of test results, checking maintenance of records in the laboratories, ensuring adherence to biomedical waste management etc.

- The operations executives should manage maximum of *three laboratories each*. They should be responsible for managing availability of phlebotomists, ILD staff and laboratory technicians, supervising phlebotomists for maintaining records (requisition forms, batch sheets, registration and report dispatch registers), monitoring logistics of sample transportation and report dispatch and addressing complaints from facility administrators/doctors on logistics issues, such as the turnaround time.

e. The district teams should take regular feedback from facility administrators and doctors about the services provided by them. In addition to addressing their ad-hoc issues, formal feedback should be taken on a weekly basis. The teams should ensure that their concerns are addressed on an urgent basis. In case of any changes in availability of tests at facilities, the respective facility administrators and doctors should be updated about the same.

ii. Zero samples in any facility should be investigated on a daily basis by the service provider. The service provider should *electronically* report to the state government daily about facilities with zero samples or a very low percentage of patients prescribed tests and the reasons for the low utilisation of services there.

iii. The service provider should inform the health facilities about absence or late arrival of the phlebotomist(s). The service provider could also track availability of its phlebotomists if phone numbers of the government health facilities are made available to the service provider.

iv. A call centre should be set up by the service provider for grievance redressal, in case the State authority does not have an existing grievance redressal call centre. To increase uptake of services of the call centre, phone number of call centre should be displayed clearly at prominent places in the health facilities as well as on the test reports. The service provider should record all feedback/complaints and action taken in its MIS and provide a monthly report to the state government.

IX. PAYMENT ADMINISTRATION

i. All tests should be free-of-cost for all patients who have been prescribed tests at government health facilities up to the district level.

ii. Payments should be made as per mechanisms agreed mutually by the state and the service provider and same should be reflected in the implementation manual and also in the Agreement.

iii. The payment will be made for tests performed by the Service Provider for which test reports have been released by the Service Provider to the respective Government health facilities. Payments will also depend on fulfillment of KPIs.

iv. Penalties should be levied from the beginning on the service provider for not meeting mutually agreed clauses mentioned in the Agreement including KPIs.

v. The invoice should contain details of Government health facilities, names of prescribing doctor, demographics of patients, names of tests, test results and data on KPIs. All the reports included in the invoices need to be certified/verified by the Nodal officers of respective Government health facilities (Chief Medical Superintendent/MO or equivalent of the hospital concerned). In his absence, the Medical Superintendent or any Medical Officer as assigned by the Superintendent may sign the documents.

vi. The payments should be disbursed electronically.

vii. The payment cycle should be of 30 days from the date of submission of invoice and billing should be on a monthly basis. Penalty clauses should also be applicable on a monthly basis.

viii. Within 30 days of the receipt of the invoice, the Authority will analyse reports and damages and penalties and release 90 percent of the total payment due after reduction of penalties and damages. A maximum of 10 percent payment can be with held for any clarification/rectification. The requisite clarification/rectification should be finished by the State Government within 45 days of receipt of invoice and balance payment will be released to the Service Provider.

ix. Penalties should also be levied if there are any delays in implementation of the project. The penalties for delay in implementation should be levied per facility and for each test.

x. The state government should seek clarifications from the service provider on ambiguous points before authorising any deductions to avoid delays in payments.

xi. The state government should ensure capacity building of the officials responsible for authorising payments.

X. INFORMATION, EDUCATION AND COMMUNICATION (IEC)

i. The state government should actively promote the services available through service provider to ensure wide acceptance among doctors and general public. The government should launch massive campaigns (even prior to roll out of the initiative) for creating awareness about the free diagnostics initiative through multiple channels including:

   a. Posters, pamphlets, banners and inserts (with OPD card and reports).

   b. Local newspapers and TV.

   c. 104 services.

   d. ANMs and ASHAs should be sensitised about the initiative in their regular review meetings and they should disseminate information at sub-centre and village level respectively.

   e. Medical officers should talk about the initiative at community meetings with people's representatives.

   f. Information should be disseminated at meetings of Gram Sabha with the government officials and public.

   g. Doctors should talk about the initiative to their patients.

ii. The state government should ensure that only name of the initiative is mentioned on the free diagnostics initiative-related communication and not the service provider's name. Citing service provider's name can cause confusion among patients.

iii. A combined list of tests (provided in-house and through the service provider) should be displayed for clarity of patients about the entire basket of tests available at the government health facilities.

iv. A banner should be displayed at the health facilities, guiding patients to reach out to the facility administrator in case of unavailability of tests through the service provider.

v. There should be a clear display of laboratory timings at the health facilities (in OPD, outside laboratory and at registration counter for laboratory).

ANNEXURES

Annexure 1A

LIST OF DIAGNOSTIC TESTS AT HEALTH FACILITIES

Table 1 : List of diagnostic tests at Sub Health Centres/Health and Wellness Centres (SC)

S. No.	Diagnostic test	Human resource required for conducting the test at sub-centre	Product/equipment required for testing
1	Hemoglobin	ANM/MLHP	Digital Hemoglobinometer
2	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	ASHA/ANM/MPW/MLHP	Rapid card test (Dipstick)
3	Urine test for ph, specific gravity, Leucocyte esterase glucose, bilirubin, urobilinogen, ketone, hemoglobin, protein, nitrite	ANM/MLHP	Multiparameter urine strip (dipstick)
4	Blood sugar	ASHA/ANM/MPW/MLHP	Glucometer
5	Malaria test	ASHA/ANM/MPW/MLHP	Rapid card test
6	HIV (Antibodies to HIV 1&2)	ANM/MLHP	Rapid card test
7	Dengue	ANM/MLHP	Rapid card test for NS1 antigen and IgM antibody
8	Visual Inspection – Acetic Acid	ANM/MLHP	Manual
9	HbsAg test for Hepatitis B	ANM/MLHP	Rapid card test
10	Smear for Filaria (endemic areas only)*	ANM/MLHP	Microscopy
11	Rapid Test Kit for Syphilis	ANM/MLHP	Rapid Kit
12	Test for iodine in salt (used for food)	ASHA/ANM/MPW/MLHP	Iodine in salt testing kit
13	Water testing for fecal contamination and chlorination	ASHA/ANM/MPW/MLHP	Strip method
14	Sputum for AFB (Sample collection only; transported to TB microscopy centre for testing)	Sample collection only by ANM/ MLHP	-

**Only for endemic areas*

Table 2 : List of diagnostic tests at Primary Health Centres/HWC (PHCs)

S.No.	Diagnostic test	Few tests to be conducted at PHC. Other tests to be sent to nearest hub laboratory of CHC/SDH/DH (in which case sample transported from PHC to the hub laboratory). Samples for few tests including advanced tests to be sent only to mother lab of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
1	Hemoglobin	a. PHC b. Hub lab (CHC/SDH/DH)	The samples for these tests will be transported to the nearest hub laboratory at CHC/ SDH/DH. If transportation time of samples from PHC to nearest hub laboratory is high because of large distance or poor road connectivity, then these tests will be carried out at PHC itself and the PHC will then be provided with a hematology analyser.	a. ANM/Lab Tech b. Lab Tech	a. Digital Hemoglobinometer b. Hematology analyser
2	Total leucocyte count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
3	Differential leucocyte count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
4	Platelet count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
5	Complete blood count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
6	Erythrocyte sedimentation rate	Hub lab (CHC/SDH/DH)		Lab tech	Manual with reading using ESR analyser
7	Blood group and Rh typing	PHC		Lab tech	Blood group kit (manual)
8	Peripheral blood film	Hub lab (CHC/SDH/DH)		Lab tech	Microscopy
9	Reticulocyte count	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
10	Absolute eosinophil count	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
11	Bleeding time and clotting time	PHC		ANM/Lab tech	Manual
12	Sickling Test for Sickle cell anemia	Hub lab (CHC/SDH/DH)			Manual with microscopy
13	Quantitative test for G6PD enzyme deficiency	Hub lab (CHC/SDH/DH)		Lab tech	Fluorometry

S.No.	Diagnostic test	Few tests to be conducted at PHC. Other tests to be sent to nearest hub laboratory of CHC/SDH/DH (in which case sample transported from PHC to the hub laboratory). Samples for few tests including advanced tests to be sent only to mother lab of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
14	a. MP slide method and b. Malaria rapid test	PHC	If lab technician is not available at PHC, the sample could be sent to the nearest microscopy centre of a PHC/CHC/ SDH/DH	a. Lab tech b. ANM/Lab tech	a. Microscopy b. Rapid card tests for combined P.Falciparum and P.vivax
15	Prothrombin Time (PT)	Hub lab (CHC/SDH/DH)		Lab tech	Automated coagulation analyser
16	Activated partial thromboplastin time (APTT)	Hub lab (CHC/SDH/DH)		Lab tech	Automated coagulation analyser
17	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	PHC		ANM/Lab tech	Rapid card test
18	Urine test for ph, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	PHC		Lab tech	Multiparameter urine strip (dipstick)
19	Urine Microscopy	PHC		Lab tech	Microscopy
20	24-hours urinary protein	PHC (if manual)/Hub lab (CHC/ SDH/DH) if automated		Lab tech	Manual/Fully automated biochemistry analyser
21	Urine for microalbumin	Hub lab (CHC/SDH/DH)		Lab tech	Turbidometer/ Nephelometer
22	Urine for creatinine and Albumin to creatinine ratio (ACR)	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser

S.No.	Diagnostic test	Few tests to be conducted at PHC. Other tests to be sent to nearest hub laboratory of CHC/SDH/DH (in which case sample transported from PHC to the hub laboratory). Samples for few tests including advanced tests to be sent only to mother lab of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
23	Stool for ova and cyst	PHC	If lab technician is not available at PHC, the sample could be sent to the hub laboratory	Lab tech	Microscopy
24	Stool for Occult Blood	Hub Lab (CHC/SDH/DH)		Lab tech	Manual Kit
25	Test for Dengue	PHC	a. PHC for rapid b. Mother lab (DH) for confirmatory	a. ANM/Lab tech b. Lab tech	a. Rapid card test for combined NS1 antigen and IgM antibody b. ELISA
26	RPR/VDRL test for syphilis	PHC		ANM/Lab tech	Rapid card test
27	HIV test (Antibodies 1/2 and HIV 1/2)	PHC	Need to follow guidelines from NACO, and protocol for new-born screening (ICTC centre level)	ANM/Lab tech	Rapid card test
28	Hepatitis B surface antigen test	PHC		ANM/Lab tech	Rapid card test
30	HCV Antibody Test (Anti HCV)	PHC		ANM/Lab tech	Rapid card test
31	Sputum for AFB	PHC	If lab technician is not available at PHC, the sample could be sent to the nearest microscopy centre of a PHC/CHC/ SDH/DH	Lab tech	Microscopy
32	Typhoid test (IgM)	PHC		ANM/Lab tech	Rapid card test

S.No.	Diagnostic test	Few tests to be conducted at PHC. Other tests to be sent to nearest hub laboratory of CHC/SDH/DH (in which case sample transported from PHC to the hub laboratory). Samples for few tests including advanced tests to be sent only to mother lab of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
33	Blood sugar	a. PHC b. Hub lab	The samples for these tests will be transported to the nearest hub laboratory at CHC/ SDH/DH. If transportation time of samples from PHC to nearest hub laboratory is high because of large distance or poor road connectivity, then these tests will be carried out at the PHC itself and the PHC will then be provided a semi-automated biochemistry analyser.	a. ANM/Lab tech b. Lab tech	a. Glucometer b. Fully automated Biochemistry analyser
34	Glucose Tolerance Test (GTT)	Hub lab -(CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
35	S. Bilirubin (T)	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
36	S. Bilirubin direct and indirect	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
37	Serum creatinine	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
38	Blood Urea	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
39	Uric acid	Hub lab (CHC/SDH/DH)			Fully automated biochemistry analyser
40	SGPT	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
41	SGOT	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
42	S. Alkaline Phosphatase	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
43	S.Total Protein	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
44	S. Albumin & AG ratio	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
45	S. Total Cholesterol	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser

S.No.	Diagnostic test	Few tests to be conducted at PHC. Other tests to be sent to nearest hub laboratory of CHC/SDH/DH (in which case sample transported from PHC to the hub laboratory). Samples for few tests including advanced tests to be sent only to mother lab of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
46	S. Triglycerides	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
47	S.VLDL	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
48	S.HDL	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
49	S. LDL	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
50	Serum Sodium	Hub Lab (CHC/SDH/DH)		Lab tech	Indirect ion selective electrode Electrolyte Analyser
51	S.Potassium	Hub Lab (CHC/SDH/DH)		Lab tech	Indirect ion selective electrode Electrolyte Analyser
52	Serum Calcium	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
53	Smear for RTI/ STD	Hub lab (CHC/SDH/DH)		Lab tech	Wet mounting, gram staining
54	Gram staining for clinical specimen	Hub lab (CHC/SDH/DH)		Lab tech	Microscopy
55	Throat swab for Diphtheria	Mother lab (DH)		Lab tech	Microscopy
56	Visual Inspection Acetic Acid (VIA)	PHC		ANM	Manual
57	rK39 for Kala Azar*	PHC (endemic areas only)		Lab tech	Rapid card test
58	Smear for Filaria*	Hub lab (CHC/SDH/DH) (if Microscopy)		Lab tech	Microscopy
59	TB – Mantoux	PHC		Lab tech	Manual

S.No.	Diagnostic test	Few tests to be conducted at PHC. Other tests to be sent to nearest hub laboratory of CHC/SDH/DH (in which case sample transported from PHC to the hub laboratory). Samples for few tests including advanced tests to be sent only to mother lab of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
60	RA factor (Quantitative)	Hub lab (CHC/SDH/DH)		Lab tech	Turbidometer
61	CRP(including new born) (Quantitative)	Hub lab (CHC/SDH/DH)		Lab tech	Turbidometer
62	TSH (including for new-born screening)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
63	Urine Culture and antimicrobial sensitivity	Mother lab (DH)		Microbiologist/ Pathologist	Manual culture and automated bacterial identification and antimicrobial sensitivity
64	Pap smear	Mother lab (DH)		Pathologist	Microscopy

**Only for endemic areas*

Table 3 : List of diagnostic tests at Community Health Centres (CHCs)

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
1	Hemoglobin	a. CHC b. Hub lab (CHC/SDH/DH)		a. ANM/Lab Tech b. Lab Tech	a. Digital Hemoglobinometer b. Hematology analyser
2	Total leucocyte count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
3	Differential leucocyte count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
4	Platelet count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
5	Complete blood count	Hub lab (CHC/SDH/DH)		Lab tech	Hematology analyser
6	Erythrocyte sedimentation rate	Hub lab (CHC/SDH/DH)		Lab tech	Manual with reading using ESR analyser.
7	Blood group and Rh typing	CHC		Lab tech	Blood group kit (manual)
8	Blood cross matching	Hub lab (CHC/SDH/DH)		Lab tech	Manual
9	Peripheral blood film	Hub lab (CHC/SDH/DH)		Lab tech	Microscopy
10	Reticulocyte count	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
11	Absolute eosinophil count	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
12	Bleeding time and clotting time	CHC		ANM/Lab tech	Manual
13	Fibrinogen degradation products (FDP)	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
14	D-Dimer	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
15	Coombs test direct with titre	Hub lab (CHC/SDH/DH)		Lab Tech	Manual
16	Coombs test indirect with titre	Hub lab (CHC/SDH/DH)		Lab Tech	Manual

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
17	Sickling Test for screening of Sickle cell anemia*	Hub lab (CHC/SDH/DH)		Lab tech	Manual with microscopy
18	Sickle cell test rapid for screening of Sickle cell anemia (Strip test)*	CHC		ANM/Lab tech	Rapid
19	NESTROFT Test for screening of Thalassemia*	Hub lab (CHC/SDH/DH)		Lab tech	Manual
20	DCIP test for screening HbE hemoglobinopathy*	CHC		Lab tech	Manual
21	Quantitative test for G6PD enzyme deficiency	Hub lab (CHC/SDH/DH)		Lab tech	Fluorometry
22	a. MP slide method and b. Malaria rapid test	CHC		a. Lab tech b. ANM/Lab tech	a. Microscopy b. Rapid card tests for combined P.Falciparum and P.vivax
23	Prothrombin Time (PT) and INR	Hub lab (CHC/SDH/DH)		Lab tech	Automated coagulation analyser
24	Activated partial thromboplastin time	Hub lab (CHC/SDH/DH)		Lab tech	Automated coagulation analyser
25	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	CHC		ANM/Lab tech	Rapid card test
26	Urine test for ph, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	CHC		Lab tech	Multiparameter urine strip (dipstick)
27	Urine Microscopy	CHC		Lab tech	Microscopy

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
28	24-hours urinary protein	CHC (if manual)/Hub lab (CHC/ SDH/DH) if automated		Lab tech	Manual method/ Fully automated biochemistry analyser
29	Urine for microalbumin	Hub lab (CHC/SDH/DH)		Lab tech	Turbidometer/ Nephelometer
30	Urine for creatinine and Albumin to creatinine ratio (ACR)	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
31	Stool for ova and cyst	CHC		Lab tech	Microscopy
32	Stool for Occult Blood	Hub Lab (CHC/SDH/DH)		Lab tech	Manual Kit
33	Semen analysis	CHC		Lab tech	Microscopy (with neubaeur chamber and slide)
34	Test for Dengue	a. CHC for rapid b. Mother lab (DH) for confirmatory		a. ANM/Lab tech b. Lab tech	a. Rapid card test for combined NS1 antigen and IgM antibody b. ELISA
35	RPR/VDRL test for syphilis	CHC		ANM/Lab tech	Rapid card test
36	HIV test (Antibodies 1/2 and HIV 1/2)	Mother lab (DH)	Need to follow guidelines from NACO, and protocol for new-born screening (ICTC centre level)	Lab tech	Chemiluminescence analyser
37	Hepatitis B surface antigen test	a. CHC b. Mother lab (DH) for Chemiluminiscence		a. ANM/Lab tech b. Lab tech	a. Rapid card test b. Chemiluminis-cence assay

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
38	HCV Antibody Test (Anti HCV)	CHC/Mother lab (DH)		a. ANM/Lab tech b. Lab tech	a. Rapid card test b. Chemilumines-cence analyser
39	Sputum, pus etc. for AFB	CHC		Lab tech	Microscopy
40	Typhoid test (IgM)	CHC		ANM/Lab tech	Rapid card test
41	Blood sugar	a. CHC b. Hub lab		a. ANM/Lab tech b. Lab tech	a. Glucometer b. Fully automated Biochemistry analyser
42	Glucose Tolerance test (GTT)	Hub lab -(CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
43	S. Bilirubin (T)	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
44	S. Bilirubin direct and indirect	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
45	Serum creatinine	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
46	Blood Urea	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
47	SGPT	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
48	SGOT	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
49	S. Alkaline Phosphatase	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
50	S.Total Protein	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
51	S. Albumin & AG ratio	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
52	S.Globulin	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
53	S. Total Cholesterol	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
54	S. Triglycerides	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
55	S.VLDL	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
56	S.HDL	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
57	S. LDL	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
58	S. GGT	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
59	S. Uric acid	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
60	S. Amylase	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
61	S.Iron	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
62	Total Iron binding capacity	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
63	Glycosylated haemoglobin (HbA1C)	Hub lab (CHC/SDH/DH)/Mother lab (DH) if HPLC		Lab tech	Fully automated biochemistry analyser/HPLC

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
64	S. Sodium	Hub Lab (CHC/SDH/DH)		Lab tech	Indirect ion selective electrode Electrolyte Analyser
65	S. Potassium	Hub Lab (CHC/SDH/DH)		Lab tech	Indirect ion selective electrode Electrolyte Analyser
66	Serum Calcium	Hub lab (CHC/SDH/DH)		Lab tech	Fully automated biochemistry analyser
67	S.Magnesium	Hub lab (CHC/SDH/DH)		Lab tech	Indirect ion selective electrode Electrolyte Analyser
68	Smear for RTI/STD	Hub lab (CHC/SDH/DH)		Lab tech	Wet mounting, gram staining
69	Gram staining for clinical specimen	Hub lab (CHC/SDH/DH)		Lab tech	Microscopy
70	Throat swab for Diphtheria	Mother lab (DH)		Lab tech	Microscopy
71	Stool for hanging drop for Vibrio Cholera	Mother lab (DH)		Lab tech	Microscopy
72	Visual Inspection Acetic Acid (VIA)	CHC		ANM	Manual
73	rK39 for Kala Azar*	CHC (endemic areas only)		Lab tech	Rapid card test
74	Smear for Filaria*	Hub lab (CHC/SDH/DH)		Lab tech	Microscopy
75	TB – Mantoux	CHC		Lab tech	Manual
76	S. TSH (including for new-born screening)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
77	S.Free T3	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
78	S.Free T4	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
79	S. Ferritin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
80	Troponin - I/ Troponin – T	CHC			Rapid card test

S.No.	Diagnostic test	For large CHCs: Test to be conducted at the hub lab within that CHC and for few tests including highly advanced tests samples transported to mother laboratory of DH. For small CHCs: Few tests to be conducted at CHC. Other tests sent to nearest hub laboratory at CHC/SDH/DH (in which case sample transported from CHC to the hub laboratory). Few other tests including advanced tests sent to Mother laboratory of DH	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
81	S.Beta HCG	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
82	S.Prolactin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
83	S. Anti-Mullerian hormone (AMH)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
84	Rubella IgG	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
85	Anti-cyclic citrullinated peptide (anti-CCP)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
86	RA factor (Quantitative)	Hub lab (CHC/SDH/DH)		Lab tech	Turbidometer
87	CRP (including new born) (Quantitative)	Hub lab (CHC/SDH/DH)		Lab tech	Turbidometer
88	Cytology	Mother lab (DH)		Pathologist	Microscopy
89	Pap smear	Mother lab (DH)		Pathologist	Microscopy
90	Histopathology	Mother lab (DH)		Pathologist	Microscopy
91	Hemoglobin electrophoresis/ HPLC	Mother lab (DH)		Pathologist	Electrophoresis machine/HPLC machine
92	Blood culture	Mother lab (DH)		Microbiologist/ Pathologist	Automated
93	Urine Culture	Mother lab (DH)		Microbiologist	Manual
94	Other cultures (pus, throat swab etc.)	Mother lab (DH)		Microbiologist/ Pathologist	Manual
95	Organism identification and antimicrobial sensitivity for cultures	Mother lab (DH)		Microbiologist/ Pathologist	Automated
96	Nucleic Acid Amplification Test (NAAT) for TB	a. CHC b. Mother lab (DH)		As per RNTCP guidelines	Nucleic Acid Amplification Machine
97	Early Infant Diagnostic test for HIV - Qualitative HIV-1 DNA PCR (ICTC)			As per NACO guidelines	Nucleic Acid Amplification Machine

Table 4 : List of diagnostic tests at Sub District Hospital (SDHs)

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
1	Hemoglobin	Hub lab of SDH		a. ANM/Lab Tech b. Lab Tech	a. Digital Hemoglobinometer b. Hematology analyser
2	Total leucocyte count	Hub lab of SDH		Lab tech	Hematology analyser
3	Differential leucocyte count	Hub lab of SDH		Lab tech	Hematology analyser
4	Platelet count	Hub lab of SDH		Lab tech	Hematology analyser
5	Complete blood count	Hub lab of SDH		Lab tech	Hematology analyser
6	Erythrocyte sedimentation rate	Hub lab of SDH		Lab tech	Manual with reading using ESR analyser.
7	Blood group and Rh typing	Hub lab of SDH		Lab tech	Blood group kit (manual)
8	Blood cross matching	Hub lab of SDH		Lab tech	Manual
9	Peripheral blood film	Hub lab of SDH		Lab tech	Microscopy
10	Reticulocyte count	Hub lab of SDH		Lab Tech	Manual
11	Absolute eosinophil count	Hub lab of SDH		Lab Tech	Manual
12	Bleeding time and clotting time	Hub lab of SDH		ANM/Lab tech	Manual
13	Fibrinogen degradation products (FDP)	Hub lab of SDH		Lab Tech	Manual
14	D-Dimer	Hub lab of SDH		Lab Tech	Manual
15	Coombs test direct with titre	Hub lab of SDH		Lab Tech	Manual
16	Coombs test indirect with titre	Hub lab of SDH		Lab Tech	Manual
17	Sickling Test for screening of Sickle cell anemia*	Hub lab of SDH		Lab tech	Manual with microscopy
18	Sickle cell test rapid for screening of Sickle cell anemia*	Hub lab of SDH		ANM/Lab tech	Rapid
19	NESTROFT Test for screening of Thalassemia*	Hub lab of SDH		Lab tech	Manual
20	DCIP test for screening HbE hemoglobinopathy*	Hub lab of SDH		Lab tech	Manual
21	Quantitative test for G6PD enzyme deficiency	Hub lab of SDH		Lab tech	Fluorometry

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
22	a. MP slide method and b. Malaria rapid test	Hub lab of SDH		a. Lab tech b. ANM/Lab tech	a. Microscopy b Rapid card tests for combined P. Falciparum and P. vivax
23	Prothrombin Time (PT) and INR	Hub lab of SDH		Lab tech	Automated coagulation analyser
24	Activated partial thromboplastin time	Hub lab of SDH		Lab tech	Automated coagulation analyser
25	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	Hub lab of SDH		ANM/Lab tech	Rapid card test
26	Urine test for ph, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	Hub lab of SDH		Lab tech	Multiparameter urine strip (dipstick)
27	Urine Microscopy	Hub lab of SDH		Lab tech	Microscopy
28	24-hours urinary protein	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
29	Urine for microalbumin	Hub lab of SDH		Lab tech	Turbidometer/ Nephelometor
30	Urine for creatinine and Albumin to creatinine ratio (ACR)	Hub lab (CHC/SDH/ DH)		Lab tech	Fully automated biochemistry analyser
31	Stool for ova and cyst	Hub lab of SDH		Lab tech	Microscopy
32	Stool for Occult Blood	Hub lab of SDH		Lab tech	Manual Kit
33	Semen analysis	Hub lab of SDH		Lab tech	Microscopy (with neubaeur chamber and slide)
34	Test for Dengue	a. Hub lab of SDH for rapid b. Mother lab (DH) for confirmatory		a. ANM/Lab tech b. Lab tech	a. Rapid card test for combined NS1 antigen and IgM antibody b. ELISA
35	RPR/VDRL test for syphilis	Hub lab of SDH		ANM/Lab tech	Rapid card test
36	HIV test (Antibodies 1/2 and HIV 1/2)	Mother lab (DH)	Need to follow guidelines from NACO,	Lab tech	Chemiluminescence analyser

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
			and protocol for new-born screening (ICTC centre level)		
37	Hepatitis B surface antigen test	a. Hub lab of SDH for emergency b. Mother lab (DH) for Chemiluminiscence		a. ANM/Lab tech b. Lab tech	a. Rapid card test for emergency and b. Chemiluminiscence assay
38	HCV Antibody Test (Anti HCV)	a. Hub lab of SDH for emergency b. Mother lab (DH) for Chemiluminiscence		a. ANM/Lab tech b. Lab tech	a. Rapid card test for emergency and b. Chemiluminiscence assay
39	Sputum, pus etc. for AFB	Hub lab of SDH		Lab tech	Microscopy
40	Typhoid test (IgM)	Hub lab of SDH		ANM/Lab tech	Rapid card test
41	Blood sugar	Hub lab of SDH		a. ANM/Lab tech b. Lab tech	a. Glucometer b. Fully automated Biochemistry analyser
42	Glucose Tolerance test (GTT)	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
43	S. Bilirubin (T)	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
44	S. Bilirubin direct and indirect	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
45	Serum creatinine	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
46	Blood Urea	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
47	SGPT	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
48	SGOT	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
49	S. Alkaline Phosphatase	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
50	S.Total Protein	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
51	S. Albumin & AG ratio	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
52	S.Globulin	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
53	S. Total Cholesterol	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
54	S. Triglycerides	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
55	S.VLDL	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
56	S.HDL	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
57	S. LDL	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
58	S. GGT	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
59	S. Uric acid	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
60	S. Amylase	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
61	S.Iron	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
62	S. Total Iron binding capacity	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
63	S.LDH	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
64	Glycosylated haemoglobin (HbA1C)	Hub lab of SDH/ Mother lab (DH) if HPLC		Lab tech	Fully automated biochemistry analyser/HPLC
65	S. Sodium	Hub lab of SDH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
66	S. Potassium	Hub lab of SDH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
67	S. Calcium	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser
68	S.Chloride	Hub lab of SDH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
69	S. Magnesium	Hub lab of SDH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
70	Smear for RTI/STD	Hub lab of SDH)		Lab tech	Wet mounting, gram staining
71	Gram staining for clinical specimen	Hub lab of SDH		Lab tech	Microscopy
72	Throat swab for Diphtheria	Mother lab (DH)		Lab tech	Microscopy
73	Stool for hanging drop for Vibrio Cholera	Mother lab (DH)		Lab tech	Microscopy
74	Visual Inspection Acetic Acid (VIA)	Hub lab of SDH		ANM	Manual
75	rK39 for Kala Azar*	Hub lab of SDH)		Lab tech	Rapid card test
76	Smear for Filaria*	Hub lab of SDH		Lab tech	Microscopy
77	TB – Mantoux	Hub lab of SDH		Lab tech	Manual
78	Leptospirosis*	Mother lab (DH)		Lab tech	Rapid
79	S.TSH (including for new-born screening)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
80	S.Free T3	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
81	S.Free T4	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
82	S.Ferritin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
83	Troponin - I/Troponin – T	Hub lab of SDH			Rapid card test
84	S.Beta HCG	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
85	S.Prolactin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
86	S. Anti-Mullerian hormone (AMH)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
87	S. Alfa Feto protein	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
88	S. CA-125	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
89	S. CEA	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
90	S.Procalcitonin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
91	S. PSA	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
92	S.Vitamin B12	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
93	Total IgE	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
94	S. Vitamin D	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
95	Rubella IgG	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
96	Anti-cyclic citrullinated peptide (anti-CCP)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
97	RA factor (Quantitative)	Hub lab of SDH		Lab tech	Turbidometer
98	CRP (including new born) (Quantitative)	Hub lab of SDH		Lab tech	Turbidometer
99	Cytology	Mother lab (DH)		Pathologist	Microscopy
100	Pap smear	Mother lab (DH)		Pathologist	Microscopy
101	Fluid analysis (Cell count, biochemistry including Glucose, Protein, LDH, ADA and cytology)	Hub lab of SDH for cell count and Biochemistry and Mother lab (DH) for cytology		Pathologist for cytology. Lab tech for cell count and biochemistry	Fully automated biochemistry analyser, Haematology analyser, Microscopy
102	Histopathology	Mother lab (DH)		Pathologist	Microscopy

S. No.	Diagnostic test	Test to be conducted at the hub lab within that SDH and for few tests including highly advanced tests samples transported to mother laboratory of DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
103	Blood culture	Mother lab (DH)		Microbiologist/ Pathologist	Automated
104	Urine culture	Mother lab (DH)		Microbiologist/ Pathologist	Manual
105	Other cultures (pus, throat swab etc.)	Mother lab (DH)		Microbiologist/ Pathologist	Manual
106	Fungal culture	Mother lab (DH)		Microbiologist/ Pathologist	Manual
107	Organism identification and antimicrobial sensitivity for all above mentioned cultures	Mother lab (DH)		Microbiologist/ Pathologist	Automated
108	Hemoglobin electrophoresis/HPLC	Mother lab (DH)		Pathologist	Electrophoresis machine/HPLC machine
109	Protein electrophoresis	Mother lab (DH)		Pathologist	Electrophoresis machine
110	Nucleic Acid Amplification Test (NAAT) for TB	Mother lab (DH)		As per RNTCP guidelines	Nucleic Acid Amplification Machine
111	Early Infant Diagnostic test for HIV - Qualitative HIV-1 DNA PCR (ICTC)			As per NACO guidelines	Nucleic Acid Amplification Machine

**Only for endemic areas*

Table 5: List of diagnostic tests at District Hospital (DHs)

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
1	Hemoglobin	Hub lab of DH		a. ANM/Lab Tech b. Lab Tech	a. Digital Hemoglobinometer b. Hematology analyser
2	Total leucocyte count	Hub lab of DH		Lab tech	Hematology analyser
3	Differential leucocyte count	Hub lab of DH		Lab tech	Hematology analyser
4	Platelet count	Hub lab of DH		Lab tech	Hematology analyser
5	Complete blood count	Hub lab of DH		Lab tech	Hematology analyser
6	Erythrocyte sedimentation rate	Hub lab of DH		Lab tech	Manual with reading using ESR analyser.
7	Blood group and Rh typing	Hub lab of DH		Lab tech	Blood group kit (manual)
8	Blood cross matching	Hub lab of DH		Lab tech	Manual
9	Peripheral blood film	Hub lab of DH		Lab tech	Microscopy
10	Reticulocyte count	Hub lab of DH		Lab Tech	Manual
11	Absolute eosinophil count	Hub lab of DH		Lab Tech	Manual
12	Bleeding time and clotting time	Hub lab of DH		ANM/Lab tech	Manual
13	Fibrinogen degradation products (FDP)	Hub lab of DH		Lab Tech	Manual
14	D-Dimer	Hub lab of DH		Lab Tech	Manual
15	Coombs test direct with titre	Hub lab of DH		Lab Tech	Manual
16	Coombs test indirect with titre	Hub lab of DH		Lab Tech	Manual
17	Sickling Test for screening of Sickle cell anemia*	Hub lab of DH		Lab tech	Manual with microscopy
18	Sickle cell test rapid for screening of Sickle cell anemia*	Hub lab of DH		ANM/Lab tech	Rapid
19	NESTROFT Test for screening of Thalassemia*	Hub lab of DH		Lab tech	Manual
20	DCIP test for screening HbE hemoglobinopathy*	Hub lab of SDH		Lab tech	Manual

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
21	Quantitative test for G6PD enzyme deficiency	Hub lab of DH		Lab tech	Fluorometry
22	a. MP slide method and b. Malaria rapid test	Hub lab of DH		a. Lab tech b. ANM/Lab tech	a. Microscopy b. Rapid card tests for combined P.Falciparum and P.vivax
23	Prothrombin Time (PT) and INR	Hub lab of DH		Lab tech	Automated coagulation analyser
24	Activated partial thromboplastin time	Hub lab of DH		Lab tech	Automated coagulation analyser
25	Mixing study and Factor VIII Assay for Hemophilia	Mother lab of DH		Lab tech	Automated Coagulation analyser
26	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	Hub lab of DH		ANM/Lab tech	Rapid card test
27	Urine test for ph, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	Hub lab of DH		Lab tech	Multiparameter urine strip (dipstick)
28	Urine Microscopy	Hub lab of DH		Lab tech	Microscopy
29	24-hours urinary protein	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
30	Urine for microalbumin	Hub lab of DH		Lab tech	Turbidometer/ Nephelometer
31	Stool for ova and cyst	Hub lab of DH		Lab tech	Microscopy
32	Stool for Occult Blood	Hub lab of DH		Lab tech	Manual Kit
33	Semen analysis	Hub lab of DH		Lab tech	Microscopy (with neubaeur chamber and slide)
34	Test for Dengue	a. Hub lab of DH for rapid b. Mother lab (DH) for confirmatory		a. ANM/Lab tech b. Lab tech	a. Rapid card test for combined NS1 antigen and IgM antibody b. ELISA
35	RPR/VDRL test for syphilis	Hub lab of DH		ANM/Lab tech	Rapid card test

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
36	HIV test (Antibodies 1 and 2)	Mother lab (DH)	Need to follow guidelines from NACO, and protocol for new-born screening (ICTC centre level)	Lab tech	Chemiluminescence analyser
37	Hepatitis B surface antigen test	a. Hub lab of DH for emergency b. Mother lab (DH) for Chemiluminiscence		a. ANM/Lab tech b. Lab tech	a. Rapid card test for emergency and b. Chemiluminiscence assay
38	IgM antibody to hepatitis B core antigen (IgM anti-HBc)	Mother lab (DH) for Chemiluminiscence		Lab tech	Chemiluminiscence assay
39	HCV Antibody Test (Anti HCV)	a. Hub lab of DH b. Mother lab (DH) for Chemiluminiscence		a. ANM/Lab tech b. Lab tech	a. Rapid card test for emergency and b. Chemiluminiscence assay
40	Sputum, pus etc. for AFB	Hub lab of DH		Lab tech	Microscopy
41	Typhoid test (IgM)	Hub lab of DH		ANM/Lab tech	Rapid card test
42	Blood sugar	Hub lab of DH		a. ANM/Lab tech b. Lab tech	a. Glucometer b. Fully automated Biochemistry analyser
43	Glucose Tolerance test (GTT)	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
44	S. Bilirubin (T)	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
45	S. Bilirubin direct and indirect	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
46	Serum creatinine	Hub lab of DH		Lab tech	Fully automated biochemistry analyser

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
47	Blood Urea	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
48	SGPT	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
49	SGOT	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
50	S. Alkaline Phosphatase	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
51	S. Total Protein	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
52	S. Albumin & AG ratio	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
53	S. Globulin	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
54	S. Total Cholesterol	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
55	S. Triglycerides	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
56	S. VLDL	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
57	S. HDL	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
58	S. LDL	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
59	S. GGT	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
60	S. Uric acid	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
61	S. Amylase	Hub lab of DH		Lab tech	Fully automated biochemistry analyser

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
62	S. Iron	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
63	S. Total Iron binding capacity	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
64	S. LDH	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
65	Glycosylated haemoglobin (HbA1C)	Hub lab of DH/Mother lab (DH) if HPLC		Lab tech	Fully automated biochemistry analyser/HPLC
66	S. Sodium	Hub lab of DH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
67	S. Potassium	Hub lab of DH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
68	S. Calcium	Hub lab of DH		Lab tech	Fully automated biochemistry analyser
69	S.Ionised Calcium	Hub lab of DH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
70	S.Chloride	Hub lab of DH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
71	S.Magnesium	Hub lab of DH		Lab tech	Indirect ion selective electrode Electrolyte Analyser
72	Arterial blood gas test	Hub lab of SDH		Lab tech	Blood gas analyser
73	Smear for RTI/STD	Hub lab of DH		Lab tech	Wet mounting, gram staining
74	Smear for leprosy	Mother lab (DH)		Lab tech	Microscopy
75	Gram staining for clinical specimen	Hub lab of DH		Lab tech	Microscopy
76	Throat swab for Diphtheria	Mother lab (DH)		Lab tech	Microscopy
77	Stool for hanging drop for Vibrio Cholera	Mother lab (DH)		Lab tech	Microscopy
78	Visual Inspection Acetic Acid (VIA)	Hub lab of DH		ANM	Manual

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
79	rK39 for Kala Azar*	Hub lab of DH		Lab tech	Rapid card test
80	Smear for Filaria*	Hub lab of DH		Lab tech	Microscopy
81	TB – Mantoux	Hub lab of DH		Lab tech	Manual
82	Japanese Encephalitis IgM - Blood, CSF (confirmatory)	Mother lab (DH)		Lab tech	ELISA
83	Scrub typhus Test*	Mother lab (DH if ELISA)/Hub lab of DH (Rapid)		Lab tech	ELISA/Weil Felix
84	Test for Leptospirosis*	Mother lab (DH)		Lab tech	ELISA
85	Test for Chikungunya	Mother lab (DH)		Lab tech	ELISA
86	IgM for Measles	Mother lab (DH)		Lab tech	ELISA
87	IgM for Hepatitis A	Mother lab (DH)		Lab tech	ELISA
88	IgM for Hepatitis E	Mother lab (DH)		Lab tech	ELISA
89	Rapid antigen detection test for Bacterial meningitis (Meningococci)	Mother lab (DH)		Pathologist	Rapid Latex agglutination test
90	S.TSH (including for new-born screening)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
91	S.Free T3	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
92	S.Free T4	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
93	S. Ferritin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
94	Troponin - I/Troponin – T	Hub lab of DH			Rapid card test
95	S.Beta HCG	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
96	S.Prolactin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
97	S. Anti-Mullerian hormone (AMH)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
98	S. Alfa Feto protein	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
99	S. CA-125	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
100	S. CEA	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
101	S.Procalcitonin	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
102	S. PSA	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
103	S.Vitamin B12	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
104	S. Vitamin D	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
105	TORCH IgM and IgG	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
106	S. Thyroid peroxidase antibody	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
107	Anti-cyclic citrullinated peptide (anti-CCP)	Mother lab (DH)		Lab tech	Chemiluminescence immunoassay
108	RA factor (Quantitative)	Hub lab of DH		Lab tech	Turbidometer
109	CRP(including new born) (Quantitative)	Hub lab of DH		Lab tech	Turbidometer
110	Anti-nuclear antibody (ANA)	Mother lab (DH)		Lab tech	Immunofluorescent microscopy
111	Cytology	Mother lab (DH)		Pathologist	Microscopy
112	Pap smear	Mother lab (DH)		Pathologist	Microscopy
113	CSF analysis (Glucose, CSF protein, ADA, cell count)	Hub lab of SDH		Lab tech	Fully automated biochemistry analyser, Haematology analyser
114	Fluid analysis (Cell count, biochemistry including Glucose, Protein, LDH and cytology)	Hub lab of DH for cell count and Biochemistry and Mother lab (DH) for cytology		Pathologist for cytology. Lab tech for cell count and biochemistry	Fully automated biochemistry analyser, Haematology analyser, Microscopy
115	Histopathology	Mother lab (DH)		Pathologist	Microscopy
116	Bone marrow examination	Mother lab (DH)		Pathologist	Microscopy
117	Immunohistochemistry	Mother lab (DH)		Pathologist	Manual
118	CD4 count	Mother lab (DH)		Microbiologist/ Pathologist	Flow cytometer
119	Viral load count for HCV	Mother lab (DH)		Microbiologist/ Pathologist	PCR

S. No.	Diagnostic test	Test to be conducted at the hub lab within the DH and for few tests including highly advanced tests samples transported to mother laboratory of DH which could be located outside or inside DH.	Remarks	Human resource required for conducting the test at sub centre	Product/Equipment Required
120	Viral load count for HBV	Mother lab (DH)		Microbiologist/ Pathologist	PCR
121	Blood culture	Mother lab (DH)		Microbiologist/ Pathologist	Automated
122	Urine culture	Mother lab (DH)		Microbiologist/ Pathologist	Manual
123	Fungal culture	Mother lab (DH)		Microbiologist/ Pathologist	Manual
124	Other cultures (pus, throat swab etc.)	Mother lab (DH)		Microbiologist/ Pathologist	Manual
125	Culture for Diptheria	Mother lab (DH)		Microbiologist/ Pathologist	Manual
126	Culture of stool specimen for Vibrio cholerae and other common bacterial enteropathogens	Mother lab (DH)		Microbiologist/ Pathologist	Manual
127	Organism identification and antimicrobial sensitivity for cultures	Mother lab (DH)		Microbiologist/ Pathologist	Automated
128	Mycobacterial culture and DST	State TB lab		As per RNTCP guidelines	Manual for liquid culture/Automated for solid culture; Automated DST
129	Hemoglobin electrophoresis/HPLC	Mother lab (DH)		Pathologist	Electrophoresis machine/HPLC machine
130	Protein electrophoresis	Mother lab (DH)		Pathologist	Electrophoresis machine
131	Nucleic Acid Amplification Test (NAAT) for TB	Mother lab (DH)		As per RNTCP guidelines	Nucleic Acid Amplification Machine
132	Early Infant Diagnostic test for HIV - Qualitative HIV-1 DNA PCR (ICTC)			As per NACO guidelines	Nucleic Acid Amplification Machine
133	Quantitative virological nucleic acid test for HIV			As per NACO guidelines	Nucleic Acid Amplification Machine
134	Test for drug overdose	Mother lab (DH)		Lab tech	Card Test

**Only for endemic areas*

ANNEXURE 1B:

LIST OF EQUIPMENT FOR EACH TYPE OF LABORATORY

Table 1 : List of equipment for subcentre

S.No.	Equipment for subcentre
1	Digital Hemoglobinometer
2	Glucometer
3	Test tubes and racks

Table 2 : List of equipment for basic laboratories at PHCs and small CHCs

S.No.	Equipment for basic laboratories at PHCs and small CHCs
1	Digital Hemoglobinometer
2	Glucometer
3	Improved neubauer chamber/Haemocytometer
4	Colorimeter
5	Semiautomated Biochemistry analyser (if PHC/small CHC is remote with limited connectivity to higher health facilities or transportation time of more than 2 hours to higher health facilities) No facility should use Semiautomated Biochemistry analyser if its average daily test load is more than 50 Biochemistry tests.
6	Hematology analyser (if PHC/small CHC is remote with limited connectivity to higher health facilities or transportation time of more than 2 hours to higher health facilities)
7	Urine analyser (If test load for urine >20 samples/day)
8	Microscope (Binocular, LED FM)
9	Nucleic Acid Amplification Machine at CHC
10	Rotor/shaker
11	ESR analyser (if PHC/small CHC is remote with limited connectivity to higher health facilities or transportation time of more than 2 hours to higher health facilities)
12	Centrifuge (4 tube/8 tube/16 tube)
13	Refrigerator
14	Needle syringe destroyer – Electronic
15	Micropipettes of fixed and variable volumes
16	Alarm clock
17	Blood collection tubes (K2 EDTA, Sodium fluoride, Citrate, Gel and clot activation)
18	Air conditioner with stabiliser (if analysers installed in the laboratory)
19	Computer with UPS
20	Scanner
21	Printer
22	Bar code reader

Table 3 : List equipment for hub laboratories (non-Mother lab)

S.No.	Equipment for hub laboratories (non-Mother lab)
Hematology	
1	Improved neubauer chamber/Haemocytometer
2	Digital Hemoglobinometer (Only at sample collection sites at the health facilities)
3	3-part Haematology cell counter (analyser)
4	ESR analyser
5	Automated Coagulation analyser (atleast 4 channel)
6	Binocular Microscope LED
7	Centrifuge (8 tube/16 tube)
8	Refrigerator
Biochemistry	
9	Glucometer/Colorimeter (Only at sample collection sites at the health facilities for testing Blood Sugar)
10	Fully automated Biochemistry analyser
11	Electrolyte analyser with indirect ion selective electrode
12	Centrifuge (8 tube/16 tube)
13	Refrigerator
Clinical Pathology	
14	Urine analyser
15	Binocular Microscope LED
16	Improved neubauer chamber/Haemocytometer
Immunology and Serology	
17	Turbidometer
18	Rotor/Shaker
19	Centrifuge (8 tube/16 tube)
20	Refrigerator
Microbiology equipment	
21	Nucleic Acid Amplification Machine
22	Binocular Microscope LED
Blood Storage	
23	Blood bank refrigerator
Miscellaneous	
24	Hot air oven
25	Refrigerator
26	Deep freezer (-20 degree celsius)

S.No.	Equipment for hub laboratories (non-Mother lab)
27	Needle syringe destroyer – Electronic
28	Incubator
29	Water bath
30	Micropipettes of fixed and variable volumes
31	Autoclave
32	Monopan analytic weighing scale
33	Alcohol thermometer
34	Table top pH meter-Digital combined electrode
35	Digital Thermometer With -50 c to +150 c Measurement Range at Interval of 0.1 c
36	RO plant/Deioniser
37	Timer stop watch
38	Alarm clock
39	Blood collection tubes (K2 EDTA, Sodium fluoride, Citrate, Gel and clot activation)
40	Air conditioner with stabiliser
41	Computer with UPS
42	Scanner
43	Printer
44	Bar code reader

Table 4 : List of equipment for Mother laboratory at District hospital (Catering to advanced tests of DH and all health facilities in the District and routine tests of DH and the nearby spoke health facilities)

S.No.	Equipment for Laboratory	Number of Units Required
Hematology		
1	Improved neubauer chamber/ Haemocytometer	2
2	Digital Hemoglobinometer (Only at DH sample collection area for emergencies)	2
3	5-part Haematology cell counter (analyser)	1 analyser for a maximum of 150 Hematology samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 40-60 samples per hour.
4	ESR analyser	1 analyser for a maximum of 100 ESR samples per day
5	Automated Coagulation analyser (atleast 4 channel)	1 analyser for 200 coagulation study samples per day
6	Fluorometer	1
7	Binocular Microscope LED	2 or 3 depending on requirement
8	Electrophoresis machine	1

S.No.	Equipment for Laboratory	Number of Units Required
9	High pressure liquid chromatography (HPLC)	1 machine for 100 samples of Hemoglobinopathies/HbA1C
10	Centrifuge (8 tube/16 tube)	1-2 depending on requirement
11	Refrigerator	1-2 depending on requirement
Biochemistry		
12	Glucometer (Only at sample collection areas in the DH for emergencies)	2-6 depending on requirement
13	Fully automated Biochemistry analyser	1 analyser for a maximum of 400 Biochemistry samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 400 tests per hour. Permissible daily sample load for analysers with lesser or more higher throughput can be calculated accordingly.
14	Electrolyte analyser with indirect ion selective electrode	1 analyser for a maximum of 200 tests of electrolytes per day
15	Blood gas analyser	1 machine per 30 ICU beds
16	Centrifuge (8 tube/16 tube)	2-3 depending on requirement
17	Refrigerator	2-4 depending on requirement
Clinical Pathology		
18	Urine analyser	1 analyser for a maximum of 150 urine samples per day
19	Binocular Microscope LED	2 or 3 depending on requirement
20	Improved neubauer chamber/Haemocytometer	2
Immunology and Serology		
21	Fully automated Chemiluminescence immunoassay	1 analyser for a maximum of 400 immunoassay and serology samples per day. The sample load is recommended for the analyser with a capacity (throughput) of 400 tests per hour. Permissible daily sample load for analysers with lesser or more higher throughput can be calculated accordingly.
22	Fully automated ELISA reader and washer	1 analyser for a maximum of 180 samples of ELISA per day
23	Turbidometer	1 analyser per 200 tests of turbidometry per day
24	Rotor/Shaker	1 or 2 depending on requirement
25	Centrifuge (8 tube/16 tube)	2 or 3 depending on requirement
26	Refrigerator	1 or 2 depending on requirement
Microbiology equipment		
27	Binocular Microscope LED	2 or 3 depending on requirement

S.No.	Equipment for Laboratory	Number of Units Required
28	Automated Blood Culture/Liquid Media System with Smart Rapid detection	1 machine for a maximum of 50 blood culture samples per day
29	Automated Organism Identification and Antimicrobial sensitivity system	1 machine for a maximum of 200 culture samples per day
30	Culture hood/Class 1 Biosafety cabinet	1 or 2 depending on requirement
31	Incubator	2-4 depending on requirement
32	Laminar flow	1
Histopathology equipment		
33	Binocular Microscope LED	2 or more depending on requirement
34	Rotary microtome	1-2
35	Knife sharpner	2
36	Block wax trimmer	1
37	Paraffin dispenser	1
38	Automated tissue processor	1
39	Slide staining racks	
40	Tissue Floatation Bath with Digital Temperature Controller and display	1
41	Antigen retrieval unit	1
42	Hot Plate with Digital Temperature Controller	1-2
43	Cryostat Instrument for Frozen Section	1
44	Embedding Station	1
45	Wax embel bath	
46	Bone cutter with saw	2
47	Immunohistochemistry stainer	1
Cytology equipment		
48	Improved neubauer chamber/Haemocytometer	2
49	Binocular Microscope LED	2
50	Cytocentrifuge	1-2 depending on requirement
51	Liquid Based Cytology System	1
52	Refrigerator	1
Other equipment		
53	Immunofluorescent microscope	1
54	Flow cytometer	1
55	Nucleic Acid Amplification Machine	1 or more depending on sample load
56	Refrigerator	1-2 depending on requirement

S.No.	Equipment for Laboratory	Number of Units Required
Blood bank		
57	Blood bank refrigerator	
58	Deep Freezer -80 degree Celsius	
59	Refrigerated centrifuge	
60	Horizontal prevaccum autoclave	
61	3 part Hematology analyser	
62	Automated coagulation analyser	
63	Laminar air flow Bench (Biosafety cabinet)	
64	Sterile connecting device	
65	Blood Mixer and Collector	
66	Platelet Incubator and Platelet Agitator	
67	Plasma Thawing Bath	
68	Manual Plasma Expresser	
69	Automated component processor (Automated plasma separator)	
70	Dielectric tube sealer	
71	Refrigerated water bath (cryobath)	
Miscellaneous		
72	Hot air oven	2-3 depending on requirement
73	Refrigerator	2-3 for Store depending on requirement
74	Deep freezer (-20 degree celsius)	1
75	Needle syringe destroyer – Electronic	At every sample collection site
76	Incubator	1 or 2 depending on requirement
77	Water bath	1
78	Micropipettes of fixed and variable volumes	Depending on requirement
79	Autoclave	1
80	Monopan analytic weighing scale	1 or 2 depending on requirement
81	Alcohol thermometer	2
82	Table top pH meter-Digital combined electrode	1
83	Digital Thermometer With -50 c to +150 c Measurement Range at Interval of 0.1 c	1
84	RO plant/Deioniser	1
85	Timer stop watch	2
86	Alarm clock	2
87	Blood collection tubes (K2 EDTA, Sodium fluoride, Citrate, Gel and clot activation)	As per requirement

S.No.	Equipment for Laboratory	Number of Units Required
88	Air conditioner with stabiliser	1-2 air conditioner for each section of laboratory
89	Computer with UPS	1-2 in each section of laboratory and at registration counter
90	Scanner	1-2 depending on requirement
91	Printer	1 in each section of laboratory
92	Bar code reader	2-4 depending on requirement

Table 5 : Mapping of tests with equipment

Mapping of tests with equipment	
Equipment type	**Tests (listed in Free Diagnostics Initiative) recommended to be conducted on the equipment**
Digital Hemoglobinometer	Haemoglobin
Glucometer	Blood sugar
Haemocytometer	a. Haematology: TLC, Platelet count, Total RBC count (haemocytometer to be used for these tests only in absence of haematology analyser) b. Clinical Pathology: Semen cell count, Fluid cell count
Colorimeter	Haemoglobin, Blood sugar
Haematology cell counter (analyser)	a. Haematology: Complete blood count, Haemoglobin, TLC, DLC, Platelet count, Total RBC count, MCV, MCH, MCHC, RDW b. Fluid cell count (in some analysers)
ESR analyser	ESR
Semi-automated Biochemistry analyser	Blood sugar, Blood Urea, S. Creatinine, S. Bilirubin total, S. Bilirubin (D&I), SGOT, SGPT, S. Alkaline phosphatase, S. Total protein, S. Albumin, S. Amylase, S. Total Cholesterol, S. Triglyceride, S. VLDL, S. HDL, S.LDL, S. Uric acid, S. LDH, RA factor, S. CRP
Fully automated Biochemistry analyser	Blood sugar, Blood Urea, S. Creatinine, S. Bilirubin total, S. Bilirubin (D&I), SGOT, SGPT, S. Alkaline phosphatase, S. Total protein, S. Albumin, S. Amylase, S. Total Cholesterol, S. Triglyceride, S. VLDL, S. HDL, S. LDL, S. Uric acid, S. LDH, RA factor, S.CRP, HbA1C, Fluid biochemistry (Sugar, protein, LDH), S. Iron, S. Total Iron Binding Capacity, S. Calcium
Electrolyte analyser	S. Ionised Calcium, S. Potassium, S. Sodium, S. Magnesium, S.Chloride
Blood gas analyser	Arterial blood gas test
Turbidometer	RA factor, S.CRP, HbA1C, Urine microalbumin
Automated Coagulation analyser	Prothrombin time, APTT, INR
Urine analyser	Complete urine analysis
ELISA reader cum washer	Antibodies to HCV, HIV antibodies (Anti HIV 1 and 2), Dengue (NS1 antigen and antibodies), Antibodies for Chikungunya, Leptospirosis, Japanese Encephalitis, Scrub typhus, Hepatitis A and E and Measles
Fully automated chemiluminescence immunoassay	TSH, T3, T4, Troponin T/I, Antibodies to HCV, HIV antibodies (Anti HIV 1 and 2), Hepatitis surface antigen (HbsAg), S. Ferritin, S. Prolactin, S. Beta HCG, S. Anti-Mullerian hormone (AMH), TORCH, S.CEA, S. CA-125, S.PSA, S.AFP
HPLC	HbA1C, Hemoglobinopathies
Electrophoresis	Hemoglobinopathies and protein disorders
Automated Blood Culture/Liquid Media System with Smart Rapid detection	Alert of presence of bacteria in Blood culture
Automated Organism Identification and Antimicrobial sensitivity system	Bacterial identification and antibiotic sensitivity
Culture hood	For culture
Incubator	For incubation of cultures
Rotor/shaker	VDRL
Immunofluoroscent microscope	Antinuclear antibody test
Fluorometer	G6PD enzyme deficiency test

Annexure 2
SUGGESTIVE CHECKLIST FOR GAP ANALYSIS FOR HUMAN RESOURCES AND EQUIPMENT

2A. Checklists for equipment and HR for various levels of facilities

Table 1: Information regarding Laboratory Services under Free Diagnostic initiative for PHCs

District Name	Name of PHC	Total number of patients who visited the PHC in the last one year (Total patient load of OPD+IPD of the health facility).	No. of permanent lab technicians currently posted in PHC (Please mention number)	No. of contractual lab technicians currently posted in PHC (Please mention number)	Is Hematology cell counter present in the PHC (Yes if present, No if absent)

Table 1 (Conti.) : Information regarding Laboratory Services under Free Diagnostic initiative for PHCs

District Name	Name of PHC	Is semiautomated Biochemistry analyser present in the PHC (Yes if present, No if absent)	Is Colorimeter present in the PHC (Yes if present, No if absent)	Is Glucometer present in the PHC (Yes if present, No if absent)	Is Digital Hemoglobinometer present in the PHC (Yes if present, No if absent)

Table 1 (Conti.) : Information regarding Laboratory Services under Free Diagnostic initiative for PHCs

District Name	Name of PHC	Is 4-tube/8 tube centrifuge present in the PHC (Yes if present, No if absent)	Is rotor/shaker present in the PHC (Yes if present, No if absent)	Is binocular microscope present in the PHC (Yes if present, No if absent)	If any other equipment present, please mention the name

Table 1 (Conti.) : Information regarding Laboratory Services under Free Diagnostic initiative for PHCs

District Name	Name of PHC	For how many types of tests is there a shortage of reagents?	No. of test types available through in-house lab	No. of tests conducted through in-house lab in last one year	No. of test types available through PPP	No. of tests conducted through PPP lab in last one year

Table 2: Information regarding Laboratory Services under Free Diagnostic Initiative for CHC or equivalent of CHC

District name	Name of CHC	Total number of patients who visited the CHC in the last one year (Total patient load of OPD+IPD of the health facility).	No. of permanent lab technicians currently posted (Please mention number)	No. of contractual lab technicians currently posted (Please mention number)	Is Hematology cell counter present in the CHC (Yes if present, No if absent)	Is semiautomated biochemistry analyser present in the CHC (Yes if present, No if absent)

Table 2 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for CHC or equivalent of CHC

District name	Name of CHC	Is fully automated Biochemistry analyser present in the hospital (Yes if present, No if absent)	Is Turbidometer for following tests present in the hospital - RA factor, S.CRP, ASLO? (Yes if equipment present, No if absent)	Is ESR analyser present in the CHC? (Yes if present, No if absent)	Is Coagulation analyse (for doing Prothrombin time) present in the CHC? (Yes if present, No if absent)	Is Urine analyser present in the CHC? (Yes if present, No if absent)

Table 2 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for CHC or equivalent of CHC

District name	Name of CHC	Is Electrolyte analyser present in the CHC? (Yes if present, No if absent)	Is HbA1C analyser present in the CHC? (Yes if present, No if absent)	Is Colorimeter present in the CHC (Yes if present, No if absent)	Is Glucometer present in the CHC (Yes if present, No if absent)	Is Digital Hemoglobinometer present in the CHC (Yes if present, No if absent)

Table 2 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for CHC or equivalent of CHC

District name	Name of CHC	Is binocular microscope present in the CHC (Yes if present, No if absent)	Is 8-tube/16 tube centrifuge present in the CHC (Yes if present, No if absent)	Is rotor/shaker present in the CHC (Yes if present, No if absent)	Is incubator present in the CHC (Yes if present, No if absent)	If any other equipment present, please mention the name

Table 2 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for CHC or equivalent of CHC

District name	Name of CHC	For how many types of tests is there a shortage of reagents?	No. of test types available through in-house lab	No. of tests conducted through in-house lab in last one year	No. of test types available through PPP	No. of tests conducted through PPP lab in last one year

Table 3: Information regarding Laboratory Services under Free Diagnostic Initiative for Sub-District and District Hospitals

District name	Name of hospital	Type of hospital (SDH/CH/GH/WH/ DH/other)	Total number of patients who visited the facility in last one year (Total patient load of OPD+IPD of the health facility).	No. of permanent lab technicians currently posted (Please mention number)	No. of contractual lab technicians currently posted (Please mention number)

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District name	Name of Hospital	Is Hematology cell counter present in the hospital (Yes if present, No if absent)	Is semiautomated Biochemistry analyser present in the hospital (Yes if present, No if absent)	Is fully automated Biochemistry analyser present in the hospital (Yes if present, No if absent)	Is ESR analyser present in the hospital? (Yes if present, No if absent)	Is Urine analyser present in the hospital? (Yes if present, No if absent)

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District name	Name of Hospital	Is Coagulation analyser machine for Prothrombin time present in the hospital? (Yes if present, No if absent)	Is Electrolyte analyser present in the hospital? (Yes if present, No if absent)	Is Turbidometer for following tests present in the hospital - RA factor, S.CRP, ASLO? (Yes if equipment present, No if absent)	Is ELISA reader and washer present in the hospital? (Yes if equipment present, No if absent)	Is fully automated Immunoassay analyser for TSH present in the hospital? (Yes if equipment present, No if absent)

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District name	Name of Hospital	Type of hospital (SDH/CH/GH/WH/ DH/other)	Is HbA1C analyser present in the hospital? (Yes if present, No if absent)	Is Colorimeter present in the hospital (Yes if present, No if absent)	Is Glucometer present in the hospital (Yes if present, No if absent)

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District Name	Name of Hospital	Is Digital Hemoglobinometer present in the hospital (Yes if present, No if absent)	Is binocular microscope present in the hospital (Yes if present, No if absent)	Is 8-tube/16 tube centrifuge present in the hospital (Yes if present, No if absent)	Is rotor/ shaker present in the hospital (Yes if present, No if absent)

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District Name	Name of Hospital	Is incubator present in the hospital (Yes if present, No if absent)	Is culture hood / Biosafety cabinet present in the hospital (Yes if present, No if absent)	Is automated Blood culture equipment present in the hospital (Yes if present, No if absent)	Is automated organism identification and antimicrobial sensitivity equipment present in the hospital (Yes if present, No if absent)

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District Name	Name of Hospital	Are following tests done in the hospital - Fluid examination (Ascitic, pleural, CSF) and Semen analysis? (Yes if tests done/No if tests not done)	Are following tests done in the hospital - Blood and Urine culture? (Yes if tests done/No if tests not done)	Are following tests done in the hospital - Histopathology and Cytopathology? (Yes if tests done/No if tests not done)	Is there a Pathologist or any other Lab medicine specialist present in the hospital (Yes if present, No if absent)?

Table 3 (Cont.): Information regarding Laboratory Services under Free Diagnostic Initiative for SubDistrict and District Hospitals

District Name	Name of Hospital	For how many types of tests is there a shortage of reagents?	No. of test types available through in-house lab	No. of tests conducted through in-house lab in last one year	No. of test types available through PPP	No. of tests conducted through PPP lab in last one year

2B: Gap analysis checklist for civil (and other) work used in Rajasthan

मुख्यमंत्री निःशुल्क जाँच योजना – सामुदायिक स्वास्थ्य केन्द्र					
लैबोरेट्री/एक्स–रे/ईसीजी एवं अन्य तैयारियों के मूल्यांकन हेतु चैकलिस्ट					
अस्पताल का नामः		चिकित्सक का नाम व मो.नं.		अस्पताल की शैय्या क्षमता	
दिनांकः		ई–मेलः			
28 प्रस्तावित जाँचो में उपलब्ध जाँचो की संख्या					
I - आधारभूत संरचना एवं फर्नीचर (Infrastructure & Furniture)					
1.0	**माइनर सिविल वर्क (Minor Civil Work)**				
1.1	अन्य अनावश्यक सामग्री पूर्णतया हटाना।				हाँ/नहीं
1.2	वर्तमान में अस्पताल नवीनिकरण व सुसज्जा का कार्य शुरू करना।				हाँ/नहीं
1.3	आवश्यकतानुसार माईनर सिविल कार्य (सुक्ष्म मरम्मत/रंगाई – पुताई/पार्टीशन) शुरू करना।				हाँ/नहीं
1.4	विभिन्न स्थानों की उपलब्धता (एल्यूमिनीयम ग्लास पार्टीशन द्वारा) सुनिश्चित करना।				
	1. स्टाफ के लिये कक्ष	हाँ/नहीं		2. सेम्पल संग्रहण कक्ष	हाँ/नहीं
	3. जांच कक्ष	हाँ/नहीं		4. रिकॉर्ड रखने का स्थान	हाँ/नहीं
	5. कन्ज्यूमेबलस स्टोरेज स्थान	हाँ/नहीं		6. पंजीकरण एवं रिपोर्ट वितरण काउन्टर	हाँ/नहीं
	7. सुविधायें (Toilets)	हाँ/नहीं		8. रोगीयों हेतु प्रतीक्षा स्थान	हाँ/नहीं
1.5	वेन्टीलेशन हेतु Exhaust Fan की उपलब्धता				हाँ/नहीं
1.6	नमी/आर्द्रता रहित (फर्श, छत/दीवारें) वातावरण की उपलब्धता				हाँ/नहीं
1.7	अस्पताल में ओ.पीडी. एवं भर्ती मरीजों (24 X 7) हेतु अलग–अलग "सेम्पल संग्रहण कार्नर" का निर्माण।				हाँ/नहीं
1.8	एक से अधिक "सेम्पल संग्रहण कार्नर" होने की स्थिति में उनका संख्याकन करना।				
1.9	सिंक की उपलब्धता				हाँ/नहीं
2.0	एक्स–रे कक्ष में AERB Guide Lines अनुसार–पार्टीशन	हाँ/नहीं		एक्स–रे वर्कस हेतु TLD बैज (Personal Monotering Device)	हाँ/नहीं
2. **फर्नीचर (Furniture) की उपलब्धता**					
		उपलब्ध हाँ/नहीं			उपलब्ध हाँ/नहीं
2.1	रोगियो हेतु कुर्सियां/स्टूल		2.6	जाँच रसायनो को रखने हेतु रेक्स	
2.2	केबिनेट/अलमारी		2.7	कुर्सियां	
2.3	अग्निशमन यन्त्र		2.8	टेबिल	
2.4	लेबोरेट्री कक्ष		2.9	एक्स–रे कक्ष	
2.5	ईसीजी कक्ष				
3.	**विभिन्न जाँचों सूचना पट्ट (Boards) एवं साईनेज की स्थिति**				
3.1	सेम्पल संग्रहण स्थान पर "मुख्यमंत्री निःशुल्क जांच योजना" का बोर्ड लगाना				हाँ/नहीं

मुख्यमंत्री निःशुल्क जाँच योजना – सामुदायिक स्वास्थ्य केन्द्र					
3.2	दिशा इंगीत करने हेतु साईनेज एवं दिशा सूचक निशान (तीर के निशान) लगाना।				हाँ/नहीं
3.3	जाँच होने एवं रिपोर्ट प्राप्ती का समय अंकित करना।				हाँ/नहीं
3.4	अस्पताल में होने वाली निःशुल्क जाँचों की सूची को चस्पा करना।				हाँ/नहीं
3.5	लैब प्रभारी, तकनीशियन एवं अन्य कार्मिकों के नाम एवं सम्पर्क सूत्र (फोन नम्बर) लैब के बाहर लिखना।				हाँ/नहीं
3.6	शिकायत कक्ष/कन्ट्रोल रूम का नम्बर लिखना।				हाँ/नहीं
3.7	धूम्रपान निषेध, बायोसेफ्टी एवं आग से संबंधित चेतावनी चिन्ह दीवार पर चस्पा करना।				हाँ/नहीं
3.8	अग्निशमन वाहन एवं पुलिस कन्ट्रोल रूम का दूरभाष नम्बर दीवार पर चस्पा करना।				हाँ/नहीं
II - मानव संसाधन (Manpower)					
1	**आवश्यक मानव संसाधन के नाम एवं मो. नं. अंकित करे।**				
	1. जाँच प्रभारी (एमएनजेवाई)		2. लैब सहायक		
	3. लैब तकनीशियन				
	4. हैल्पर/क्लीनर		5. डाटा ऑपरेटर		
	6. ईसीजी टैक्निशियन		7. रेडियोग्राफर		
	8. गार्ड		9. अन्य		
III - जांच उपकरण (Diagnostic Equipments) की उपलब्धता					
1	**जाँच उपकरण उपलब्ध एवं कार्यशील स्थिति**				
		उपलब्ध हाँ/नहीं			उपलब्ध हाँ/नहीं
1.1	सेल काउण्टर		1.2	सेमी ऑटो एनालाइजर	
1.3	एक्स–रे मशीन		1.4	ईसीजी मशीन	
1.5	आवश्यक क्लिनीकल पैथोलॉजी उपकरण		1.6	आवश्यक माईक्रोबायोलोजीकल उपकरण	
1.7	आवश्यक बायोकेमीस्ट्री जांच उपकरण		1.8	आवश्यक हिमेटोलॉजी उपकरण	
1.9	रेफ्रिजरेटर		2.0	माईक्रोस्कोप	
IV- जांच किट व रसायनों की उपलब्धता (Avaibility of Reagents, Kits & Counsumables)					
1.	जाँच रसायनों की उपलब्धता (Reagents in Cabinets)				
1.1	आवश्यक रसायनों एवं कन्जयूमेबल्स की स्थानीय स्तर पर उपलब्धता सुनिश्चित करना।				हाँ/नहीं
1.2	3–5 माह के लिए जांच रसायन एवं अन्य कन्जयूमेबल्स की उपलब्धता।				हाँ/नहीं
1.3	जांच रसायन व्यवस्थित रूप से रखना।				हाँ/नहीं
1.4	तरल रसायन एवं भारी सामान सुविधानुसार उंचाई पर कैबिनेट में रखना।				हाँ/नहीं

मुख्यमंत्री निःशुल्क जाँच योजना – सामुदायिक स्वास्थ्य केन्द्र					
1.5	सभी रसायनों के कन्टेनरों पर लैबील सुनिश्चित करना।				हाँ/नहीं
1.6	जांच रसायनों का फीफो (First Expiry First Out-FEFO) पद्धति अनुसार ही उपयोग सुनिश्चित करना।				हाँ/नहीं
1.7	ज्वलनशील पदार्थ को अलग से स्टोरेज करना।				हाँ/नहीं
1.8	ज्वलनशील रसायनों हेतु लाइटप्रुफ्ड कंटेनर्स का उपयोग करना।				हाँ/नहीं
1.9	जांच रसायन को अपने मूल कंटेनर में ही रखना।				हाँ/नहीं
1.10	हानिकारक एवं विषैले तत्वों को उचित लेबल लगाकर कैबिनेट में रखना।				हाँ/नहीं
1.11	उपकरणो को काम में लेने एवं रख–रखाव के संबंध में गाइडलाइन का उपयोग करना।				हाँ/नहीं
1.12	उपकरणो हेतु Log Book संधारित करना।				हाँ/नहीं
1.13	जैविक कचरे के निस्तारण हेतु अलग–अलग रंग के कन्टेनर उपयोग में लेना। (बी.एम.डब्ल्यू.)				हाँ/नहीं
V - रिकार्ड संसाधन (Record Keeping)					
1.1	रजिस्टर उपलब्धता				
	1. स्टॉक रजिस्टर	हाँ/नहीं		3. रिपोर्ट डिस्पैच रजिस्टर	हाँ/नहीं
	2. टेस्ट रिकॉर्ड रजिस्टर	हाँ/नहीं		4. विभिन्न रिपोर्ट प्रपत्र	हाँ/नहीं
	5. स्टीकर्स (सैम्पल पहचान हेतु)	हाँ/नहीं			
	लैब से सम्बन्धित प्रमुख समस्याएं जिनका निराकरण प्राथमिकता के आधार पर करना				
क्षेत्र समस्याऐं				अपेक्षित समाधान	
1	मानव संसाधन				
2	सिविल कार्य				
3	उपकरण				
	सेल काउण्टर				
	सेमी ऑटो एनलाइजर				
	एक्स–रे मशीन				
	ईसीजी मशीन				
4	फर्नीचर				
5	जांच रसायनों की उपलब्धता एवं भण्डारण				
6	28 प्रस्तावित जांचों में से अनुपलब्ध जांचों की संख्या एवं विवरण बताये				
7	अन्य विवरण				

Annexure 3

CHECKLIST FOR EQUIPMENT RECEIPT USED IN RAJASTHAN

CHECK LIST FOR EQUIPMENT RECEIPT

उपकरण चेक लिस्ट

Following checklist to be ensured while receiving the delivery of newly supplied equipment

उपकरण की प्राप्ति के समय कम्पनी द्वारा प्रदायगी सामान की पुष्टी के लिये चेकलिस्ट

S. No.	Particulars/विवरण		Yes/हाँ	No/नही
1	**Packing पैकिंग**			
	(i)	Total number of boxes received (as per invoices/challan/R.R./technical specifications) कुल प्राप्त बॉक्स (चालान/इनवाईस/तकनीकी मापदण्ड अनुसार)		
	(ii)	Whether the supplier present during the time of delivery/received through transportation उपकरण प्रदायगी के समय प्रदायकर्ता की उपस्तिथी		
	(iii)	Whether the equipment packed in good condition प्रदायगी उपकरण की पैकिंग की स्थिति ठीक है।		
2	**Unpacking उपकरण खोलने पर**			
	(i)	Whether equipment is received in good condition उपकरण ठीक स्थिति में पाया गया		
	(ii)	If received in damaged condition has this been mentioned in the delivery challan invoice and informed to higher authority and supplier/manufacturer उपकरण ठीक नहीं पाये जाने पर प्रदायकर्ता/निर्माता के डिलेवरी चालान/इनवाईस पर स्थिति को उल्लेखित किया गया।		
	(iii)	Whether all spare parts/accessories/consumables received as per order/ technical specifications उपकरण के सभी स्पेयर पार्टस/एसेसरीज क्रय आदेश/ तकनीकी मापदण्ड अनुसार पाये गये।		
	(iv)	Whether equipment is inspected by procurement agency and inspection report is received during delivery उपकरण प्रदायगी के साथ प्रोक्यूरमेंट एजेंसी का निरीक्षण प्रतिवेदन प्रस्तुत किया गया है।		
3	**Installation उपकरण स्थापना**			
	(i)	Whether equipment is fitted properly उपकरण सुव्यवस्थित स्थापित किया गया है		
	(ii)	Whether demonstration of equipment given properly उपकरण का डिमांस्ट्रेशन किया गया।		
	(iii)	Whether equipment is working satisfactorily उपकरण संतोषजनक कार्यशील है।		
	(iv)	Whether the operational training provided to the staff and nos. of staff trained उपकरण संचालन के लिये स्टाफ को ट्रेनिंग/प्रशिक्षण दिया गया। ..... स्टाफ प्रशिक्षित है।		
	(v)	Whether operational manual and maintenance manual provided by supplier/ manufacturer उपकरण प्रदायकर्ता द्वारा उपकरण का आप्रेशन एवं में टेनेन्स मेन्यूवल उपलब्ध कराया गया।		
4	**Warranty**			
	(i)	Whether warranty card & terms of warranty received		
5	Stock Book entry page no. स्टाक बुक प्रविष्ठी पेज नम्बर			
6	Contact person for repair & maintenance (Address & Phone Nos.)			

Annexure 4

PERCENTAGE SHARE OF EACH TEST AT VARIOUS LEVELS OF GOVERNMENT HEALTH FACILITIES IN GUJARAT (2017-18)

Table 1 : Percentage share of each type of test ordered at District Hospitals in Gujarat in year 2017-18

S. No.	Name of test	Percentage share of each test
1	Haemoglobin (HB)	4.6
2	Total Leukocyte count(TLC)	1.2
3	Differential Leukocyte Count (DLC)	1.2
4	Malaria slide test	0.6
5	Erythrocyte Sedimentation Rate (ESR)	0.1
6	Bleeding Time (BT)	0.1
7	Clotting Time (CT)	4.6
8	PBF	1.3
9	Complete Blood Count (CBC)	2.9
10	ABO-RH typing	1.2
11	Total Eosinophilic Count	0.3
12	Red Blood Count (RBC)	0.9
13	Platelet Count	5.7
14	Packed Cell Volume (PCV)	2.0
15	Comb's test- Direct	2.9
16	Comb's test –Indirect	1.2
17	Prothrombin Time test INR	0.3
18	Cell count and Biochemistry of CSF, pleural fluid and ascetic fluid	0.9
19	Semen analysis	5.7
20	Pap's smear	2.0
21	Urine Sugar	3.9
22	Urine Albumin	2.0
23	Urine Microscopy	0.9
24	Urine bile salts	1.1
25	Urine bile pigments	5.8
26	Urine ketone bodies	2.0
27	Urine occult blood	3.9
28	Urine sugar	2.4
29	Urine albumin	1.3
30	Urine pH	1.2
31	Urine specific gravity	5.9
32	Urine multi strip Method	2.0

S. No.	Name of test	Percentage share of each test
33	HB1AC %	1.0
34	Random Blood Sugar	1.0
35	Blood Glucose - Fasting (FPG)	0.2
36	Post Prandial blood Glucose (PP2PG)	0.2
37	Blood Urea	1.3
38	S. Creatinine	1.4
39	S. Bilirubin- Total	0.4
40	S. Bilirubin- Direct	0.4
41	SGOT	1.6
42	SGPT	1.7
43	(Alkaline Phosphatase)	0.4
44	S. Total Protein	0.4
45	S. Albumin	1.6
46	S. Sodium	1.7
47	S. Potassium	0.5
48	S. CK - MB	0.4
49	S. Amylase	1.6
50	S. Total cholesterol	1.8
51	S. Triglyceride	0.5
52	S. V.L.D.L	0.4
53	S. HDL	1.6
54	S. Lipase	1.8
55	S.LDH	0.5
56	TSH	0.4
57	Total T3	1.6
58	Total T4	1.8
59	RPR test	0.3
60	HIV Rapid test	0.5
61	Sputum for AFB	0.1
62	WIDAL slide test	0.2
63	Dengue IgM antibody ELISA Test	0.0
64	Dengue NS1 antigen ELISA Test	0.0
65	RA	0.0
66	ASLO titre	0.0
67	HBsAg Rapid Test	0.3
68	HBsAg ELISA test	0.0
69	S. CRP	0.1
70	Hepatitis A ELISA	0.0

S. No.	Name of test	Percentage share of each test
71	Hepatitis E ELISA	0.0
72	Cholera Culture and antibiotic sensitivity	0.0
73	Blood Culture and antibiotic sensitivity	0.0
74	Diphtheria culture and antibiotic sensitivity	0.0
75	Measles IgM antibody	0.0
76	Chikungunya IgM antibody ELISA	0.0
77	HCV antibody Rapid test	0.1
78	Anti-Leptospira IgG/IgM antibodies –Rapid	0.0
79	Urine Pregnancy Test (UPT)	0.1
80	Urine Culture and antibiotic sensitivity	0.0
81	Stool for OVA And Cyst	0.0

Table 2 : Percentage share of each type of test ordered at Sub-district hospitals in Gujarat in year 2017-18

S.No.	Name of test	Percentage share of each test
1	Urine Pregnancy test (UPT)	1.1
2	Blood Sugar (RBS)	6.3
3	Blood Sugar (FASTING)	0.7
4	Blood Sugar (PPP)	0.5
5	Urine Albumin	6.0
6	Urine Sugar	5.9
7	Haemoglobin (Hb)	9.7
8	Total Leukocyte Count (TLC)	7.8
9	Differential Leukocyte Count (DLC)	7.4
10	Blood for Malarial Parasite	6.1
11	ESR	0.8
12	Pap smear	0.1
13	Blood Group	2.6
14	S. Widal Test	2.0
15	RPR test	1.6
16	HIV Rapid Test	3.8
17	Sputum For AFB	1.6
18	Red Blood Count(RBC)	4.1
19	HBSG	1.9
20	Bleeding Time (min)	0.3
21	Clotting Time (min)	0.3
22	CBC	6.7

S.No.	Name of test	Percentage share of each test
23	Platelet count	5.2
24	Packed Cell Volume (PCV)	4.3
25	Blood Urea	1.2
26	S. Creatinine	1.4
27	S. Bilirubin- Total	1.2
28	S. Bilirubin- Direct	1.1
29	S. Total protein	0.5
30	S. albumin	0.1
31	S. Total Cholesterol	0.2
32	S. SGPT	1.3
33	Urine Microscopy	5.1
34	Urine Complete strip method	1.3

Table 3 : Percentage share of each type of test ordered at CHCs in Gujarat in year 2017-18

S.No.	Name of test	Percentage share of each test
1	Urine Pregnancy test (UPT)	1.9
2	Blood Sugar (RBS)	10.3
3	Blood Sugar (FASTING)	1.1
4	Blood Sugar (PPP)	0.9
5	Urine Albumin	6.7
6	Urine Sugar	6.7
7	Haemoglobin (Hb)	11.2
8	Total Leukocyte Count (TLC)	5.6
9	Differential Leukocyte Count (DLC)	5.3
10	Blood for Malarial Parasite	11.0
11	ESR	0.5
12	Pap smear	0.1
13	Blood Group	3.0
14	S. Widal Test	1.9
15	RPR test	1.9
16	HIV Rapid Test	6.0
17	Sputum For AFB	2.4
18	Red Blood Count (RBC)	3.7
19	HBSG	1.9
20	Bleeding Time (min)	0.2
21	Clotting Time (min)	0.2

S.No.	Name of test	Percentage share of each test
22	CBC	4.6
23	Platelet count	3.9
24	Packed Cell Volume (PCV)	2.7
25	Blood Urea	0.2
26	S. Creatinine	0.3
27	S. Bilirubin-Total	0.3
28	S. Bilirubin-Direct	0.3
29	S. Total protein	0.1
30	S. albumin	0.2
31	S. Total Cholesterol	0.2
32	S. SGPT	0.3
33	Urine Microscopy	3.3
34	Urine Complete strip method	1.2

Table 4 : Percentage share of each type of test ordered at PHCs in Gujarat in year 2017-18

S.No.	Name of test	Percentage share of each test
1	Urine Pregnancy test (UPT)	11.6
2	Blood Sugar (RBS)	4.6
3	Blood Sugar (FASTING)	0.4
4	Blood Sugar (PPP)	0.4
5	Urine Albumin	2.2
6	Urine Sugar	2.2
7	Haemoglobin (Hb)	1.1
8	Total Leukocyte Count (TLC)	0.4
9	Differential Leukocyte Count (DLC)	10.7
10	Blood for Malarial Parasite	4.2
11	ESR	19.3
12	Pap smear	1.8
13	Blood Group	2.7
14	S. Widal Test	3.1
15	RPR test	2.3
16	HIV Rapid Test	0.6
17	Sputum For AFB	10.8
18	Red Blood Count (RBC)	4.9
19	HBSG	16.7

Annexure 5

MONITORING INDICATORS FOR IN-HOUSE DIAGNOSTIC SERVICES

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
1	Percentage of government health facilities serviced under Free Diagnostics Initiative	State, district	Yearly	
2	Total number of tests notified/ provided at each level of facility	State	Yearly	
3	Total number of patients tested	State, district, facility, OPD, IPD, women, children and tribal patients	Monthly	
4	Total number of tests conducted – test-wise	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
5	Patient to test ratio	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
6	Percentage of patients with 1,2,3.....n number of tests prescribed	State, district and facility	Monthly	
7	Percentage of government health facilities with zero samples for more than 10% of working days	State, district and facility	Monthly	
8	Percentage and types of tests which are unavailable for a total of more than three working days in a month	State, district and facility	Monthly	
9	Percentage of laboratories with NABL accreditation	State and district	Yearly	
10	Percentage of tests accredited under NABL	Laboratory	Half-yearly	
11	Percentage of laboratories which underwent yearly internal audit	State, district and laboratory	Yearly	
12	Sample rejection rate	State, district, facility, OPD, IPD and laboratory	Monthly	Sample haemolysed, sample clotted, insufficient sample, delay for prothrombin time and labelling error
13	Percentage of tests repeated on request of clinicians	State, district, facility, clinician, OPD, IPD and type of test	Monthly	Re-run/re-sampling requisition form to be filled by the laboratory. For patient identification for repeat testing, unique ID of patients

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
				(Aadhaar card/any other ID proof) can be used.
14	Percentage of tests with results outside the biological reference interval (test-wise)	State, district, facility, clinician, OPD, IPD and type of test	Monthly	
15	EQAS/Inter-laboratory comparison, IQC, traceability of kits and out-of-control situations			
a.	Percentage of tests for which	State, district, laboratory	Monthly	
	i) EQAS			
	ii) IQC			
	iii) Inter lab comparison (ILC)			
	iv) Traceability of kits was done			
b.	Percentage of tests for which	State, district, laboratory	Monthly	Records of borderline/ unacceptable SDI scores for EQAS/ILC, violated Westgard rules for IQC and failed traceability of kits along with corrective actions for both EQAS/ ILC (borderline/ unacceptable) and IQC (violated Westgard rules) to be maintained in electronic format.
	i) SDI of EQAS was between 2 to 3 and >3			
	ii) SDI of inter-lab comparison was between 2 to 3 and >3			
	iii) IQC Westgard rules (5+1) were violated			
	iv) Traceability of kits failed			
c.	Percentage of out of range EQAS/ ILC and IQC for which corrective actions were taken	State, district, laboratory	Monthly	
16	Percentage of equipment calibrated annually	State, district, laboratory	Yearly	
17	Percentage of equipment which are interfaced - equipment-wise	State, district and laboratory	Yearly	
18	Average a. frequency and b. duration of equipment downtime (equipment-wise)	State, district and laboratory	Monthly	
19	Training			
a.	Percentage of district diagnostics team members undergoing induction training followed by refresher training (yearly for diagnosticians and quarterly for senior technicians) and competency assessment by MD/ DNB/Diploma (post MBBS)	State, district and laboratory	Yearly	

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
b.	Percentage of laboratory managers and laboratory technicians undergoing induction/orientation training followed by half yearly refresher training and competency assessment by MD/DNB/Diploma (post MBBS)	State, district and laboratory	Yearly	
c.	Percentage of laboratory technicians at non hub laboratories (PHCs/small CHCs), ANMs and ILD persons undergoing induction/ orientation training followed by yearly refresher training and competency assessment	State, district and laboratory	Yearly	
20	Cold chain			
a.	Percentage of tests received at the hub laboratory for which cold chain was inadequate	State, district, laboratory, separate for PHCs, CHCs, SDHs and DHs	Monthly	Temperature monitoring device to be used for charting the temperature
b.	Percentage of tests received by mother laboratory from hub laboratories for which cold chain was inadequate	State, district and laboratory	Monthly	Temperature monitoring device to be used for charting the temperature
21	**Turnaround time**			
	Percentage of tests for which turnaround time is within the prescribed limit	State, district, facility, OPD, IPD and type of test	Monthly	Total TAT: From time of sample collection till time of receipt of printed report or electronic report (in case printing facility not available at health facility). For critical test results: Time from sample collection to receipt of report at the health facility through automated messaging
Total TAT = pre-analytical + analytical + post analytical TAT				
i.	Pre-analytical TAT for rapid/point-of-care tests: 1 hour at all facilities Pre-analytical TAT for routine tests not requiring additional transportation from hub to mother laboratory:			

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
ii.	**PHCs and small CHCs (spokes):** Tests should be received at the testing laboratory within 7 hours of sample collection. **Large CHCs,SDHs, DHs where hub laboratory is located:** Tests should be received at the testing laboratory within 1 hour of sample collection.			
iii.	Pre-analytical TAT for advanced tests conducted at mother laboratory: **DHs, SDHs:** 2 hours for Blood Culture, fluid cytology and 20 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required). **CHCs, PHCs:** 10 hours for Blood Culture, fluid cytology and 27 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required).			
iv.	Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab			Turnaround time for testing listed in Annexure 7
v	Analytical TAT (test result verification): Test results verification within 1 hour of testing			
vi	Post-analytical TAT: Percentage of test reports (electronic) received at the facility within 5 minutes of report verification.			
vii	Post analytical TAT: Percentage of IPD and Emergency reports printed within 1 hour of receipt of electronic reports.			
	Total TAT for rapid/point-of-care tests: i + iv + v + vii			
	Total TAT for routine and advanced tests: ii + iii + iv + v + vi + vii			
	TAT for critical results: i + ii + iii + iv + v + 30 minutes through automated messaging			
	Percentage of test reports received through automated messaging at the government health facilities within stipulated TAT from time of sample collection			

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
22	Budget			
a.	Total budget spent on laboratory services	State	Yearly	
b.	Percentage of budget spent under each head (Equipment, HR, reagents and consumables, training)	State	Yearly	

Annexure 6

LIST OF FAQs ON DIAGNOSTIC SERVICES USED IN RAJASTHAN

प्रश्न 1: ''मुख्यमंत्री निःशुल्क जाँच योजना'' क्या है?

उत्तरः ''मुख्यमंत्री निःशुल्क जाँच योजना'' के तहत राजकीय चिकित्सालय में उपचार के लिए आने वाले मरीजों को रोग निदान हेतु आवश्यक मूलभूत जांच निःशुल्क उपलब्ध करवाई जायेगी।

प्रश्न 2: इस योजना का लाभ किसे मिलेगा?

उत्तरः राजकीय अस्पतालों में उपचार के लिये आने वाले सभी आउटडोर व भर्ती मरीजों को इस योजना का लाभ मिलेगा।

प्रश्न 3: अस्पताल में जाने वाले मरीजों को जांच कहां करवानी होगी?

उत्तरः राजकीय अस्पताल में चिकित्सक से परामर्श के पश्चात् पर्ची दिखाने पर चिकित्सालय में ही स्थापित निःशुल्क जाँच केन्द्र पर जाँच निःशुल्क करवाई जा सकेगी।

प्रश्न 4: क्या जाँच के लिए मरीज को पैसे देने पड़ेगें?

उत्तरः नही! अस्पताल के निःशुल्क जांच केन्द्र पर जांच निःशुल्क की जाएगी।

प्रश्न 5: क्या सभी प्रकार की जांच निःशुल्क होगी?

उत्तरः प्रथम चरण में रोग निदान के लिए आवश्यक मूलभूत जांचे निःशुल्क उपलब्ध करवाई जा रही है।

प्रश्न 6: निःशुल्क जांच के लिए मरीज को अगर किसी प्रकार की कठिनाई हो तो किस से सम्पर्क करें?

उत्तरः तुरन्त चिकित्सा संस्थान के प्रभारी/ब्लॉक/सी.एम.ओ./सी.एम.एच.ओ. जिला कलेक्ट्रेट के हेल्पलाईन से संपर्क करें अथवा टेलीफोन नम्बर : 0141–2225624 या फिर ई.मेलः rmsc.mnijy@gmail.com पर अपनी शिकायत दर्ज कराय।

प्रश्न 7: क्या एपीएल मरीजों को ओ.पी.डी. व आई.पी.डी. में एम.आर.एस. के द्वारा निर्धारित पर्ची शुल्क देना पड़ेगा?

उत्तरः हां, एमआरएस के द्वारा निर्धारित पर्ची शुल्क पूर्व की भांति ही लगेगा। इसे अस्पताल में अच्छी सेवा प्रदान करने हेतु खर्च किया जाता है।

प्रश्न 8: क्या राजस्थान के मूल निवासी होने का कोई प्रमाण पत्र देना होगा?

उत्तरः नहीं, इसके लिए कोई प्रमाण पत्र की आवश्यकता नही है, जो भी मरीज अस्पताल में आयेगा और जिसे जांच की आवश्यकता होगी उसकी जांच निःशुल्क की जायेगी।

प्रश्न 9: क्या निजी अस्पताल/निजी चिकित्सक को दिखाने वाले मरीजों की भी राजकीय संस्थान में निःशुल्क जांच की जाएगी?

उत्तरः नही, राजकीय अस्पताल में दिखाने पर ही निःशुल्क जांच की जाएगी। निजी अस्पताल के चिकित्सक की पर्ची पर निःशुल्क जांच नही की जाएगी।

प्रश्न 10: क्या निःशुल्क जांच की सुविधा सब–सेन्टर, प्राइमरी, सैकण्डरी एवं मेडिकल कॉलेज चिकित्सा संस्थानों में उपलब्ध करवाई जाएगी?

उत्तरः हां, सभी चिकित्सा संस्थानों के स्तर के अनुसार अलग–अलग संख्या में निःशुल्क जांचे उपलब्ध करवाई जाएगी।

प्रश्न 11: निःशुल्क जांच योजना में चिकित्सा संस्था प्रभारी का क्या दायित्व होगा?

उत्तरः योजना के अन्तर्गत सभी प्रकार की जानकारी उपलब्ध करवाना और यह सुनिश्चित करवाना कि कोई भी मरीज निःशुल्क जांच सुविधा से वंचित ना रहे एवं कम समय में मरीज को जाँच उपलब्ध हो सके।

प्रश्न 12: मुख्यमंत्री जीवन रक्षा कोष एवं मुख्यमंत्री सहायता कोष की योजना का क्या होगा?

उत्तरः मुख्यमंत्री जीवन रक्षा कोष एवं मुख्यमंत्री सहायता कोष की योजना पूर्व की भांति यथावत रहेगी।

प्रश्न 13: जांच केन्द्रों का समय क्या होगा।

उत्तरः जांच केन्द्र ओ.पी.डी. समय में खुले रहेगें और मेडिकल कॉलेज अस्पताल व जिला अस्पतालों में कम से कम एक जांच केन्द्र 24 घण्टे खुला रहेगा।

प्रश्न 14: क्या पैन्शनर्स व राज्य कर्मचारियों के पुर्नभरण की व्यवस्था बन्द होगी।

उत्तरः नहीं। उपलब्ध जांच निःशुल्क की जाएगी व अन्य आवश्यक जांचों का पुर्नभरण पूर्व की भांति ही यथावत किया जाएगा।

Annexure 7

Recommended total turnaround time for in-house and PPP (Time from sample collection from patient at the health facility to time of electronic receipt of report at the health facility)

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
1	Hemoglobin	a. 30 minutes b. 2 hours	a. Digital Hemoglobinometer b. Hematology analyser	a. 30 minutes b. 5 hours	a. 30 minutes b. 10 hours
2	Total leucocyte count	2 hours	Hematology analyser	5 hours	10 hours
3	Differential leucocyte count	2 hours	Hematology analyser	5 hours	10 hours
4	Platelet count	2 hours	Hematology analyser	5 hours	10 hours
5	Complete blood count	2 hours	Hematology analyser	5 hours	10 hours
6	Erythrocyte sedimentation rate	1 hour	Manual with reading using ESR analyser	4 hours	9 hours
7	Blood group and Rh typing	1 hour	Blood group kit (manual)	4 hours	9 hours
8	Blood cross matching	2 hours	Manual	5 hours	10 hours
9	Peripheral blood film	4 hours	Microscopy	7 hours	12 hours
10	Reticulocyte count	6 hours	Manual	9 hours	14 hours
11	Absolute eosinophil count	6 hours	Manual	9 hours	14 hours
12	Bleeding time and clotting time	5 minutes	Manual	5 minutes	5 minutes
13	Fibrinogen degradation products (FDP)	1 hour	Coagulation analyser/ Manual using latex agglutination	4 hours	9 hours
14	D-Dimer	1 hour	Coagulation analyser/ Manual using latex agglutination	4 hours	9 hours
15	Coombs test direct with titre	4 hours	Manual	7 hours	12 hours
16	Coombs test indirect with titre	4 hours	Manual	7 hours	12 hours
17	Sickling Test for screening of Sickle cell anemia*	8 hours	Manual with microscopy	11 hours	16 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
18	Sickle cell test rapid for screening of Sickle cell anemia*	8 hours	Rapid	11 hours	16 hours
19	NESTROFT Test for screening of Thalassemia*	8 hours	Manual	11 hours	16 hours
20	DCIP test for screening HbE hemoglobinopathy*	8 hours	Manual	11 hours	16 hours
21	Quantitative test for G6PD enzyme deficiency	4 hours	Manual/ Fluorometry	7 hours	17 hours
22	a. MP slide method and b. Malaria rapid test	a. 4 hours b. 30 minutes	a. Microscopy b. Rapid card tests for combined P.Falciparum and P.vivax	a. 7 hours b. 3.5 hours	a. 12 hours b. 8.5 hours
23	Prothrombin Time (PT) and INR	2 hours	Automated coagulation analyser	5 hours	10 hours
24	Activated partial thromboplastin time	2 hours	Automated coagulation analyser	5 hours	10 hours
25	Mixing study and Factor VIII Assay for Hemophilia	6 hours	Automated coagulation analyser	9 hours	14 hours
26	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	30 minutes	Rapid card test	3.5 hours	8.5 hours
27	Urine test for ph, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	1 hour	Multiparameter urine strip (dipstick)	1 hour	1 hour
28	Urine Microscopy	2 hours	Microscopy	5 hours	10 hours
29	24-hours urinary protein	6 hours	Fully automated biochemistry analyser	9 hours	14 hours
30	a. Urine for microalbumin b. Urine for Creatinine & ACR	6 hours	a. Turbidometer/ Nephelometer b. Fully automated Biochemistry analyser	9 hours	14 hours
31	Stool for ova and cyst	6 hours	Microscopy	9 hours	14 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
32	Stool for Occult Blood	6 hours	Manual Kit	9 hours	14 hours
33	Semen analysis	1 hour	Microscopy (with neubaeur chamber and slide)	3 hours	8 hours
34	Test for Dengue a. Rapid b. ELISA	a. 30 minutes b. 12 hours	a. Rapid card test for combined NS1 antigen and IgM antibody b. ELISA	a. 3.5 hours b. 15 hours	a. 8.5 hours b. 25 hours
35	RPR/VDRL test for syphilis	12 hours	Rapid card test	15 hours	20 hours
36	HIV test (Antibodies 1 and 2) a. Rapid b. Immunoassay analyser	a. 30 minutes b. 2 hours	a. Rapid card test b. Chemiluminiscence assay	a. 3.5 hours b. 5 hours	a. 8.5 hours b. 15 hours
37	Hepatitis B surface antigen test a. Rapid b. Immunoassay analyser	a. 30 minutes b. 2 hours	a. Rapid card test b. Chemiluminiscence assay	a. 3.5 hours b. 5 hours	a. 8.5 hours b. 15 hours
38	HCV Antibody Test (Anti HCV) a. Rapid b. Immunoassay analyser	a. 30 minutes b. 2 hours	a. Rapid card test b. Chemiluminiscence assay	a. 3.5 hours b. 5 hours	a. 8.5 hours b. 15 hours
39	Sputum, pus etc. for AFB	6 hours	Microscopy	9 hours	14 hours
40	Typhoid test (IgM)	2 hours	Rapid card test	5 hours	10 hours
41	Blood sugar a. Rapid b. Biochemistry analyser	a. 30 minutes b. 1 hour	a. Glucometer b. Fully automated Biochemistry analyser	a. 30 minutes b. 4 hours	a. 30 minutes b. 9 hours
42	Glucose Tolerance test (GTT)	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
43	S. Bilirubin (T)	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
44	S. Bilirubin direct and indirect	2 hours	Fully automated biochemistry analyser	5 hours	10 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
45	Serum creatinine	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
46	Blood Urea	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
47	SGPT	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
48	SGOT	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
49	S. Alkaline Phosphatase	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
50	S. Total Protein	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
51	S. Albumin & AG ratio	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
52	S. Globulin	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
53	S. Total Cholesterol	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
54	S. Triglycerides	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
55	S. VLDL	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
56	S. HDL	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
57	S. LDL	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
58	S. GGT	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
59	S. Uric acid	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
60	S. Amylase	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
61	S. Iron	6 hours	Fully automated biochemistry analyser	9 hours	14 hours
62	S. Total Iron binding capacity	6 hours	Fully automated biochemistry analyser	9 hours	14 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
63	S. LDH	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
64	Glycosylated haemoglobin (HbA1C)	6 hours	Fully automated biochemistry analyser/ HPLC	9 hours	19 hours
65	S. Sodium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
66	S. Potassium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
67	S. Calcium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
68	S. Chloride	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
69	S. Magnesium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
70	Smear for RTI/STD	12 hours	Wet mounting, gram staining	15 hours	20 hours
71	Smear for leprosy	24 hours	Microscopy	27 hours	37 hours
72	Gram staining for clinical specimen	4 hours	Microscopy	7 hours	12 hours
73	Throat swab for Diphtheria	4 hours	Microscopy	7 hours	12 hours
74	Stool for hanging drop for Vibrio Cholera	4 hours	Microscopy	7 hours	12 hours
75	Visual Inspection Acetic Acid (VIA)	30 minutes	Manual	30 minutes	30 minutes
76	rK39 for Kala Azar*	30 minutes	Rapid card test	3.5 hours	8.5 hours
77	Smear for Filaria*	12 hours	Microscopy	15 hours	25 hours
78	TB-Mantoux	72 hours	Manual	72 hours	72 hours
79	Japanese Encephalitis IgM *	12 hours (if batch testing) for ELISA	ELISA	15 hours (if batch testing) for ELISA	
80	Scrub typhus Test*	24 hours (if batch testing)	ELISA/Weil Felix	27 hours (if batch testing)	37 hours (if batch testing)
81	Test for Leptospirosis*	24 hours (if batch testing)	ELISA	27 hours (if batch testing)	37 hours (if batch testing)

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
82	Test for Chikungunya	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
83	IgM for Measles	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
84	IgM for Hepatitis A	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
85	IgM for Hepatitis E	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
86	Rapid antigen detection test for Bacterial meningitis (Meningococci)	30 minutes	Rapid Latex agglutination test	3.5 hours	
87	S. TSH (including for new-born screening)	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
88	S. Free T3	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
89	S. Free T4	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
90	Ferritin	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
91	Troponin - I/Troponin - T	5 minutes	Rapid card test	5 minutes	5 minutes
92	S. Beta HCG	30 minutes	a. Rapid b. Chemiluminescence immunoassay	a. 2.5 hours b. 3.5 hours	a. 7.5 hours a. 13.5 hours
93	S. Prolactin	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
94	S. Alfa Feto protein	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
95	S. CA-125	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
96	S. CEA	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
97	S. Procalcitonin	30 minutes	Chemiluminescence immunoassay	3.5 hours	8.5 hours
98	S. Anti-Mullerian hormone (AMH)	24 hours	Chemiluminescence immunoassay	27 hours	37 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
99	S. PSA	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
100	S. Vitamin B12	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
101	S. Vitamin D	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
102	TORCH IgM and IgG, Rubella IgG	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
103	S. Thyroid peroxidase antibody	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
104	Anti-cyclic citrullinated peptide (anti-CCP)	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
105	RA factor (Quantitative)	24 hours	Turbidometer	27 hours	32 hours
106	CRP (including new born) (Quantitative)	2 hours	Turbidometer	5 hours	10 hours
107	Pap smear	48 hours	Microscopy	68 hours	75 hours
108	Cytology (FNAC etc.)	48 hours	Microscopy	68 hours	75 hours
109	Fluid cytology	12 hours	Microscopy	15 hours	25 hours
110	CSF analysis (Sugar, protein, ADA, cell count)	1 hour	Fully automated biochemistry analyser, Haematology analyser	4 hours	9 hours
111	Fluid analysis (Cell count, biochemistry)	1 hour	Fully automated biochemistry analyser, Haematology analyser, Microscopy	4 hours	9 hours
112	Anti-nuclear antibody (ANA)	7 days	Immunofluoroscent Microscopy	8 days	8 days
113	Histopathology	96 hours (4 days)	Microscopy	120 hours (5 days)	120 hours (5 days)
114	Frozen section for histopathology	96 hours (4 days)	Microscopy	120 hours (5 days)	120 hours (5 days)
115	Bone marrow examination	72 hours (3 days)	Microscopy	96 hours (4 days)	96 hours (4 days)
116	Immunohistochemistry	96 hours (4 days)	Manual	120 hours (5 days)	120 hours (5 days)
117	CD4 count	48 hours	Flow cytometer	68 hours	75 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
118	Viral load count for HCV	48 hours	PCR	68 hours	75 hours
119	Viral load count for HBV	48 hours	PCR	68 hours	75 hours
120	Blood culture and antimicrobial sensitivity	1st report 48 hours; 2nd report 120 hours (5 days)	Automated	1st report 48 hours; 2nd report 120 hours (5 days)	1st report 58 hours; 2nd report 120 hours (5 days)
121	Urine culture and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
122	Other cultures (pus, throat swab etc.) and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
123	Culture for Diptheria and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
124	Culture of stool specimen for Vibrio cholerae and other common bacterial enteropathogens and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
125	Mycobacterial culture and DST	4-8 weeks	State TB laboratory	4-8 weeks	4-8 weeks
126	Hemoglobin electrophoresis/HPLC	72 hours (3 days)	Electrophoresis machine/HPLC machine	96 hours (4 days)	96 hours (4 days)
127	Protein electrophoresis	72 hours (3 days)	Electrophoresis machine	96 hours (4 days)	96 hours (4 days)
128	Nucleic Acid Amplification Test for TB	48 hours	Nucleic Acid Amplification Machine	68 hours	75 hours
129	Nucleic Acid Amplification Test for HIV	48 hours	Nucleic Acid Amplification Machine	68 hours	75 hours

**For endemic areas*

Annexure 8

KEY PERFORMANCE INDICATORS AND MONITORING INDICATORS FOR IMPLEMENTING LABORATORY SERVICES IN PPP MODE

1. Key Performance Indicators (KPIs)

S.No.	KPI	Prescribed limit for penalty	Remarks
1	Percentage of facilities where service provider has started providing full-fledged services for all tests within stipulated time.	Service provider should have started its full-fledged services for all tests in 100 percent of DHs, 90 percent of SDHs and 80 percent of CHCs and PHCs within stipulated time. For remaining facilities, a maximum of one extra year could be provided to the service provider for initiation of services.	
2	Percentage of tests (in per-test model) or patients (in per-patient model) for which turnaround time is within the prescribed limit	Total turnaround time to be achieved for 100% of tests/ patients	a. Total TAT = pre-analytical + analytical + post analytical TAT (from time of sample collection till time of receipt of printed report or electronic report (in case printing facility not available at health facility) b. In per-patient model, any test of the patient which exceeds prescribed turnaround time will be counted as exceeded turnaround time for the patient.
			i. Pre-analytical TAT for routine tests not requiring additional transportation from L2 to mother laboratory: PHCs, CHCs: Tests should be received at the testing laboratory within 7 hours of sample collection. SDHs, DHs: Tests should be received at the testing laboratory within 2 hours of sample collection. ii. Pre-analytical TAT for advanced tests conducted at mother laboratory: DHs, SDHs: 2 hours for Blood Culture, fluid cytology and 20 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required). CHCs, PHCs: 10 hours for Blood Culture, fluid cytology and 27 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required).

S.No.	KPI	Prescribed limit for penalty	Remarks
			iii. Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab iv. Analytical TAT (report verification): Test result verification within 1 hour of testing v. Post-analytical TAT: Percentage of test reports (electronic) received at the facility within 5 minutes of test result verification. vi. Post analytical TAT: Percentage of IPD and Emergency reports printed within 1 hour of receipt of electronic reports.
			Total TAT: i + ii + iii + iv + v + vi
			Total TAT for critical test results and emergency samples: i + ii + iii + iv + v + 30 minutes through automated messaging
3	Percentage of working days in a month when each type of test is available at each Government health facility	Unavailability of tests not to exceed a total of more than three working days in a month at each Government health facility	
4	Percentage of working days in a month when sampling services are available at each Government health facility	Unavailability of sampling services not to exceed a total of more than three working days in a month at each Government health facility	
5	Percentage of tests for which service provider participated in EQAS/inter-laboratory comparison and IQC	Service provider to participate in EQAS/inter laboratory proficiency testing and IQC for 100% of tests	
6	Percentage of tests for which EQAS/ Interlaboratory comparison and IQC for which appropriate corrective and preventive actions were taken	Appropriate corrective and preventive actions to be taken for 100% of EQAS/ILC and IQC	Appropriateness of corrective and preventive actions to be validated by third party
7	Percentage of tests or samples for which cold chain is adequate	Cold chain to be adequate for atleast 95% of samples	a) One sample implies any one sample of a patient (haematology, Biochemistry, urine, fluid etc.) b) Temperature monitoring device to be used for charting the temperature

S.No.	KPI	Prescribed limit for penalty	Remarks
8	Percentage of district level Quality managers and laboratory technicians at testing laboratories who underwent induction training followed by half-yearly refresher training and competency assessment by MD/DNB/Diploma (post MBBS) or PhD in Biochemistry/ Pathology/ Microbiology	At least 95% of district level Quality managers and laboratory technicians at testing laboratories to undergo induction training followed by half-yearly refresher training and competency assessment by MD/DNB/Diploma (post MBBS) or PhD in Biochemistry/Pathology/ Microbiology	
9	Percentage of laboratories of service provider accredited under NABL for all tests within three years of signing of contract	100% of laboratories of service provider to be accredited under NABL for all tests within 3 years of signing of contract	

2. Monitoring indicators

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
1	Percentage of public health facilities serviced by the private provider	State	Quarterly	
2	Total number of patients tested	State, district, facility, OPD, IPD, women, children and tribal patients	Monthly	
3	Total number of tests conducted – test-wise	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
4	Patient to test ratio	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
5	Percentage of tests with 1,2,3...n number of tests prescribed	State, district and facility	Monthly	
6	Percentage of government health facilities with zero samples for more than 10% of working days	State, district and facility	Monthly	
7	Percentage and types of tests which are unavailable for a total of more than three working days in a month	State, district and facility	Monthly	
8	Average of frequency and duration of unavailability of sampling services at government health facilities	State, district and facility	Monthly	Services unavailable due to absence of sampling/sample pick-up staff, consumables for sampling not available etc.
9	Percentage of service provider's laboratories with NABL accreditation	State and district	Half-yearly	
10	Percentage of tests accredited under NABL	Laboratory and test-wise	Half-yearly	
11	Percentage of laboratories which underwent third party annual audits by NABL accredited laboratory	State, district and laboratory	Yearly	
12	Percentage of outsourced laboratories which are NABL accredited for the referred tests	State, district and laboratory	Yearly	

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
13	Percentage of laboratories which underwent yearly internal audit	State, district and laboratory	Yearly	
14	Sample rejection rate	State, district, facility, OPD, IPD and laboratory	Monthly	Sample haemolysed, sample clotted, insufficient sample, delay for prothrombin time and labelling error
15	Percentage of tests repeated on request of clinicians	State, district, facility, clinician, OPD, IPD and type of test	Monthly	Re-run/re-sampling requisition form to be filled by the laboratory. For patient identification for repeat testing, unique ID of patients (Aadhaar card/any other ID proof) can be used.
16	Percentage of test results outside the biological reference interval (test-wise)	State, district, facility, clinician, PD, IPD and type of test	Monthly	
17	IQC, EQAS, Interlaboratory comparison and traceability of kits			
a.	Percentage of tests for which i. EQAS ii. IQC iii. Inter lab comparison iv. Traceability of kits was done	State, district, laboratory	Monthly	
b.	Percentage of tests for which i. SDI of EQAS was between 2 to 3 and >3 ii. SDI of Inter lab comparison was between 2 to 3 and >3 iii. IQC Westgard rules (5+1) were violated iv. Traceability of kits failed	State, district, laboratory	Monthly	Records of borderline/ unacceptable SDI scores for EQAS/ ILPT, violated Westgard rules for IQC and failed traceability of kits along with corrective actions for both EQAS (borderline/ unacceptable) and IQC (violated Westgard rules) to be maintained in electronic format.

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
c.	Percentage of out of range EQAS/ ILC and IQC for which corrective actions were taken	State, district, laboratory	Monthly	i. EQAS of >2 SDI ii. SDI of inter lab comparison was >2 iii) IQC tests (for which westgard rules (5+1) were violated) iv) Traceability of kits failed. Records to be maintained in electronic format.
d.	Percentage of corrective actions taken which were accurate	State, district, laboratory	Monthly	
18	Percentage of tests verified by MD/DNB/Diploma (post MBBS) pathology/biochemistry/ microbiology	State, district, laboratory and test-wise	Monthly	
19	Percentage of equipment calibrated annually	State, district, laboratory	Yearly	
20	Percentage of equipment which are interfaced - equipment-wise	State, district and laboratory	Half-yearly	
21	Average a. frequency and b. duration of equipment downtime (equipment-wise)	State, district and laboratory	Monthly	
22	Training			
a.	Percentage of district level Quality managers and laboratory technicians at testing laboratories undergoing induction training followed by half-yearly refresher training and competency assessment by MD/DNB/ Diploma (post MBBS) or PhD in Biochemistry/Pathology/ Microbiology	State, district and laboratory	Half-yearly	
b.	Percentage of phlebotomists and ILDs undergoing induction training followed by yearly refresher training by district level Quality managers	State, district and laboratory	Half-yearly	
23	Cold chain			

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
a.	Percentage of tests or samples received at the primary receiving/ testing laboratory for which cold chain was inadequate	State, district, laboratory, separate for PHCs, CHCs, SDHs and DHs	Monthly	i. One sample implies any one sample of a patient (haematology, biochemistry, urine, fluid etc.) ii. Temperature monitoring device to be used for charting the temperature
b.	Percentage of tests or samples received by L1 laboratories from L2 laboratories for which cold chain was inadequate	State, district and laboratory	Monthly	Temperature monitoring device to be used for charting the temperature
24	Quality of processes			
a.	Percentage of urine cultures plated within 4 hours of sample collection	State, district and laboratory	Monthly	Plating to be done at the primary receiving laboratory
b.	Percentage of peripheral smears prepared at the time of sample collection	State, district and laboratory	Monthly	Two blood smears to be prepared – first by the phlebotomist at the time of sample collection and second at the primary receiving laboratory
c.	Percentage of fluids for which TLC and DLC was done, and stained smear was prepared within 4 hours of sample collection	State, district and laboratory	Monthly	TLC and DLC to be done at the primary receiving laboratory
d.	Percentage of blood culture samples tested on automated blood culture system	State, district and laboratory	Monthly	
25	Percentage of tests or samples (patients) for which turnaround time is within the prescribed limit	State, district, facility, OPD, IPD and type of test	Monthly	Total TAT: From time of sample collection till time of receipt of printed report or electronic report (in case printing facility not available at health facility).

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
				1. For critical test results: Time from sample collection to receipt of report at the health facility through automated messaging 2. In per-patient model, any test of the patient which exceeds prescribed turnaround time will be counted as exceeded turnaround time for the patient
a. Total TAT* = pre-analytical + analytical + post analytical TAT				
i.	Pre-analytical TAT for routine tests not requiring additional transportation from L2 to L1 laboratory: PHCs, CHCs: Tests should be received at the testing laboratory within 7 hours of sample collection. SDHs, DHs: Tests should be received at the testing laboratory within 2 hours of sample collection.			
ii.	Pre-analytical TAT for advanced tests conducted at mother laboratory: DHs, SDHs: 2 hours for Blood Culture, fluid cytology and 20 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required). CHCs, PHCs: 10 hours for Blood Culture, fluid cytology and 27 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required).			
iii.	Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab			Turnaround time for testing listed in Annexure 7

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
iv.	Analytical TAT (test result verification): Test results verification within 1 hour of testing			
v.	Post-analytical TAT: Percentage of test reports (electronic) received at the facility within 5 minutes of report verification.			
vi.	Post analytical TAT: Percentage of IPD and Emergency reports printed within 1 hour of receipt of electronic reports.			
Total TAT: i + ii + iii + iv + v + vi				
	TAT for critical results: i + ii + iii + iv + v + 30 minutes through automated messaging			
	Percentage of test reports received through automated messaging at the government health facilities within stipulated TAT from time of sample collection			
b.	Printed report dispatch: In case, printing service is unavailable at PHCs, CHCs, then percentage of printed reports received at PHCs and CHCs by 9 am next working day of sample collection (for tests with analytical time upto 8 hours). For tests with analytical time of more than 8 hours, the percentage of printed reports that are received at the health facility by 9 am on the next day of validation of test reports (as per the stipulated analytical time).For SDHs and DHs the printing facility should essentially be available at the health facility.	State, district, facility (PHC/CHC), OPD, IPD and type of test		
26	Grievance redressal			
a.	Number of complaints from patients and health care staff at government health facilities and other government officials	State, district and facility	Monthly	
b.	Percentage of complaints (from patients/clinicians/for which corrective action taken within 7 days of receiving the complaints	State, district and facility	Monthly	

S.No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
27	Percentage of patients satisfied with laboratory services, including any fee charged by the service provider for laboratory services	State, district and facility	Yearly	To be monitored by the government
28	Payments			
a.	Percentage of incomplete monthly payments to service provider	State	Yearly	
b.	Percentage of monthly payments to service provider delayed by more than one week	State	Yearly	
c.	Percentage of amount deducted from invoice payment as penalties	State	Monthly	

Annexure 9

BRIEFS ON SELECT STATES IMPLEMENTING THE FREE DIAGNOSTICS INITIATIVE

i. Andhra Pradesh

Andhra Pradesh is the first state which has done a state-wide rollout of both laboratory and radiology services using a hybrid model.

a. Laboratory services under public-private partnership

The services under the public-private partnership were launched by the state on January 1, 2016 under a new flagship scheme called NTR Vaidya Pariksha scheme. The state government is providing laboratory and radiology services free of cost at public health facilities through private partners. 60% funding for the scheme is supported by NHM and the rest 40% by the state government.

Under NTR Vaidya Pariksha scheme, a single service provider has been selected through competitive bidding to provide designated laboratory tests at all the 8 DHs, 35 AHs, 192 CHCs and 1125 PHCs. The basket of tests offered by in-house laboratories and NTR Vaidya Pariksha scheme is complementary. The in-house laboratories are providing 10 to 12 basic and mostly rapid kit tests at all levels of facilities. NTR Vaidya Pariksha scheme adds a wide range of tests (42 in total) to the menu including few advanced tests. The range of tests provided under the scheme varies with the level of the facility. In PHCs - 7 basic tests, in CHCs - 21 routine tests and in AHs and DHs - 40 tests including routine and few advanced tests have been made available through the service provider.

State government's high political commitment towards the scheme, strong leadership, constant oversight and monitoring, and commitment to budgetary allocations; a speedy rollout of the scheme throughout the state within a period of three months combined with a phased operationalization of services at various levels of facilities; continuous efforts of the service provider for improving quality of services; and extensive awareness campaigns have all contributed to the successful implementation of the scheme.

The expanded basket of tests available through the service provider has led to improvement in access to laboratory services.

For providing services under NTR Vaidya Pariksha scheme, the service provider has set up 104 laboratories outside the government health facilities for conducting tests. The sampling of patients is done inside the government health facilities by the phlebotomists of the service provider. The reports are also dispatched at the government health facilities. The 104 laboratories are categorized as L1, L2 and L3. L1 (mother laboratories) provide routine and all designated advanced tests, L2 provide routine and few advanced tests and L3 laboratories provide only routine tests. Out of the 104 laboratories of the service provider, 97 were newly set up which enabled standardisation of infrastructure and processes across these laboratories as well as cost efficiency for the service provider. The new laboratories were set up through a franchisee model on a cost and revenue sharing basis.

Turnaround time was significantly delayed for most tests in the initial months of rollout and slowly improved due to continual efforts of service provider as well as close monitoring by the state government. Cold chain for sample storage and transportation needs strengthening.

Training is conducted for the laboratory technicians by district quality assurance managers (senior laboratory technicians) at the time of induction. Trainings are also conducted on ISO for senior technicians and diagnosticians. The equipment vendors also impart training at the time of installation.

The 104 laboratories are certified under ISO 9001. IQC and EQAS have been established for select tests.

The state government has instituted a robust monitoring framework since the beginning of the rollout of the scheme. This includes leveraging the state programme implementation unit for close monitoring of the scheme; a dashboard reflecting real-time data on utilization of services; monthly state-level review meetings; engaging the drug control administration (DCA) for inspection of laboratories of the service provider; supervision of the scheme by district health officials; and levying of penalties on the service provider for not meeting certain contractual clauses such as turnaround time and EQAS. The service provider monitors its services through its dedicated central and district teams.

b. Laboratory services through in-house laboratories

The state delineated the tests that would be done in-house and that would be outsourced at the outset. The in-house laboratories continued to provide most of the 10-12 designated basic tests (haemoglobin, blood sugar etc.) and uptake of in-house tests only increased after introduction of the NTR Vaidya Pariksha scheme. Many in-house laboratories however do not provide some of the designated tests because of unavailability of laboratory technicians, equipment and supply of reagents.

Basic manual equipment is used for testing at most of the laboratories. The equipment is repaired by the biomedical maintenance programme team. Across the state, 200 PHCs have vacant positions of laboratory technicians.

Technicians are responsible for maintaining the stock of reagents and consumables. The health facility places orders through e-Aushadhi on a quarterly basis. The stock is delivered within 2–7 days by the central drug store to the health facility. Stock-out situations are frequent in the facilities especially of glucometer sugar strips. In case of unavailability of the required stock at the central drug store, the facilities can purchase from local drug stores. However, if those stocks are available in the central drug store, the facilities are restricted from purchasing locally, even if issuance/transportation time is high. There are no mechanisms for ensuring quality in local procurement.

The laboratory processes are manual -- registration, labelling and reports are handwritten. The test reports are validated by the government laboratory technicians. The turnaround time (time from sample collection to report dispatch to the patients) for most tests is 10 minutes–2 hours.

There are no set quality assurance mechanisms for the in-house laboratories (except for few tests done under RNTCP, ICTC and malaria control programme) even at district hospitals.

Data on number of tests is shared by the health facilities with the district health officers on a monthly basis.

ii. Gujarat

Gujarat launched the free diagnostics scheme in 2016. The services were implemented state-wide at all levels of health facilities. The services are provided under a flagship scheme of the state called ‘Mukhya Mantri Nidan Yojna’. The scheme is mostly state-funded.

The laboratory services are provided through in-house laboratories set up within each health facility. PHCs provide 19 routine tests, CHCs and SDHs provide 30 routine tests and DHs provide 73 routine and advanced tests.

To implement the services, the state carried out a gap analysis for human resources and equipment. An essential equipment list was prepared. A state-level laboratory coordination cell was set up to assess laboratory services for manpower, equipment, reagents and consumables. The cell also prepared specifications and quality standards for equipment, reagents and consumables for procurement; monitored its purchase and supply through state medical corporation; and provided oversight for equipment management and maintenance in the state.

The layout for the laboratories was designed for each level of facility and uniform structures were set up. Need-based civil work was carried out in health facilities for the laboratories. In DHs and MCHs, additional space was provided for laboratories, if required. Existing equipment were made functional through repair and maintenance. New equipment including haematology analysers, semi-automated biochemistry analysers were procured and supplied by the state medical corporation. Some equipment were procured directly by the hospitals. Rate contracts were done (revised on an annual basis) for equipment, and reagents and consumables. The gaps in manpower were filled through regular and contractual recruitment and effective usage of existing laboratory technicians through rationalization and multi-skilling. Procurement of reagents and consumables was done based on demand. Structures were set up for central supply of reagents and consumables from government warehouses to all levels of health facilities.

The indent for equipment is done through GLCC and for reagents and consumables through e-Aushadhi. Local procurement of reagents and consumables is allowed only when state corporation has not procured. The procurement is supervised by the state laboratory coordination cell. The procurement of equipment and reagents is done through separate tender documents specific to diagnostics. The state laboratory coordination cell provides technical support in developing the tender documents.

The state has developed a management information system software and has implemented it up to the subcentre level. The software has multiple features including laboratory information system; availability of data of laboratory services (patient demographics, tests results etc.) to the government; data analytics; integration of all programmes (RNTCP, HIV, NVBDCP, IDSP, NCD, RCH) at one common platform; and linkages with GIS system to strengthen implementation and monitoring.

Training manuals and SoPs have been prepared for all levels of health facilities. Trainings are conducted by diagnosticians at district hospitals/medical college hospitals. The laboratory technicians are trained on several aspects including quality management, calibration, error prone areas, laboratory information system etc. The duration of general training is 2 days for PHCs' laboratory technicians, 3 days for CHCs' and SDHs' technicians and 5 days for those of DHs. Additional days are assigned for training on specific aspects such as quality management (6 days), laboratory information system (1 day) and calibration (2 days).

The state has set up EQAS for its in-house laboratories in district hospitals and medical college hospitals. Third party pre-dispatch testing of each batch is carried out before supply of reagents. The state has formulated a cold chain policy for storage and transport of reagents at warehouses and laboratories.

The monitoring of the scheme is carried out by the state-level expert technical committee of diagnosticians, and state- and district-level programme monitoring committees. Along with this, medical doctors in each health facility (diagnosticians/other doctors in absence of diagnosticians) have been trained to oversee the services at their respective health facilities.

iii. Rajasthan

Rajasthan is one of the first states to launch free diagnostic services in the entire state at all health facilities. The state launched the free diagnostics services in year 2012 under a flagship scheme called Mukhyamantri Nishulk Janch Yojana. The services were rolled out in a phased manner over a period of 6 months in the year 2013. Medical college hospitals, DHs and SDHs were covered in the first phase, CHCs in the second phase and PHCs and dispensaries in the third phase.

57 tests are provided at medical college hospitals, 44 tests at DHs, 28 at CHCs and 15 tests at PHCs and dispensaries through in-house laboratories set up within the health facilities. An additional list of 23 tests have recently been outsourced, most of which are advanced. The samples for outsourced tests are transported to central laboratories of the service provider. The service provider was selected through competitive bidding and payment is made on per- test basis. The in-house laboratory services are mostly state-funded.

For rollout of the in-house laboratory services, Rajasthan Medical Services Corporation (RMSC) was leveraged as the nodal agency. A detailed gap analysis was carried out for civil work, human resources and equipment. Based on the gap analysis, preparatory work was done over a period of 6 months. District officers in-charge were assigned to closely monitor the preparatory work for implementation of the diagnostic services. Necessary civil work was carried out and where required, new laboratories were set up and at select facilities, additional space was provided for laboratory.

Vacant positions of diagnosticians were filled through recruitment. Laboratory technicians were deployed from existing staff and where required, contractual recruitment was done through Rajasthan Medicare Relief Society (RMRS). The state also engages diagnosticians and technicians on a per-day basis as a stop-gap arrangement for health facilities/laboratories where the in-house positions are vacant. Computer operators were recruited through RMRS for laboratories (one for CHC and three each for SH, SDH and DH) for data collection, recording and reporting. The existing equipment was repaired and new was procured. Haematology analysers and semi-automated biochemistry analysers were procured in large numbers. Few fully-automated biochemistry analysers, ELISA readers and washers were also procured. Reagents and consumables were purchased locally by the health facilities. Annual rate contracts were established for equipment, and reagents and consumables by the state corporation. For ensuring availability of functional equipment and reagents and consumables, an EPMC was created under the oversight of state technical advisory committee. The EPMC prepared essential equipment list and essential laboratory reagents and consumables list and facilitated procurement and supply through district drug warehouses to the health facilities. A state biomedical maintenance cell was established along with zonal centres which catered to divisions/districts. The biomedical maintenance team comprises of 3 biomedical engineers at the head office of RMSCL and 7 engineers in 7 divisions of the state. The state uses a comprehensive e-Upkaran (EMMS) module for inventory management of equipment across the state till the PHC level. Real-time tracking of inventory, installation, breakdown, repair, maintenance, calibration and usage of equipment is done using this module.

Orientation trainings were conducted for laboratory staff. The duration of each training was 10 days. Medical officers were also trained. Display boards and signages were designed for health facilities.

The health facilities' in-charge were responsible for contractual recruitment of staff; training of staff; purchase of reagents and consumables; procurement of IEC material (signages, boards); and outsourcing of any services at the health facility level. The health facility could use RMRS funds, unused untied funds, annual maintenance grant and corpus funds for these activities. The expenditure was reimbursed by the state government. The state made it mandatory for health facilities to seek approvals from requisite

authorities for any outsourcing activity. The chief engineer, NRHM was assigned the responsibility of site preparation and minor repairs of the laboratories. Funds were provided to DHs, SDHs and SHs based on their bed strength.

E-Aushadhi is leveraged to capture data from health facilities on tests performed on a daily basis.

iv. Telangana

Telangana launched the free diagnostics initiative in 2018. The first phase has been rolled out in one district. All 120 health facilities (PHCs till DHs) are providing 52 tests listed in the free diagnostics initiative guidelines. The services are provided through a hub and spoke model. A state-of-the-art central laboratory has been set up by the government catering to all the 120 health facilities. Those health facilities (spokes) which have requisite equipment, continue to perform tests on those equipment and send remaining tests to the hub laboratory. The 120 facilities were made operational in a phased manner over a period of 4 months. A dry run was conducted prior to the implementation.

The state plans to roll out services in the remaining districts. An additional 47 hub laboratories will be set up to cater to these districts. The location of these hub laboratories will be planned based on distance from spoke health facilities. The maximum distance of any spoke from the hub laboratory will be 60 kilometres.

The free diagnostics initiative also aims to integrate various programmes such as NVBDCP, RBSK, NCD and JSSK. IEM laboratory is being established under RBSK. Data on diagnostics for dengue, chikungunya and noncommunicable diseases is planned to be shared.

Tata Trust and other technical experts provided technical support to the state government on service packages, equipment, infrastructure, human resource requirement and IT structure.

The patients prescribed tests at the spoke health facilities are registered electronically at these facilities for testing. Vacutainers are used for sampling and samples are barcoded. The samples are transported by a private provider. 8 mini-hubs have been set up which receive samples from the nearby spokes; from mini-hubs, the samples are transported to the central hub laboratory. The samples reach the hub laboratory by 3 pm. The samples are tested on fully automated analysers (haematology, biochemistry and immunoassay); and test results are verified by diagnosticians (Biochemist, Pathologist and Microbiologist respectively). Test reports are sent electronically to the health facilities (spokes). The health facilities print the reports the next day.

The reagents and consumables are procured by the state medical corporation. The orders for reagents and consumables are placed through laboratory management information system.

For monitoring of the programme in the district, a nodal officer has been assigned. Along with this, a dedicated operations manager supervises the hub laboratory and spokes. The laboratory head of the district hospital heads the diagnostics services in the district.

A 15-day training was conducted for laboratory technicians, prior to rollout of the services, on laboratory processes as well as on the laboratory information system. District nodal officer was also trained on the programme.

A robust laboratory management information system is in place for patient registration, barcode generation for samples and consignments, tracking of consignments, sample accession, equipment interfacing (bi-directional), recording sample rejection, report generation etc. In addition, a dashboard has been set up which provides data on laboratory services.

EQAS and IQC have been established at the hub laboratory. EQAS is done through Bio-Rad, AIIMS and CMC, Vellore. Equipment qualification testing (installation qualification, operational qualification, performance qualification, calibration and precision testing) is carried out at the time of installation.

A dedicated quality officer has been appointed to implement the ISO 15189 : 2012. NABL protocols have been adopted at the sampling facilities and at the central hub laboratory. The state aims to get the hub laboratory NABL accredited.

REQUEST FOR PROPOSAL FOR
Laboratory Services under
FREE DIAGNOSTIC INITIATIVE
Under National Health Mission
Department of Health and Family Welfare

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GOVERNMENT OF STATE

TENDER REF: NO.:

Address:

Phone:

Fax:

Email:

Website: https://

SECTION I

NOTICE INVITING TENDERS (NIT)

TENDER INVITING AUTHORITY (TIA)

Address:

URL:

Email:

Telephone:

Fax:

Tender Enquiry No.

Dated: __/__/20XX

NOTICE INVITING TENDERS

Tender Inviting Authority (TIA) invites sealed tenders/e tender from eligible service providers for supply of services as given in Section-IV of this document for the period from __/___/201X to ___/___/201X

Table 1 : Schedule of Events

S. No.	Description	Fee & Schedule
1	Date of sale of Tender Enquiry Documents	___/___/201X to ___/___/201X
2	Place of Sale of Tender Enquiry Document	O/o the TIA, NHM, STATE
3	Cost of the Tender Enquiry Document	Rs.2,000/-
4	Pre-Bid Meeting (Date & Time)	___/___/201X at 11:00 AM
5	Pre-Bid Meeting Venue	O/o the TIA
6	Closing Date and Time of Receipt of Tender	___/___/201X at 3:00 PM
7	Time, Date and Venue of Opening of Technical Tender/ Bid	___/___/201X at XX:00 PM, O/o the TIA, STATE
8	Time, Date and Venue of Opening of Financial Tender/Bid	to be informed later on .

1. Interested tenderers may obtain further information/clarification about this requirement from the above office of TIA. Tender Enquiry Documents may be purchased on payment of non-refundable fee of Rs.2,000/- per set in the form of account payee Demand Draft, drawn on a scheduled bank in India, in favour of "Tender Inviting Authority, STATE" payable at <Insert Place>
2. If requested, the Tender Enquiry Documents will be mailed by Registered Post/Speed Post to the interested tenderers, for which extra expenditure per set will be Rs.100/- for domestic post. The tenderer is to add the applicable postage cost in non-refundable fee mentioned in Para 3 above. The Tender Inviting Authority (TIA) will not be responsible for late receipt/non-receipt of tender document by the vendor.
3. Tenderer may also download the tender enquiry documents (a complete set of document is available on website) from the website https://STATEnrhm.gov.in and submit its tender by using the downloaded document, along with the required non-refundable fee as mentioned in Para 3 above. The tender paper will be rejected if the bidder changes any clause or Annexure of the bid document downloaded from the website.
4. All prospective tenderers may attend the Pre Bid meeting. The venue, date and time are indicated in Schedule of Events as in Para 2 above.
5. Tenderers shall ensure that their tenders, complete in all respects, are submitted/uploaded in case of e-tendering on or before the closing date and time indicated in the Para 2 above, failing which the tenders will be treated as late tender and rejected. The hard copy (soft copy in case of e-tendering) of Bid sent by post/courier must reach (uploaded as instructed) the above said address on or before the closing date & time indicated in Para 2 above, failing which the tenders will be treated as late tender and rejected.

6. In the event of any of the above mentioned dates being declared as a holiday/closed day for TIA the tenders will be sold/received/opened on the next working day at the appointed time.
7. The Tender Enquiry Documents are not transferable.
8. All Tenders must be accompanied by Tender fee (if downloaded from website of TIA,/e-procurement website), EMD, as mentioned against each item. EMD exemption shall be based on TIA procurement policy

TIA

<Insert State>

SECTION II

INSTRUCTIONS TO BIDDER

GENERAL INSTRUCTIONS

The bidder should prepare and submit its offer as per instructions given in this section.

1. The tenders shall be complete with all documents. Those submitted by fax or through email with attachment shall not be considered.

    a. The tenders which are for only a portion of the components of the job/service shall not be accepted. (The tenders/bids should be for all components of the job/service.)

    b. The prices quoted shall be **firm** and shall be exclusive of all taxes and duties. This shall be quoted in the format as per attached **"Annexure F"** only.

    c. The tenders (technical and financial) shall be submitted/uploaded (with a covering letter as per **"Annexure E"**) before the last date of submission. Late tenders/bids shall not be considered.

INSPECTION OF SITES

The interested bidder may inspect the government health facilities where the services are to be rendered during 10.00 AM TO 5.00 PM on all working days till last date of sale of tender as given in the tender schedule. The TIA shall not be liable for any expenditure incurred in such inspection or in the preparation of the bid(s).

EARNEST MONEY DEPOSIT (EMD)

The tender shall be accompanied by Earnest Money Deposit (EMD) as specified in the Notice Inviting Tender (NIT) in the shape of FD/Bankers guarantee from any Scheduled Bank/nationalized bank in favour of "<Tender Inviting Authority>" payable at<insert name>

a. It may be noted that no tendering entity is exempt from deposit of EMD. Tenders submitted without EMD shall be rejected. However, State may exempt bidders from EMD as per State procurement policy.

b. The EMD of unsuccessful bidder will be returned to them without any interest, after conclusion of the resultant contract. The EMD of the successful bidder will be returned without any interest, after receipt of performance security as per the terms of contract.

c. EMD of a bidder may be forfeited without prejudice to other rights of the purchaser, if the bidder withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to notice that the information/documents furnished

in its tender is incorrect, false, misleading or forged. In addition to the aforesaid grounds, the successful bidders' EMD will also be forfeited without prejudice to other rights of purchaser, if it fails to furnish the required performance security within the specified period.

PREPARATION OF TENDER

The bids shall be made in TWO SEPARATE SEALED ENVELOPES as follows: I. The **first envelopes** shall be marked in bold letter as **"TECHNOCOMMERCIAL BID"** which shall be sent with the forwarding letter **("Annexure E")** and shall include the following:

1. Receipt regarding payment of Tender Cost.
2. **E.M.D.** as above towards the cost of tender document to be attached in case bid document has been downloaded from website.
3. Confirmation regarding furnishing **Performance Security** in case of award of contract.
4. Original tender document duly stamped and signed in each page along with the Forwarding Letter confirming the performing the assignment as per **"Annexure E".**
5. Particulars of the bidder as per **"Annexure D".**
6. Copy of the Income Tax Returns acknowledgement for last 2 preceding financial years.
7. Power of attorney in favour of signatory to tender documents.
8. Copy of the certificate of registration of GST (if applicable).
9. A declaration from the bidder in the format given in the **"Annexure C"** to the effect that the firm has neither been declared as defaulter or black-listed by any competent authority of a government department under Government of India or Government of any State. The bidder should also submit the full details of penalties levied on it by the Governments in its existing contracts with these Governments/other authorities for laboratory services.

All the above document to be uploaded in case of e-tendering and Hard copy submission will not be required

In case of e-tendering TIA shall provide all the formats, document size & requisite information to the bidders

The second envelope shall contain the financial proposal and shall be marked in bold letters as "FINANCIAL BID". Prices shall be quoted in the proforma enclosed at **"Anneure F"** as per scope of work/service to be rendered. In case of e-tendering the same shall be uploaded.

TENDER VALIDITY PERIOD

The bid will be valid for 270 days after due date of submission of bid. The contract shall remain valid for 60 calendar months i.e. 5 years from the date of signing of contract. The contract may be extended for another term of 5 years based on requirement by the TIA and performance of service provider and mutual consent.

TENDER SUBMISSION

The two envelopes containing both technical and the financial bid (only in case of Manual Tender) shall be put in a bigger envelope, which shall be sealed and superscripted with No.F.3 for specific laboratory

services (5-___)-2016 due for free diagnostic service opening on ___/___/_____.

The offer shall contain no interlineations or overwriting except as necessary to correct errors, in which cases such correction must be initialed by the person or persons signing the tender. In case of discrepancy in the quoted prices, the price written in words will be taken as valid.

OPENING OF TENDERS

The technical bid will be opened at the time and date specified in the schedule. The bidders may attend the bid opening if they so desire. The bidders who are desirous of attending the technical bid opening should accompany with them the authorization letter from their respective organization.

Definitions

1. The following definitions and abbreviations, which have been used in this al shall have the meanings as indicated below:

   "Authority"/"Appellate Authority" means Tender Inviting Authority (TIA) State.

   - "Authorized Representative" shall mean any person authorized in writing by the Bidder as defined in 4.1.3/firm/society/Company/agency.
   - "Bidder" shall mean legal entity
   - "Contract or Agreement" means the written agreement entered into between the Successful bidder and contracting authority together with all the documents mentioned therein and including all attachments, Annexure etc. therein.
   - "Contracting Authority" means Mission Director, NHM, State., or appointed by the/ Mission Director, NHM,/State of respective unit or as per Tender Inviting Authority requirement.
   - "Earnest Money Deposit" (EMD) means Bid Security/monetary or financial guarantee to be furnished by a Bidder along with its Bid.
   - "Letter of Intent" (LoI) means the letter issued by Tender Inviting Authority (TIA), State to the Successful Bidder (s) for initiation of contract signing process.
   - "Performance Security" means monetary or financial guarantee to be furnished by the successful Bidder for complying to the performance standards as due under the contract placed on it.
   - "Request for Proposal (RFP)" shall mean this document and its Annexure and any other document provided or issued during the process of selection of bidder(s), seeking any clarification etc., a set of solution(s), services(s), materials and/or any combination of them, including amendments, if any.
   - "Laboratory Services" means all services intended to be covered in this RFP and include specific laboratory tests in the specified unit or as notified later, and which shall include collection and transportation of samples from the unit, testing of these samples and reporting of tests and provision of printed reports within stipulated time to patients/doctors/ health facilities.
   - "Service Provider's Laboratory" means the medical laboratories of the service provider which will provide services mentioned in the RFP after signing of the Contract with the

Tender Inviting Authority.

- "Laboratories of the Bidder" means those medical diagnostic laboratories which are fully functional at the time of bidding and are assessed by TIA for meeting the eligibility criteria in this Contract.
- "Successful bidder" shall mean the bidder, who is technically qualified and whose financial bid has been finalized.
- "Service Provider" means the successful bidder, who after, signing the Agreement, is providing the services as enumerated in the RFP.
- "Tender Inviting Authority" means Tender Inviting Authority (TIA), The tender process will be processed through Tender Inviting Authority (TIA).
- Health Facility means the Government health facility where the service provider is providing the requisite laboratory services. The health facility could be District Hospital, Sub-District Hospitals, Community Health Centers, Civil Hospital, General Hospital, Other hospital, and Primary health Centre, Health and Wellness center.
- "Unit" means the Government Health Facility (ies) (District Hospital, Sub-District Hospitals, Community Health Centers, Civil Hospitals, General Hospitals, Other hospitals, Primary health Centre, Health and Wellness centers).

Abbreviations

1. "BG" means Bank Guarantee
2. "SMSC" means State Medical Service Corporation
3. "CH" means Civil Hospital
4. "CHC" means Community Health Center
5. "CS" means Civil Surgeon
6. "DH" means District Hospital.
7. "DHS" means Director Health Services
8. "EMD" means Earnest Money Deposit
9. "LOI" means Letter of Intent
10. "MCI" means Medical Council of India
11. "MoU" means Memorandum of Understanding
12. "NABL" means National Accreditation Board for Testing and Calibration Laboratories
13. "RFP" means Request for Proposal
14. "SOP" means Standard Operating Procedure

SECTION III

EVALUATION OF TENDERS

SCRUTINY OF TENDERS

The tenders will be scrutinized by a committee appointed by the Tender Inviting Authority to determine whether they are complete and meet the essential and important requirements, conditions and whether the bidder is eligible and qualified as per criteria laid down in the Tender Enquiry Documents. The bids, which do not meet the aforesaid requirements, are liable to be treated as non-responsive and may be ignored. The decision of the Tender Inviting Authority (TIA) as to whether the bidder is eligible and qualified or not and whether the bid is responsive or not shall be final and binding on the bidders. Financial bids of only those bidders, who qualify on technical bid, will be considered and opened. No exception will be accepted regarding the same.

INFIRMITY/NON-CONFORMITY

The Tender Inviting Authority (TIA) may waive minor infirmity and/or non-conformity in a tender, provided it does not constitute any material deviation. The decision of the Tender Inviting Authority (TIA) as to whether the deviation is material or not, shall be final and binding on the bidders. No representation will be accepted regarding the same.

BID CLARIFICATION

Wherever necessary, the Tender Inviting Authority (TIA) may, at its discretion, seek clarification from the tenderers seeking response by a specified date. If no response is received by this date, the Tender Inviting Authority (TIA) shall evaluate the offer as per available information.

SECTION IV

JOB DESCRIPTION

I. RESPONSIBILITIES OF THE SERVICE PROVIDER

In the assigned Government health facilities listed in Annexure A(2)-The Service provider shall be responsible for provision of laboratory services for tests listed in Annexure A (1)1. The services will include sample collection at the Government health facilities, transportation of samples to Service provider's laboratories, testing of samples and reporting and interpretation of test results within the time frame mentioned in Annexure J and provision of reports to the patients/doctors/health facilities' Detailed scope of services' adhering to quality standards mentioned in Annexure-J'Detailed scope of services'.

II. SCOPE OF THE WORK

- The obligations of the service provider/firm under this service contract shall include service activities and commitments as detailed in Annexure J.
- All the points mentioned in the guidance document shall be applicable for service delivery.

SECTION V

ELIGIBILITY CRITERIA

ELIGIBILITY CRITERIA FOR THE BIDDER

1. (The bidder shall be registered as a legal entity. No bidder can place more than one bid in any form (Alternate bids are not allowed) The bidder shall have the following Registrations and details of the same be provided in the technical bid:

   GST Registration number (if applicable)

   PAN Number

   CA certificate of turnover, profit & loss statement for last three completed financial years

2. The bidder shall have at least three years of experience in medical laboratory services. In support of this, a Statement regarding assignment of similar nature completed or ongoing during last three years should be submittedas per proforma in Annexure-C. The bidder should obtain user's certificate regarding satisfactory implementation of the assignment or completion of assignment (in case the assignment duration is completed) from all the Government/Non Government organizations.

3. For bidding in large States, the Bidder at the time of bidding shall have at least five independent fully functional laboratories for the last three years.

   a. At the time of biddingeach of the five laboratories of the Bidder should be independently equipped for (equipment, human resource, infrastructure) and performing all the tests mentioned in the scope of services of this RFP for the last three years except molecular tests.

   b. At the time of bidding each of these five laboratories should have been performing the tests using qualified personnel (MD/DNB/Diploma post MBBS diagnosticians and laboratory technicians) for the past three years.

   c. At the time of bidding, each of the five laboratories of the Bidder should have performed at least a total of 1.5 lakh tests of any type every year for the past 3 years.

   d. At the time of bidding, atleast one laboratory of Bidder should be NABL accredited for atleast 50 percent of the tests mentioned in the scope of services of the RFP .

For bidding in small States and North eastern States, the Bidder at the time of bidding shall have at least one independent fully functional laboratory for the last three years. The one laboratory of the Bidder should meet the following criteria:

   a. At the time of bidding this one laboratory should be independently equipped for (equipment, human resource, infrastructure) and performing all the tests mentioned in the scope of services of this RFP except for molecular tests atleast for the last three years.

b. At the time of bidding, this one laboratory should have been performing all the tests mentioned in the scope of services of this RFP using qualified personnel (MD/DNB/Diploma post MBBS diagnosticians and laboratory technicians) for the past three years.

c. At the time of bidding, this one laboratory of the Bidder should have performed at least a total of 1.5 lakh tests of any type every year for the past 3 years.

d. At the time of bidding, this one laboratory of Bidder should be NABL accredited for atleast 50 percent of the tests mentioned in the scope of services of the RFP .

4. The bidders are not presently blacklisted by the Tender Inviting Authority or by any State Authority or its organizations by Government of India or its organizations. 6. The bidder shall have a minimum turnover of INR <insert value> per annum during the preceding three completed financial years.

SECTION VI

TERMS AND CONDITIONS

SERVICE AIMS

The patients visiting Government health facilities and prescribed laboratory tests at these facilities should receive requisite high-quality laboratory services at the Government health facility itself. The services should be free-of-cost for these patients. The laboratory tests should enable timely and accurate diagnosis and management of these patients. The objective is to ensure that the service provider provides laboratory services in the designated Government health facilities in the assigned districts listed in the RFP. The Services will be as per the terms and conditions mentioned in the RFP. The service provider will be liable to provide the laboratory services only to the patients who are prescribed tests at the Government health facilities. The Service Provider will not charge these patients or their attendants any fee for these services. The Contracting Authority shall be responsible to pay the fee for these services to the Service Provider.

The service provider will provide services through its own laboratories meaning the laboratories should be registered in the name of the service provider. The service provider will not be allowed to subcontract more than 10 percent of test parameters listed in the scope of services in the RFP to any other legal entity.

Service provider shall commence the proposed services within 90 days of signing the Agreement (by which date). The services shall be rolled out in a phased manner as per the details in the rollout plan detailed in Annexure J 'Detailed scope of services'.

The space allocated to the Service provider within the government facility for primary sample collection shall not be used by the service provider for any other purpose other than for services under the Contract.

All the cost within the declared scope of work including the cost of deployment of the personnel shall be borne by the Service provider. The contracting authority shall be responsible for and bear the initial cost for initial infrastructure repair work if any needed at sample collection centers set up within the government health facilities and monthly cost of water, electricity, cleaning and biomedical waste disposal at sample collection centers set up within the government health facilities.

Modification to Contract: The contract when executed by the parties shall constitute the entire contract between the parties in connection with the jobs/services and shall be binding upon the parties. Modification, if any, to the contract shall be in writing and with the consent of the parties.

After completion of the tenure of tender, the Service provider shall be allowed to vacate the space within a period of 15 days, in all the government health facilities where service provider had been providing the services.

TIA

Govt. of State

SECTION VII

ANNEXURES

Annexure - A (1)

LIST OF TESTS TO BE OUTSOURCED

List of laboratory tests will be as per the FDI guidelines (List of tests may vary for PHCs, CHCs, SDHs and DHs). Therefore, separate lists to be formed for PHCs, CHCs, SDHs and DHs.

Annexure - A (2)

List of government health facilities (with type of facility and address) where services of service provider are required.

Annexure - B

AFFIDAVIT (NON CONVICTION)

(To be furnished by the Bidder)

To
The TIA

(On Non – judicial stamp paper of Rs 100 duly attested by notary public)

I, the undersigned, do hereby certify that all the statements made in our proposal are true and correct.

The undersigned hereby certifies that Company/Society/Trust M/s_____ its directors/President/Chairperson/Trustee have not abandoned any work for the Government of <insert name of the state> or any other State Government during last five years prior to the date of this Bid.

The undersigned also hereby certifies that Company/Society/Trust M/s_____ its directors/President/Chairperson/Trustee have not been debarred/blacklisted by Government of <insert name of the state>, or any other State Government or Government of India for any work.

The undersigned further certifies that

a. Our Company/Society/Trust ..... has not been convicted in matters relating to security and integrity of the country

   The undersigned hereby authorize(s) and request(s) any bank, person, firm, Competent Contracting Authority or corporation to furnish pertinent information deemed necessary and requested by <Name of contracting authority> of Health Services, <insert name of the state>, Government of <insert name of the state> to verify this statement or regarding my (our) competence and general reputation.

   The undersigned understands and agrees that further qualifying information may be requested, and agrees to furnish any such information at the request of the <Name of contracting authority> of Health Services, <insert name of the state>.

Signed by an authorized Officer of the Company/Society/Trust

Title of Officer .....

Name of Company/Society/Trust .....

Date .....

Annexure - C

ASSIGNMENT OF SIMILAR NATURE SUCCESSFULLY COMPLETED DURING LAST THREE YEARS

Attach users' certificates (in original) regarding satisfactory completion of assignments with Government/Non Government organisations. In case of ongoing assignments, user certificate of satisfactory implementation should be attached. The bidder should also obtain signed copies of complete details of penalties levied by each of the Government organizations (it has worked with or currently working) for any non performance in provision of medical laboratory services to these organizations.

The experience of similar nature is acceptable on letter head of the bidder if he has his own Lab.

Note: Attach extra sheet for above Performa if required.

Signature.....

S.No.	Description of Work	Date of Commencement	Date of Completion (if assignment is completed)	Address of the Organisation	Percentage of payments deducted as penalties out of the total payments of the services rendered

Annexure - D

PARTICULARS OF THE BIDDER'S COMPANY

(To be submitted by all tenderers/bidders)

Name :

Registered Address

Phone/Fax/Mail id

Type of Organization:

Proprietary./Partnership/Company/Trust/Not for Profit Organization

Total Number fully functional independent laboratories of the Bidder:

Address of all fully functional independent laboratories of the Bidder :

Total Number of services personnel at the existing fully functional independent laboratories of the Bidder:

Number of service personnel:

Name	Qualification	Experience (Similar Service)

(use extra sheet if necessary)

Total number of tests conducted in the last three completed financial years in each of the fully functional laboratories of the Bidder

Names of major equipment in each of the fully functional laboratories of the Bidder

Whether the bidder has NABL/NABH/ISO or any other accreditation of its existing fully functional laboratories?

(If yes, of how many laboratories and for which all tests in each of the laboratories. Whether documents attached with techno commercial bid).

a. GST (if applicable)

b. PAN No.

c. Audited Accounts Statement for last three completed financial years

d. Copy of Income Tax Return for past three completed financial years

Company Profile: .....

Signature of Bidders

Date: Name:

Place: Office Seal:

Annexure - E

FORWARDING LETTER FOR TECHNICAL BID

(To be submitted by all tenderers/bidders on their letter head)

Date: .....

To

TIA

Sub: Tender for supply of services under Tender No.....

Sir,

We are submitting, herewith our tender for providing Laboratory Services .....

We are enclosing Receipt No..... or Bank Draft/Bankers Cheque No....., Dated ..... (Amount Rs. .....) towards tender cost/fee (if documents have been downloaded from website) and Bank Draft/Bankers Cheque No..... Dated..... (Amount Rs .....) towards Earnest Money Deposit (EMD), drawn on..... Bank in favour of TIA

We agree to accept all the terms and condition stipulated in your tender enquiry. We also agree to submit Performance Security as per Clause No. 3 of Section VI of Tender Enquiry document.

We agree to keep our office valid for the period for the period stipulated in your tender enquiry.

Enclosures:

1.

2.

3.

4.

5.

Company name and address of Tenderer.....

Signature of the Tenderer.....

Name of the signee .....

Designation of signee .....

Seal of the Tenderer.....

Annexure - F

FINANCIAL BID

Name of the Bidder	Discount percentage % quoted on CGHS Delhi rate (exclusive of all taxes)

The L1 bidder shall be selected from maximum discount percentages (%) quoted on CGHS DELHI rate The financial bid shall be inclusive of all cost including Human Resource, procurement of equipment, Reagent & consumables, infrastructure, Supply & logistics, quality assurance, maintenance and all other operational expenses as per the services defined in the scope of services.

Company name and address of Tenderer.....

Annexure - G

PROFORMA FOR BANK GUARANTEE FOR EMD

To

TIA

WHEREAS..... (Name and address of the Service Provider) (Hereinafter called “service provider” has undertaken, in pursuance of tender No..... dated ..... (Herein after “the contract”) to provided laboratory services.

AND WHEREAS it has been stipulated by you in the said contract that the service provider shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations in accordance with the contract;

AND WHEREAS we have agreed to give such a bank guarantee on behalf of the service provider;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the service provider, up to a total of..... (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the service provider to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforeside, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the service provider before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the service provider shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to **300 (days)** from the date: (indicate date)

.....

(Signature with date of the authorized officer of the Bank)

.....

Name and designation of the officer

.....

Seal, name & address of the Bank

Annexure - H

PROFORMA FOR BANK GUARANTEE FOR PERFORMANCE SECURITY

To

TIA

WHERE AS..... (Name and address of the Service Provider) (Hereinafter called “service provider” has undertaken, in pursuance of contract No..... dated ..... (Herein after “the contract”) to provide laboratory services.

AND WHEREAS it has been stipulated by you in the said contract that the service provider shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations accordance with the contract;

AND WHEREAS we have agreed to give such a bank guarantee on behalf of the service provider;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the service provider, up to a total of..... (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the service provider to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as a foreside, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the service provider before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the service provider shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to **66 (months)** from the date of signing of contract :.. (indicate date)

.....

(Signature with date of the authorized officer of the Bank)

.....

Name and designation of the officer

.....

Seal, name & address of the Bank and address of the Branch

Annexure - I

CHECKLIST

Company name and address of Tenderer .....

S. No.	Items	Whether Included YES
1	Checklist as per Annexure-I	
2	Annexure B, C, D, E, F, G, H	
3	Annual turnover Statement for last three completed financial years certified by the auditor	
4	The document such as work orders, performance reports, Agreement from the user institutions that the Bidder has relevant experience	
5	Registration documents providing the registration of the place of business and showing the details of partners/ promoters/Board of Directors etc	
6	Annual Report, Balance Sheet, Profit and Loss statement for last 3 completed financial years	
7	Income Tax returns for the last 3 completed financial years	

Annexure - J

DETAILED SCOPE OF SERVICES

A. Operational model

The service provider should use a hub and spoke model for providing laboratory services under the Agreement..

Only those patients who have been prescribed tests at the Government health facilities can avail services of the service provider.

The service provider's laboratories should be categorized as Mother laboratories (L1)and hub laboratories (L2). There should be atleast one Mother laboratory in each District and should be located inside or within 10 kilometers of the District Hospital. Mother laboratories should provide all designated routine and advanced tests (cultures, TSH, Histopathology etc.). The remaining Hub laboratories should provide all designated routine tests. The mother laboratories should cater to the District hospital and to other nearby spoke PHCs and CHCs for routine and advanced tests as well as cater to remaining Government health facilities (PHCs, CHCs, SDHs) in the district for their advanced tests. Hub laboratories should essentially be set up within 10 kilometers to sub-district hospitals and preferably in close proximity to large CHCs. The hub laboratories should cater to the facility in which/near which it is located and to nearby PHCs and CHCs (spokes) for routine tests.

The laboratories of the service provider will be set up in a manner that sample transportation time from any PHC or CHC (spoke) to the nearest service provider's laboratory (hub) will not exceed 2 hours and for DH and SDH not more than 15 minutesFor advanced tests, an additional time will be factored in for transportation of the samples to the mother laboratory in the same or different district (names of advanced tests and recommended transportation time for samples for these tests have been mentioned in Annexure J).

Each mother laboratory should have diagnosticians stationed at the laboratories -- MD/DNB/Diploma (post MBBS) in Biochemistry, Pathology and Microbiology; and laboratory medicine (optional). Hub laboratories could be managed by PhD or M.Sc. (Microbiology/Biochemistry/Laboratory medicine). The diagnosticians in the mother laboratories should remotely carry out verification of results of all routine tests and of IQC and EQAS of all hub laboratories of that district and should sign the reports. The advanced tests conducted at mother laboratory however should be physically verified by these diagnosticians for reporting.

B. Pre-rollout plan

The service provider should be given 90 days from the date of signing of the Agreement for preparation of rollout of services.

In the pre-rollout/preparatory phase, following measures are essential:

The state should institute a monitoring team for monitoring of the services at all levels including facility level. A state-level diagnostics team should be formed under the leadership of a Joint Director or Representative nominated by TIA. Members should include a Nodal officer, senior laboratory staff deputed from Government medical colleges including a senior Pathologist (MD), a senior Biochemist (MD), a senior Microbiologist (MD) and 2 senior laboratory technicians; an accounts person; a senior

IT person; and a data entry person. At district level, the district health officer and at the facility-level, the facility in-charge should be responsible for monitoring the implementation of the services and for ongoing supervision.

The service provider should map the health facilities for setting up Mother and hub laboratories and spokes and prepare a detailed logistics plan and submit to the state diagnostics team.

The service provider shall prepare and submit standard operating procedures for sample collection, transportation, storage, testing and reporting to the TIA/Contracting authority prior to starting the services and TIA shall finalize and approve the same.

For DHs and SDHs the laboratories will not be situated more than 10 kilometers away from the hospital and a travel time of upto 15 minutes. The service provider will be responsible for setting up and maintenance of the laboratories including water, electricity and cleaning in the laboratories set up within the health facilities as well as those set up outside the health facilities. The service provider will bear costs incurred on these counts. The State Government will be responsible for and bear the costs for water, electricity and cleaning at collection centers set up within the government health facilities as well as the cost for initial infrastructure repair of the collection centres.

The service provider should set up the transportation system (cold chain) for transportation of samples and the system will be duly assessed by the state diagnostics team.

After the service provider sets up the laboratories, these will be inspected by the state diagnostics team before these laboratories start providing services to the government health facilities. The equipment, quality of reagents, qualification and experience of Diagnosticians and laboratory technicians, infrastructure for cold chain, standard operating procedures, laboratory information system used in the laboratories will be assessed and approved by the State Government. Quality control systems should be instituted in the preparatory phase itself. The quality teams of service provider should carry out independent inspections of its laboratories.

The state government will have the information, education and communication (IEC) plan ready (materials for TV, radio, newspaper advertisements, banners, handouts etc.) for launching the services and on an ongoing basis.

The service provider should prepare test requisition forms and the state government will provide stamps to each doctor for putting on the requisition forms. The stamp should have name, designation, facility name and employee ID of the doctor.

The service provider should declare the list of empaneled laboratories to the state government. The empaneled laboratories should be NABL accredited for the outsourced tests. The service provider should not outsource more than 10 percent of the designated test parameters and shall take prior approval from the TIA/Contracting Authority/State Authority for outsourcing.

C. Rollout plan

The services should be rolled out in a phased manner as per the Guidance document.

Following will be ensured immediately after the rollout:

The monitoring indicators will be used from beginning of the rollout. The state will closely monitor all aspects of services including availability of sampling services and tests at the government health facilities, cold chain, transportation, quality assurance at laboratories including processing of samples, testing, quality control, verification of results and training of staff of service provider.

D. Operations

All tests should be made available to patients on all designated days. No patient will be denied any designated test by the service provider. In instances where the service provider is not able to provide any test for specified period, adequate notice should be given by the service provider to the state government and the concerned health facilities.

a. Sample collection

i. Sampling of patients should be done inside the government health facilities by the phlebotomists of the service provider. The service provider should set up sampling stations at all health facilities for sampling and report dispatch carried out by its phlebotomists. Patients who have been prescribed tests by doctors at other government health facilities should also be provided services by the service provider. For instance, a patient prescribed tests at a PHC could give her/his sample at a CHC and vice vers.

ii. In DHs and SDHs, the sampling facility should be available round-the-clock. In CHCs and FRUs, from 6am - 4pm and in PHCs 6am - 12pm.

iii. The service provider's phlebotomists should be stationed round-the-clock at DHs and SDHs on all days including Sundays and public holidays. In CHCs and FRUs, the phlebotomist should be available on call after working hours for emergency samples.

iv. In the morning shift, the service provider should station 6 phlebotomists in up to 300 bedded DHs, 8 phlebotomists in 301-500 bedded DHs, 3 phlebotomists in up to 50 bedded SDHs and 4 phlebotomists in 51-100 bedded SDHs. In the night shift and on Sundays and public holidays, the number could be less as the patient load is less. In CHCs and FRUs, 2-3 phlebotomists (as per the patient load) should be stationed from 6 am-4 pm and in day care PHCs 1 phlebotomist from 6am-12pm.

v. The phlebotomists of service provider should carry out registration, collection, labelling, and storage of samples and dispatch of the samples to the service provider's laboratories. The contracting authority will ensure that patient sample collection facilities have separate waiting and collection areas as well as a toilet facility.

vi. The percentage of samples which are unfit for testing (haemolysed/clotted/insufficient quantity) will be monitored through data provided by service provider on rejected samples as well as by the technical committee of the government during inspection of sampling stations at health facilities and inspection of service provider's laboratories.

b. Suggested work process flow

A requisition form should be provided to the doctors with a printed list of tests. The doctor will fill the patient's name. The phone number and unique ID should be filled by the phlebotomist. The tests should be mentioned as individual tests and not as profiles (e.g. liver function tests, anaemia profile) and not as group of tests (sodium/potassium/chloride).

The UHID (unique health identification) number of the patient for enrolment for laboratory services should be the Aadhaar number/registration number provided by the government health facility/ unique number provided by the laboratory. In addition, for sample identification, barcodes should be used. The UHID and barcode could be different numbers. All samples of a patient should be labelled with the same barcode number. Barcodes could be printed at the time of registration. Else, pre-printed barcodes could be used. In case the barcode is printed at the time of registration, the barcodes should have a prefix of facility ID (PH, CH, SD, DH) as well as OP and IP. The barcode

should be put on the sampling tubes/containers after registration and before collecting the sample. Barcodes should also be put on the patient's requisition form, registration register (if entry is done manually in the register) and batch sheet (sheet prepared for the transportation personnel) for proper identification of samples. An acknowledgement slip should be given to the patients for report collection. One barcode should also be put on the acknowledgement slip.

The prescription of the doctor should be scanned at the time of registration and the soft copy should be sent to the service provider's laboratory along with the patient registration details. The service provider will provide a scanner at the health facilities.

Blood samples should be collected in vacutainers. There should be no leakages of samples from the containers. The phlebotomist should ensure that all consumables for sampling including blood culture bottles (especially paediatric), PT tubes etc. are adequate in number and of good quality.

For emergency samples, there should be instructions for the receipt, labelling, processing and reporting of these samples. The instructions should include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

Biomedical waste guidelines and universal precautions should be followed by the phlebotomists including presence of fully functional needle-cutter, color-coded waste bags and personal protective gear. The service provider shall follow guidelines of the independent occupier and shall follow BME waste management rule 2016 and any other amendments applicable. The state government will be responsible for waste disposal in laboratories set up within the Government health facilities. In the laboratories set up outside, it will be responsibility of the service provider.

c. Sample Transportation

The spokes should be set up in a manner that cumulative sample transportation time from multiple health facilities to the primary receiving laboratory should not exceed 2 hours (starting from where pick-up has started). An additional time could be factored in for transportation of advanced tests from hub laboratories to mother laboratory.

Samples should be picked up from the health facilities on the same day and transported by the service provider to its laboratories for testing.

Samples should be picked up once a day from PHCs and far-off CHCs (far from testing laboratories), twice from large CHCs and every 1–1.5 hours from SDHs and DHs. Pick-up of emergency samples should be done within 15 minutes from SDHs and DHs and within 1 hour from CHCs. For CHCs, the reason for emergency sample pick up should be provided by the health facility in a form, which will ensure that the service provider sends a transportation person out of turn for only those samples which actually require urgent report.

The pick up of samples from PHCs will be at 12 pm In those PHCs, where evening OPDs are conducted, second pick up will be at the end of the OPD timing. In CHCs, the first round of sample pick up will be at 11 am and second round of sample pick up will be at 4 pm. In those CHCs, where evening OPDs are conducted, last pick up will be at the end of the OPD timing. The sample dispatch time will be recorded electronically by service provider's phlebotomist under supervision of in-house laboratory technician.

Dedicated pick-up/ILD persons should be assigned for transportation of samples from and delivery of reports to allassigned government health facilities. One ILD person each should be assigned for DHs, SDHs and large CHCs. For PHCs and remaining CHCs, each delivery personnel could manage 3–4

facilities depending on the distance from the nearest laboratory. In remote areas, the phlebotomist and the inter-laboratory delivery (ILD) person could meet halfway for sample transportation.

Applicable National regulations should be followed for the transport of infectious and other diagnostic specimens so that in the event of an accident, courier staff and the general public may not be exposed to blood and body fluids. The parcel of infectious substances should be attached with a plastic envelope containing document — Bio-hazardous diagnostic specimens.

d. Cold chain

The cold chain for sample storage should be robust at all steps:

Storage of samples at the government health facilities prior to dispatch shall be the responsibility of service provider.

Transportation from health facilities to primary receiving laboratories and from hub to mother laboratories shall be the responsibility of Service provider.

In all government health facilities, the service provider will provide a small refrigerator with power back-up for storage of samples awaiting dispatch and reagents. The service provider will provide cool boxes with adequate ice at PHCs and CHCs as back-up in case of power failure.

To ensure adequate cold chain during transportation of samples to the testing laboratories, cool boxes equipped with temperature monitoring device and containing sufficient quantity of ice packs at requisite temperature should be made available. The temperature monitoring device should monitor the temperature from sample pick up till receipt of sample at the testing laboratory. The data of temperature monitoring device should be downloaded at the testing laboratory.

e. Report dispatch

Test reports should be given by the service provider as printed reports to the government health facilities. Reports should also be e-mailed to the health facilities and to respective doctors' individual email ids by the service provider's laboratories as soon as the reports are generated at the laboratories.

Reports should be dispatched to patients or doctors by phlebotomists of the service provider.

In SDHs and DHs, the report dispatch counter should be separate from the registration counter.

f. Turnaround time

The contracting authority will monitor turnaround time of test reports.

Components of turnaround time

For an accurate analysis of the turnaround time for laboratory services, the starting point should be time of sample collection at the government health facility where the tests are prescribed and the end point should be printing of reports at the Government health facility or receipt of electronic report at the Government health facility (if printing facility not available at the health facility).

For assessing efficiency of processes at different stages of the sample cycle in terms of turnaround time, the state government will monitor pre-analytical, analytical and post-analytical turnaround times separately.

- Pre-analytical turnaround time will be broken into 2 components: a) for routine tests, time from sample collection to time of registration of the sample at the service provider's laboratory

b) For advanced tests, time from sample collection to time of registration of sample at the mother laboratory.

- Analytical turnaround time will be divided as: a) time for testing; b) time from testing to report verification.
- Post-analytical turnaround time will be divided as: a) time from verification of report to electronic report dispatch to the health facilities. b) time from electronic report dispatch of report to printing of report at the Government health facility.

Prescribed turnaround time

i. Recommended preanalytical time

- The pre-analytical time (time from sample collection for laboratory tests at the government health facility to time of registration of the sample at the testing laboratory) for routine tests should not exceed 2 hours for facilities where service provider's laboratory is situated within/in close proximity of the premises of that health facility. For samples transported from distant facilities (PHCs and small CHCs), the maximum permitted pre-analytical time should be 7 hours.
- For advanced tests such as cultures etc. for which samples need to be transported to mother laboratories in the same district, the preanalytical time should not be more than 2 hours for DHs and 10 hours for other facilities. For few other advanced tests including histopathology, FNAC, pap smear, HbA1C, Haemoglobin electrophoresis for which samples might require transportation to another district, the pre-analytical time could be 20 hours for DHs and SDHs and upto 27 hours for CHCs and PHCs.

Table 1 : Recommended Preanalytical turnaround time

Preanalytical time (Time from sample collection at the government health facility to time of registration of sample at the testing laboratory)	**PHCs, small CHCs**	**Large CHCs, FRUs, SDHs, DHs (hub laboratory located within/in close proximity to the facility)**
Routine tests sent to service provider's laboratory	7 hours	2 hours for DH and SDH and preferably for large CHCs and FRUs
Advanced tests sent to service provider's mother laboratory in the same district (cultures etc.)	10 hours	2 hours for DH, SDH and 10 hours for other facilities
Advanced tests sent to service provider's mother laboratory in a different district (such as histopathology, cytology, pap smear, electrophoresis)	Up to 27 hours	Up to 20 hours

ii. Recommended analytical turnaround time:

a. Analytical turnaround time for testing

The analytical time is different for each test and is mentioned in the table below.

b. Analytical turnaround time for verification of test results

- Verification of test results should not exceed 1 hour.

Table 2 : Recommended total turnaround time (Time from sample collection from patient at the health facility to time of electronic receipt of report at the health facility)

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
1	Hemoglobin	a. 30 minutes b. 2 hours	a. Digital Hemoglobinometer b. Hematology analyser	a. 30 minutes b. 5 hours	a. 30 minutes b. 10 hours
2	Total leucocyte count	2 hours	Hematology analyser	5 hours	10 hours
3	Differential leucocyte count	2 hours	Hematology analyser	5 hours	10 hours
4	Platelet count	2 hours	Hematology analyser	5 hours	10 hours
5	Complete blood count	2 hours	Hematology analyser	5 hours	10 hours
6	Erythrocyte sedimentation rate	1 hour	Manual with reading using ESR analyser	4 hours	9 hours
7	Blood group and Rh typing	1 hour	Blood group kit (manual)	4 hours	9 hours
8	Blood cross matching	2 hours	Manual	5 hours	10 hours
9	Peripheral blood film	4 hours	Microscopy	7 hours	12 hours
10	Reticulocyte count	6 hours	Manual	9 hours	14 hours
11	Absolute eosinophil count	6 hours	Manual	9 hours	14 hours
12	Bleeding time and clotting time	5 minutes	Manual	5 minutes	5 minutes
13	Fibrinogen degradation products (FDP)	1 hour	Coagulation analyser/ Manual using latex agglutination	4 hours	9 hours
14	D-Dimer	1 hour	Coagulation analyser/ Manual using latex agglutination	4 hours	9 hours
15	Coombs test direct with titre	4 hours	Manual	7 hours	12 hours
16	Coombs test indirect with titre	4 hours	Manual	7 hours	12 hours
17	Sickling Test for screening of Sickle cell anemia*	8 hours	Manual with microscopy	11 hours	16 hours
18	Sickle cell test rapid for screening of Sickle cell anemia*	8 hours	Rapid	11 hours	16 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
19	NESTROFT Test for screening of Thalassemia*	8 hours	Manual	11 hours	16 hours
20	DCIP test for screening HbE hemoglobinopathy*	8 hours	Manual	11 hours	16 hours
21	Quantitative test for G6PD enzyme deficiency	4 hours	Manual/ Fluorometry	7 hours	17 hours
22	a. MP slide method and b. Malaria rapid test	a. 4 hours b. 30 minutes	a. Microscopy b. Rapid card tests for combined P.Falciparum and P.vivax	a. 7 hours b. 3.5 hours	a. 12 hours b. 8.5 hours
23	Prothrombin Time (PT) and INR	2 hours	Automated coagulation analyser	5 hours	10 hours
24	Activated partial thromboplastin time	2 hours	Automated coagulation analyser	5 hours	10 hours
25	Mixing study and Factor VIII Assay for Hemophilia	6 hours	Automated coagulation analyser	9 hours	14 hours
26	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	30 minutes	Rapid card test	3.5 hours	8.5 hours
27	Urine test for ph, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	1 hour	Multiparameter urine strip (dipstick)	1 hour	1 hour
28	Urine Microscopy	2 hours	Microscopy	5 hours	10 hours
29	24-hours urinary protein	6 hours	Fully automated biochemistry analyser	9 hours	14 hours
30	a. Urine for microalbumin b. Urine for Creatinine & ACR	6 hours	a. Turbidometer/ Nephelometer b. Fully automated Biochemistry analyser	9 hours	14 hours
31	Stool for ova and cyst	6 hours	Microscopy	9 hours	14 hours
32	Stool for Occult Blood	6 hours	Manual Kit	9 hours	14 hours
33	Semen analysis	1 hour	Microscopy (with neubaeur chamber and slide)	3 hours	8 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
34	Test for Dengue a. Rapid b. ELISA	a. 30 minutes b. 12 hours	a. Rapid card test for combined NS1 antigen and IgM antibody b. ELISA	a. 3.5 hours b. 15 hours	a. 8.5 hours b. 25 hours
35	RPR/VDRL test for syphilis	12 hours	Rapid card test	15 hours	20 hours
36	HIV test (Antibodies 1 and 2) a. Rapid b. Immunoassay analyser	a. 30 minutes b. 2 hours	a. Rapid card test b. Chemiluminiscence assay	a. 3.5 hours b. 5 hours	a. 8.5 hours b. 15 hours
37	Hepatitis B surface antigen test a. Rapid b. Immunoassay analyser	a. 30 minutes b. 2 hours	a. Rapid card test b. Chemiluminiscence assay	a. 3.5 hours b. 5 hours	a. 8.5 hours b. 15 hours
38	HCV Antibody Test (Anti HCV) a. Rapid b. Immunoassay analyser	a. 30 minutes b. 2 hours	a. Rapid card test b. Chemiluminiscence assay	a. 3.5 hours b. 5 hours	a. 8.5 hours b. 15 hours
39	Sputum, pus etc. for AFB	6 hours	Microscopy	9 hours	14 hours
40	Typhoid test (IgM)	2 hours	Rapid card test	5 hours	10 hours
41	Blood sugar a. Rapid b. Biochemistry analyser	a. 30 minutes b. 1 hour	a. Glucometer b. Fully automated Biochemistry analyser	a. 30 minutes b. 4 hours	a. 30 minutes b. 9 hours
42	Glucose Tolerance test (GTT)	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
43	S. Bilirubin (T)	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
44	S. Bilirubin direct and indirect	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
45	Serum creatinine	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
46	Blood Urea	2 hours	Fully automated biochemistry analyser	5 hours	10 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
47	SGPT	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
48	SGOT	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
49	S. Alkaline Phosphatase	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
50	S. Total Protein	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
51	S. Albumin & AG ratio	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
52	S. Globulin	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
53	S. Total Cholesterol	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
54	S. Triglycerides	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
55	S. VLDL	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
56	S. HDL	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
57	S. LDL	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
58	S. GGT	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
59	S. Uric acid	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
60	S. Amylase	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
61	S. Iron	6 hours	Fully automated biochemistry analyser	9 hours	14 hours
62	S. Total Iron binding capacity	6 hours	Fully automated biochemistry analyser	9 hours	14 hours
63	S. LDH	2 hours	Fully automated biochemistry analyser	5 hours	10 hours
64	Glycosylated haemoglobin (HbA1C)	6 hours	Fully automated biochemistry analyser/ HPLC	9 hours	19 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
65	S. Sodium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
66	S. Potassium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
67	S. Calcium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
68	S. Chloride	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
69	S. Magnesium	30 minutes	Indirect ion electrode Electrolyte Analyser	3.5 hours	8.5 hours
70	Smear for RTI/STD	12 hours	Wet mounting, gram staining	15 hours	20 hours
71	Smear for leprosy	24 hours	Microscopy	27 hours	37 hours
72	Gram staining for clinical specimen	4 hours	Microscopy	7 hours	12 hours
73	Throat swab for Diphtheria	4 hours	Microscopy	7 hours	12 hours
74	Stool for hanging drop for Vibrio Cholera	4 hours	Microscopy	7 hours	12 hours
75	Visual Inspection Acetic Acid (VIA)	30 minutes	Manual	30 minutes	30 minutes
76	rK39 for Kala Azar*	30 minutes	Rapid card test	3.5 hours	8.5 hours
77	Smear for Filaria*	12 hours	Microscopy	15 hours	25 hours
78	TB-Mantoux	72 hours	Manual	72 hours	72 hours
79	Japanese Encephalitis IgM *	12 hours (if batch testing) for ELISA	ELISA	15 hours (if batch testing) for ELISA	
80	Scrub typhus Test*	24 hours (if batch testing)	ELISA/Weil Felix	27 hours (if batch testing)	37 hours (if batch testing)
81	Test for Leptospirosis*	24 hours (if batch testing)	ELISA	27 hours (if batch testing)	37 hours (if batch testing)
82	Test for Chikungunya	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
83	IgM for Measles	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
84	IgM for Hepatitis A	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
85	IgM for Hepatitis E	12 hours (if batch testing)	ELISA	15 hours (if batch testing)	25 hours (if batch testing)
86	Rapid antigen detection test for Bacterial meningitis (Meningococci)	30 minutes	Rapid Latex agglutination test	3.5 hours	
87	S. TSH (including for new-born screening)	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
88	S. Free T3	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
89	S. Free.T4	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
90	Ferritin	6 hours	Chemiluminescence immunoassay	9 hours	19 hours
91	Troponin - I/Troponin - T	5 minutes	Rapid card test	5 minutes	5 minutes
92	S. Beta HCG	30 minutes	a. Rapid b. Chemiluminescence immunoassay	a. 2.5 hours b. 3.5 hours	a. 7.5 hours a. 13.5 hours
93	S. Prolactin	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
94	S. Alfa Feto protein	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
95	S. CA-125	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
96	S. CEA	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
97	S. Procalcitonin	30 minutes	Chemiluminescence immunoassay	3.5 hours	8.5 hours
98	S. Anti-Mullerian hormone (AMH)	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
99	S. PSA	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
100	S. Vitamin B12	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
101	S. Vitamin D	24 hours	Chemiluminescence immunoassay	27 hours	37 hours

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
102	TORCH IgM and IgG, Rubella IgG	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
103	S. Thyroid peroxidase antibody	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
104	Anti-cyclic citrullinated peptide (anti-CCP)	24 hours	Chemiluminescence immunoassay	27 hours	37 hours
105	RA factor (Quantitative)	24 hours	Turbidometer	27 hours	32 hours
106	CRP (including new born) (Quantitative)	2 hours	Turbidometer	5 hours	10 hours
107	Pap smear	48 hours	Microscopy	68 hours	75 hours
108	Cytology (FNAC etc.)	48 hours	Microscopy	68 hours	75 hours
109	Fluid cytology	12 hours	Microscopy	15 hours	25 hours
110	CSF analysis (Sugar, protein, ADA, cell count)	1 hour	Fully automated biochemistry analyser, Haematology analyser	4 hours	9 hours
111	Fluid analysis (Cell count, biochemistry)	1 hour	Fully automated biochemistry analyser, Haematology analyser, Microscopy	4 hours	9 hours
112	Anti-nuclear antibody (ANA)	7 days	Immunofluoroscent Microscopy	8 days	8 days
113	Histopathology	96 hours (4 days)	Microscopy	120 hours (5 days)	120 hours (5 days)
114	Frozen section for histopathology	96 hours (4 days)	Microscopy	120 hours (5 days)	120 hours (5 days)
115	Bone marrow examination	72 hours (3 days)	Microscopy	96 hours (4 days)	96 hours (4 days)
116	Immunohistochemistry	96 hours (4 days)	Manual	120 hours (5 days)	120 hours (5 days)
117	CD4 count	48 hours	Flow cytometer	68 hours	75 hours
118	Viral load count for HCV	48 hours	PCR	68 hours	75 hours
119	Viral load count for HBV	48 hours	PCR	68 hours	75 hours
120	Blood culture and antimicrobial sensitivity	1st report 48 hours; 2nd report 120 hours (5 days)	Automated	1st report 48 hours; 2nd report 120 hours (5 days)	1st report 58 hours; 2nd report 120 hours (5 days)

S. No.	Diagnostic test	Analytical turnaround time for testing for DHs, SDHs, CHCs, PHCs (Time from receipt of sample at the testing laboratory till time of completion of testing)	Method /Equipment Required	Total turnaround time=Preanalytical time of storage and transportation of sample+Analytical time for testing+ Analytical time for report verification+Postanalytical time of electronic report disptach	
				Total turnaround time for all cases of DHs, SDHs and emergency cases of CHCs	Total turnaround time for non emergency cases of CHCs and all cases of PHCs
121	Urine culture and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
122	Other cultures (pus, throat swab etc.) and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
123	Culture for Diptheria and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
124	Culture of stool specimen for Vibrio cholerae and other common bacterial enteropathogens and antimicrobial sensitivity	48 hours	Manual culture with automated bacterial identification and antimicrobial sensitivity	48 hours	48 hours
125	Mycobacterial culture and DST	4-8 weeks	State TB laboratory	4-8 weeks	4-8 weeks
126	Hemoglobin electrophoresis/HPLC	72 hours (3 days)	Electrophoresis machine/HPLC machine	96 hours (4 days)	96 hours (4 days)
127	Protein electrophoresis	72 hours (3 days)	Electrophoresis machine	96 hours (4 days)	96 hours (4 days)
128	Nucleic Acid Amplification Test for TB etc.	48 hours	Nucleic Acid Amplification Machine	68 hours	75 hours

** For endemic areas*

iii. Recommended Post analytical turnaround time

- **Electronic report dispatch:**
  - The turnaround time from verification to electronic report dispatch should not exceed 5 minutes.
  - The test results which fall in critical range and test results for samples labelled as 'emergency' should be automatically recorded and sent through automated messaging system to the concerned doctors within 30 minutes of verification of the reports. The turnaround time for automated messaging of test results in critical range and emergency samples will be closely monitored by the contracting authority.

The contracting authority will keep a close watch on the turnaround time for each kind of test at each type of facility (PHCs, CHCs, SDHs, DHs) and for OPD/IPD/emergency and for routine, advanced, emergency and critical tests.

Monitoring of the turnaround time will require a robust IT system, which tracks the sample status almost instantaneously. This IT system should be integrated between Government health facilities, hub laboratories and mother laboratories; and each case is closed only after generation of the report and its final receipt by the patient.

g. Printed reports

Time of printing/receipt of printed reports at the government health facilities will be defined, recorded and closely monitored for each type of facility by the service provider as well as by the contracting authority.

Test reports shall be given by the service provider as printed reports to the government health facilities. Printers shall be made available by the service provider at all assigned facilities to enable printing of reports, as and when the reports are ready. In exceptional cases, where printing facility cannot be made available, the reason (s) for the same shall be documented. In such cases, the reports shall be printed at service provider's laboratory. Cost of printing will be borne by the Service Provider. Reports shall also be e-mailed to the health facilities and to respective doctors' individual email ids by the service provider's laboratories as soon as the reports are generated at the laboratories.

The patients should be informed about the day of collection of printed reports based on the turnaround time of the tests. For the reports which would be received on the next day of sample collection, the patient should be called to collect those reports next day and not after 2-3 days. The registration slip given to the patient at the time of registration for tests should clearly mention report collection day in the local language.

For OPD cases, printed reports should be made available to the patients by 9 am next working day from sample collection day (for tests with analytical time upto 8 hours). For tests with analytical time of more than 8 hours, the printed reports should be made available at the health facility by 9 am on the next day of validation of test reports (as per the stipulated analytical time).

For IPD and emergency cases, the reports should be printed as soon as these are received from the laboratory and provided to the concerned department.

Service provider will create web based portal/mobile application for report download.

h. Patients' records

Records of the test reports should be maintained in the service provider's laboratory information system. However, the contracting authority will be the sole owner of all patients' records.

If the service provider outsources its IT systems, there must be a tri-partite IPR Agreement signed for all systems developed for the project among outsourced partner, service provider and the state government.

i. Laboratories of the service provider

The service provider will establish high quality laboratories for providing requisite services under the Agreement. In newly established as well as existing laboratories (if applicable), the service provider will ensure standardization of infrastructure and processes.

1. Equipment

All laboratories of the service provider should have appropriate and adequate equipment for all designated routine and advanced tests. Equipment less than seven years old only will be used. All laboratories should maintain electronic records for equipment calibration. All equipment should be calibrated on requisite intervals. Equipment like centrifuge, pipettes and culture hood should also be calibrated.

The equipment maintenance plan should be prepared and followed. Calibration of equipment should be closely monitored by the state government.

a. Electronic records of equipment breakdown should be maintained by the service provider.

b. During breakdown, the facility should use the back-up equipment. In case of absence of back-up equipment, the service provider should ensure that the services are not denied to the patients and the samples are sent for testing to the nearest laboratory of the service provider.

c. All equipment should be interfaced with the laboratory information system including coagulation analyzer, urine analyzer, electrolyte analyzer to reduce pre- and post-analytical errors resulting due to manual entries. Interfacing should be monitored by the state government.

2. Reagents and consumables

The service provider should declare the list of brands and vendors of reagents and consumables, which will be used in all its laboratories.

3. Human resources

All mother laboratories should have MD/DNB/Diploma (post MBBS) pathologists and biochemists and microbiologists.

Each hub laboratory should be headed by a PhD or M.Sc. (Biochemistry/Microbiology/other medical laboratory fields).

The minimum qualifications of laboratory technicians stationed in laboratories should be DMLT. Those with B.Sc., M.Sc. degrees should be given preference at the time of recruitment. Each mother laboratory should have minimum 7 technicians (at least 4 senior technicians with more than 5 years of experience) in the morning shift. In the night shift, there could be fewer technicians. Hub laboratories should have at least 4 technicians (at least 2 senior technicians with more than 5 years of experience) in the morning shift. During high season and epidemics, the service provider should arrange for extra laboratory technicians at its laboratories to manage the extra test load during such times (this is a common practice in private laboratories).

For phlebotomy, DMLT technicians fresh pass outs or with experience or ANMs with at least 2 years of experience should be employed.

4. Training

The service provider should make focused and concerted efforts for building capacity across various categories of staffs.

The laboratory staff should receive induction, refresher and on-job trainings.

Induction trainings should be conducted by a diagnostician (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/Laboratory medicine) or PhD Biochemistry/Microbiology. The training should be conducted for 15 days and it should be recorded.

Refresher trainings should be conducted every 6 months by a diagnostician (MD/DNB/Diploma Biochemistry/Pathology/Microbiology/Laboratory medicine) or PhD Biochemistry/Microbiology. Each training should be conducted for 5 days and it should be recorded.

For phlebotomists and transportation staff, refresher trainings should be conducted on a yearly basis. The duration of each training should be 1 full day.

5. Records

The quality and technical records that need to be maintained by each laboratory. The Laboratory Information System should have the provision to store and retrieve these records:

- Staff qualifications, training and competency records
- Request for examination
- Records of receipt of samples (including emergency samples, samples rejected and repeat orders) in the laboratory and samples which are sent to mother laboratories or outsourced to other laboratories.
- Information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts)
- Instrument maintenance records, including internal and external calibration records
- Calibration functions and conversion factors
- Quality control records
- Accident records and action taken, Risk management records
- Nonconformities identified and immediate or corrective action taken
- Preventive actions taken
- Complaints and action taken
- Records of internal and external audits
- Interlaboratory comparisons of examination results
- Records of quality improvement activities

6. Quality assurance

All laboratories should be certified under ISO 9001 within 1 year of rollout.

Effective quality control – IQC and Proficiency testing (EQAS/inter-laboratory comparison programme) should be established

Internal Quality control

The daily QC values should be documented along with the calculation of %CV from the monthly QC data. The laboratory should maintain control charts to demonstrate stability of the analytical measuring systems.

Proficiency testing

The laboratory should participate in External Quality Assessment Scheme (EQAS)/Inter-laboratory comparison as defined in NABL 163.

An ongoing association should be established with agencies such as CMC Vellore, National Institute of Biologicals, AIIMS etc. for EQAS.

QC data

The validation of IQC data should be real-time. The service provider diagnosticians should be responsible for reporting IQC and EQAS data, managing out-of-range IQC and EQAS and guiding corrective and preventive actions.

The laboratories should maintain electronic records for out-of-range IQC and EQAS. The corrective and preventive actions for out-of-range IQC and EQAS should be defined in MIS and records of these actions should be maintained. These records should be submitted to the contracting authority on a quarterly basis.

NABL accreditation and audits

The service provider shall obtain NABL accreditation of all Mother laboratories and the laboratories catering to District hospitals within 2 years of signing of the contract. The bidder shall obtain NABL accreditation of all other laboratories within 3 years of signing of the contract. The laboratories mentioned here are the laboratories of Service provider which shall provide services to the Contracting Authority under this RFP. NABL accreditation shall be obtained for all tests which are listed in the RFP and are conducted by the respective laboratories. The Service provider shall renew the NABL accreditation for all these laboratories for all tests every two years.

The Service Provider shall have third party performance annual audit done by a NABL Accredited laboratory for all its laboratories every year at its own cost. The highlights of internal and external audits shall be shared with the State Authority. The laboratories mentioned here are the laboratories of Service provider which are providing services to the Authority under this contract.

Assuring quality of test results

- Verification of test results : All test results should be verified by qualified MD/Diploma (post MBBS)/DNB post MBBS pathologists/biochemists/microbiologists/laboratory medicine. Hematology and clinical pathology results should be validated by pathologists; biochemistry and immunoassay test results by biochemists/pathologists/laboratory medicine; and serology and microbiology test results by microbiologists.
- The service provider should give clear instructions to the laboratory technicians not to conduct tests on erroneous equipment or when results are erroneous due to unknown causes.
- Till the equipment is rectified or the root cause analysis is carried out for other technical faults, the samples for those tests should be sent to the nearby laboratories of the service provider.
- Nodal officers of the government health facilities should ensure that all events of erroneous results are recorded at health facilities and the report is sent to the contracting authority.
- The contracting authority will keep a close watch on test result values for any significant deviations. Analytical monitoring reports will be assessed by the contracting authority every month.
- The records of repeat orders should be maintained electronically at the service provider's laboratories and monitored for tests which are repeated most frequently.
- The service provider should send 1 percent of samples tested at hub laboratories for testing to the mother laboratories every 6 months for verification of test results of its hub laboratories and submit reports to the state government.

Sample rejection rates

Each event of sample rejection should be recorded electronically and monitored by service providers for sample rejection rates of individual laboratories.

The laboratories should also record the source of rejected samples – facility type, OPD/IPD etc.

E. Supervision and monitoring

- A dashboard should be created and made available in the public domain by the service provider in the initial stages of the rollout. Key performance indicators shall be provided to Service provider by the Contracting authority prior to project implementation
- Monthly review meetings will be conducted by the Contracting Authority, District health officials and State Program Management Unit. They will provide feedback in these meetings on the progress of the initiative. The service provider should present progress on the initiative as well as actions taken on concerns raised in the previous meetings.

Key performance indicators and monitoring indicators for implementing laboratory services in PPP mode

1. Key Performance Indicators (KPIs)

S. No.	KPI	Prescribed limit for penalty	Remarks
1	Percentage of facilities where service provider has started providing full-fledged services for all tests within stipulated time.	Service provider should have started its full-fledged services for all tests in 100 percent of DHs, 90 percent of SDHs and 80 percent of CHCs and PHCs within stipulated time. For remaining facilities, a maximum of one extra year could be provided to the service provider for initiation of services.	
2	Percentage of tests (in per-test model) or patients (in per-patient model) for which turnaround time is within the prescribed limit.	Total turnaround time to be achieved for 100% of tests/ patients.	a. Total TAT = pre-analytical + analytical + post analytical TAT (from time of sample collection till time of receipt of printed report or electronic report (in case printing facility not available at health facility) b. In per-patient model, any test of the patient which exceeds prescribed turnaround time will be counted as exceeded turnaround time for the patient. i. Pre-analytical TAT for routine tests not requiring additional transportation from L2 to mother laboratory: **PHCs, CHCs:** Tests should be received at the testing laboratory within 7 hours of sample collection. **SDHs, DHs:** Tests should be received at the testing laboratory within 2 hours of sample collection. ii. Pre-analytical TAT for advanced tests conducted at mother laboratory: **DHs, SDHs:** 2 hours for Blood Culture, fluid cytology and 20 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required). **CHCs, PHCs:** 10 hours for Blood Culture, fluid cytology and 27 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required).

S. No.	KPI	Prescribed limit for penalty	Remarks
			iii. Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab iv. Analytical TAT (report verification): Test result verification within 1 hour of testing v. Post-analytical TAT: Percentage of test reports (electronic) received at the facility within 1 hour of test result verification. vi. Post analytical TAT: Percentage of reports printed within 1 hour of receipt of electronic reports.
			Total TAT: i + ii + iii + iv + v + vi
			Total TAT for critical test results and emergency samples: i + ii + iii + iv + v + 30 minutes through automated messaging
3	Percentage of working days in a month when each type of test is available at each Government health facility	Unavailability of tests not to exceed a total of more than three working days in a month at each Government health facility	
4	Percentage of working days in a month when sample collection services are available at each Government health facility	Unavailability of sample collection sample collection services not to exceed a total of more than three working days in a month at each Government health facility	
5	Percentage of tests for which service provider participated in EQAS/inter-laboratory comparison and IQC	Service provider to participate in EQAS/inter laboratory proficiency testing and IQC for 100% of tests	
6	Percentage of tests for which EQAS/Interlaboratory comparison and IQC for which appropriate corrective and preventive actions were taken	Appropriate corrective and preventive actions to be taken for 100% of EQAS/ILC and IQC	Appropriateness of corrective and preventive actions to be validated by third party
7	Percentage of tests or samples for which cold chain is adequate	Cold chain to be adequate for atleast 95% of samples	a. One sample implies any one sample of a patient (haematology, Biochemistry, urine, fluid etc.) b. Temperature monitoring device to be used for charting the temperature

S. No.	KPI	Prescribed limit for penalty	Remarks
8	Percentage of district level Quality managers and laboratory technicians at testing laboratories who underwent induction training followed by half-yearly refresher training and competency assessment by MD/DNB/Diploma (post MBBS) or PhD in Biochemistry/Pathology/ Microbiology	At least 95% of district level Quality managers and laboratory technicians at testing laboratories to undergo induction training followed by half-yearly refresher training and competency assessment by MD/DNB/Diploma (post MBBS) or PhD in Biochemistry/Pathology/ Microbiology	
9	Percentage of laboratories of Service provider accredited under NABL for all tests within three years of signing of contract	100% of laboratories of Service provider to be accredited under NABL for all tests within 3 years of signing of contract	

2. Monitoring indicators

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
1	Percentage of public health facilities serviced by the private provider	State	Quarterly	
2	Total number of patients tested	State, district, facility, OPD, IPD, women, children and tribal patients	Monthly	
3	Total number of tests conducted – test-wise	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
4	Patient to test ratio	State, district, facility, OPD, IPD, clinician and intra-speciality comparison	Monthly	
5	Percentage of tests with 1,2,3...n number of tests prescribed	State, district and facility	Monthly	
6	Percentage of government health facilities with zero samples for more than 10% of working days	State, district and facility	Monthly	
7	Percentage and types of tests which are unavailable for a total of more than three working days in a month	State, district and facility	Monthly	
8	Average of frequency and duration of unavailability of sampling services at government health facilities	State, district and facility	Monthly	Services unavailable due to absence of sampling/sample pick-up staff, consumables for sampling not available etc.
9	Percentage of service provider's laboratories with NABL accreditation	State and district	Half-yearly	
10	Percentage of tests accredited under NABL	Laboratory and test-wise	Half-yearly	
11	Percentage of laboratories which underwent third party annual audits by NABL accredited laboratory	State, district and laboratory	Yearly	
12	Percentage of outsourced laboratories which are NABL accredited for the referred tests	State, district and laboratory	Yearly	

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
13	Percentage of laboratories which underwent yearly internal audit	State, district and laboratory	Yearly	
14	Sample rejection rate	State, district, facility, OPD, IPD and laboratory	Monthly	Sample haemolysed, sample clotted, insufficient sample, delay for prothrombin time and labelling error
15	Percentage of tests repeated on request of clinicians	State, district, facility, clinician, OPD, IPD and type of test	Monthly	Re-run/re-sampling requisition form to be filled by the laboratory. For patient identification for repeat testing, unique ID of patients (Aadhaar card/any other ID proof) can be used.
16	Percentage of test results outside the biological reference interval (test-wise)	State, district, facility, clinician, PD, IPD and type of test	Monthly	
17	IQC, EQAS, Interlaboratory comparison and traceability of kits			
a.	Percentage of tests for which i. EQAS ii. IQC iii. Inter lab comparison iv. Traceability of kits was done	State, district, laboratory	Monthly	
b.	Percentage of tests for which i. SDI of EQAS was between 2 to 3 and >3 ii. SDI of Inter lab comparison was between 2 to 3 and >3 iii. IQC Westgard rules (5+1) were violated iv. Traceability of kits failed	State, district, laboratory	Monthly	Records of borderline/ unacceptable SDI scores for EQAS/ ILPT, violated Westgard rules for IQC and failed traceability of kits along with corrective actions for both EQAS (borderline/ unacceptable) and IQC (violated Westgard rules) to be maintained in electronic format.

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
c.	Percentage of out of range EQAS/ ILC and IQC for which corrective actions were taken	State, district, laboratory	Monthly	
d.	Percentage of corrective actions taken which were accurate	State, district, laboratory	Monthly	
18	Percentage of tests verified by MD/DNB/Diploma (post MBBS) pathology/biochemistry/ microbiology	State, district, laboratory and test-wise	Monthly	
19	Percentage of equipment calibrated annually	State, district, laboratory	Yearly	
20	Percentage of equipment which are interfaced - equipment-wise	State, district and laboratory	Half-yearly	
21	Average a. Frequency and b. Duration of equipment downtime (equipment-wise)	State, district and laboratory	Monthly	
22	Training			
a.	Percentage of district level Quality managers and laboratory technicians at testing laboratories undergoing induction training followed by half-yearly refresher training and competency assessment by MD/DNB/ Diploma (post MBBS) or PhD in Biochemistry/Pathology/ Microbiology	State, district and laboratory	Half-yearly	
b.	Percentage of phlebotomists and ILDs undergoing induction training followed by yearly refresher training by district level Quality managers	State, district and laboratory	Half-yearly	
23	Cold chain			
a.	Percentage of tests or samples received at the primary receiving/ testing laboratory for which cold chain was inadequate	State, district, laboratory, separate for PHCs, CHCs, SDHs and DHs	Monthly	i. One sample implies any one sample of a patient (haematology, biochemistry, urine, fluid etc.) ii. Temperature monitoring device to be used for charting the temperature

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
b.	Percentage of tests or samples received by L1 laboratories from L2 laboratories for which cold chain was inadequate	State, district and laboratory	Monthly	Temperature monitoring device to be used for charting the temperature
24	Quality of processes			
a.	Percentage of urine cultures plated within 4 hours of sample collection	State, district and laboratory	Monthly	Plating to be done at the primary receiving laboratory
b.	Percentage of peripheral smears prepared at the time of sample collection	State, district and laboratory	Monthly	Two blood smears to be prepared – first by the phlebotomist at the time of sample collection and second at the primary receiving laboratory
c.	Percentage of fluids for which TLC and DLC was done, and stained smear was prepared within 4 hours of sample collection	State, district and laboratory	Monthly	TLC and DLC to be done at the primary receiving laboratory
d.	Percentage of blood culture samples tested on automated blood culture system	State, district and laboratory	Monthly	
25	Percentage of tests or samples (patients) for which turnaround time is within the prescribed limit	State, district, facility, OPD, IPD and type of test	Monthly	Total TAT: From time of sample collection till time of receipt of printed report or electronic report (in case printing facility not available at health facility). For critical test results: Time from sample collection to receipt of report at the health facility through automated messaging In per-patient model, any test of the patient which exceeds prescribed

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
				turnaround time will be counted as exceeded turnaround time for the patient
a. Total TAT* = pre-analytical + analytical + post analytical TAT				
i.	Pre-analytical TAT for routine tests not requiring additional transportation from L2 to L1 laboratory: PHCs, CHCs: Tests should be received at the testing laboratory within 7 hours of sample collection. SDHs, DHs: Tests should be received at the testing laboratory within 2 hours of sample collection.			
ii.	Pre-analytical TAT for advanced tests conducted at mother laboratory: DHs, SDHs: 2 hours for Blood Culture, fluid cytology and 20 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required). CHCs, PHCs: 10 hours for Blood Culture, fluid cytology and 27 hours for histology, FNAC, TSH, electrophoresis (if transportation to a different district is required).			
iii.	Analytical TAT (testing): Tests conducted within stipulated time from time of receipt of sample at the testing lab			Turnaround time for testing listed in Annexure J (Section Prescribed turnaround time)
iv.	Analytical TAT (test result verification): Test results verification within 1 hour of testing			
v.	Post-analytical TAT: Percentage of test reports (electronic) received at the facility within 1 hour of report verification.			
vi.	Post analytical TAT: Percentage of reports printed within 1 hour of receipt of electronic reports.			
Total TAT: i + ii + iii + iv + v + vi				

S. No.	Monitoring indicator	Level of data analysis	Frequency of monitoring	Remarks
	TAT for critical results: i + ii + iii + iv + v + 30 minutes through automated messaging			
	Percentage of test reports received through automated messaging at the government health facilities within stipulated TAT from time of sample collection			
b.	Printed report dispatch: In case, printing service is unavailable at PHCs, CHCs, then percentage of printed reports received at PHCs and CHCs by 9 am next working day of sample collection (for tests with analytical time upto 8 hours). For tests with analytical time of more than 8 hours, the percentage of printed reports that are received at the health facility by 9 am on the next day of validation of test reports (as per the stipulated analytical time).For SDHs and DHs the printing facility should essentially be available at the health facility.	State, district, facility (PHC/CHC), OPD, IPD and type of test		
26	Grievance redressal			
a.	Number of complaints from patients and health care staff at government health facilities and other government officials	State, district and facility	Monthly	
b.	Percentage of complaints (from patients/clinicians/for which corrective action taken within 7 days of receiving the complaints	State, district and facility	Monthly	
27	Percentage of patients satisfied with laboratory services, including any fee charged by the service provider for laboratory services	State, district and facility	Yearly	To be monitored by the government
28	Payments			
a.	Percentage of incomplete monthly payments to service provider	State	Yearly	
b.	Percentage of monthly payments to service provider delayed by more than one week	State	Yearly	
c.	Percentage of amount deducted from invoice payment as penalties	State	Monthly	

Data of patients availing laboratory services should to be captured electronically by the service provider at the point of sample collection for seamless flow and data integration. Also, the time of sample collection should be recorded to track the pre-analytical turnaround time. The service provider should inform the health facilities about absence or late arrival of the phlebotomist(s). The service provider could also track availability of its phlebotomists if phone numbers of the government health facilities are made available to the service provider.

SERVICE LEVEL AGREEMENT

For Laboratory Services under
FREE DIAGNOSTIC INITIATIVE
Under National Health Mission
Department of Health and Family Welfare

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SERVICE LEVEL AGREEMENT

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SERVICE LEVEL AGREEMENT BETWEEN

CONTRACTING AUTHORITY

.....

AND

SERVICE PROVIDER

.....

TO PROVIDE LABORATORY SERVICES UNDER FREE DIAGNOSTICS SERVICE INITIATIVE

UNDER

NATIONAL HEALTH MISSION

SERVICE LEVEL AGREEMENT

DECLARATION BY SERVICE PROVIDER

1. BACKGROUND

To address the need for accessible and quality diagnostics in public health facilities, the Contracting Authority under the aegis of National Health Mission launched the Free Diagnostics Initiative. The Free Diagnostics Initiative is intended to provide a set of essential diagnostics at all levels of healthcare facilities so that health care providers can make rational decisions regarding treatment and patients can benefit by getting their tests conducted within the Government health facilities free of cost.

<NAME OF THE CONTRACTING AUTHORITY > DESIROUS of utilizing the services relating to Laboratory tests under Free Diagnostic Scheme in <name of the identified region/Unit> had invited tenders from eligible bidders vide TE No _____ dated _____. <Name of the Service Provider> having submitted his bid in response to the tender enquiry and having been found technically qualified as per the conditions in the same TE, has been awarded the contract by the competent authority in the <Contracting AUTHORITY>. <Name of the Service Provider> has also performed required obligations after the award of contract was communicated to him.

This AGREEMENT (hereinafter called the "Contract" or "Agreement") is made on the <insert date>, between:

<insert name and address of the Tender Inviting Authority> (hereinafter referred to as the **"Contracting Authority"** which expression will, unless repugnant to the context or meaning thereof, include its administrators, successors and assigns) of the **first part**;

And

M/s <insert name of the selected bidder> represented by its <insert name and designation> –, a Company incorporated under the provisions of the Companies Act, 1956 (No. 1 of 1956) and having its registered of office at <insert name and address of the company>**,** (hereinafter referred to as the **"Service Provider"** which expression will, unless repugnant to the context or meaning thereof, include its successors and permitted assigns and substitutes) of the **second part**.

WHEREAS

a. The Contracting Authority has requested the Service Provider to provide certain Services and deliverables as defined in the Scope of Work in the RFP (hereinafter called the "Services");

b. The Service Provider, having represented to the contracting authority that Service provider has agreed to provide the Services on the terms and conditions set forth in this Contract.

   Service provider has agreed to Financial Bid/Quote accepted by the Tender Inviting Authority = INR

NOW THEREFORE the Parties hereby agree as follows:

1. The following documents will be deemed to form and be read and construed as part of this Contract/ Agreement, this agreement sets schedules and the priority of the documents will be as follows:

   a. The Letter of Acceptance;

   b. The Service Provider's Bid with activity schedules;

   c. The RFP with all the stipulated conditions with corrigendum;

   d. The Specifications/Scope of Work/Terms of Reference etc. amended if any;

   e. The Price Bid/Financial Bid.

2. The mutual rights and obligations of the Tender Inviting Authority (TIA) and the Service Provider will be as set forth in the Contract, in particular:

   a. The Service Provider will carry out the Services in accordance with the provisions of the Contract; and

   b. The Tender Inviting Authority (TIA) will make payments to the Service Provider in accordance with the provisions of the Contract.

2. SERVICE AIMS

The patients visiting Government health facilities and prescribed laboratory tests at these facilities should receive requisite high-quality laboratory services at the Government health facility itself. The services should be free-of-cost for these patients. The laboratory tests should enable timely and accurate diagnosis and management of these patients. The objective of this Agreement is to ensure that the service provider provides laboratory services in the designated Government health facilities in the assigned districts listed in the RFP with all the stipulated conditions with corrigendum vide TE No _____ dated _____. (Name of the State). The Services will be as per the terms and conditions mentioned in the RFP. Under this Agreement, the service provider is liable to provide the laboratory services only to the patients who are prescribed tests at the Government health facilities. The Service Provider will not charge these patients or their attendants any fee for these services. The Contracting Authority shall be responsible to pay the fee for these services to the Service Provider.

3. SERVICE DESCRIPTIONS AND RESPONSIBILITIES

The Service descriptions and responsibilities will be the same as mentioned in the scope of services of RFP with all the stipulated conditions with corrigendum vide TE No _____ dated _____.

4. INFORMATION AND REPORTING REQUIREMENTS

All Information and Reporting Requirements will be the same as mentioned in RFP with all the stipulated conditions with corrigendum; vide TE No _____ dated _____.

5. PERFORMANCE

All performance criteria including turnaround time etc. will be the same as mentioned in RFP with all the stipulated conditions with corrigendum; vide TE No _____ dated _____.

6. DATA PROTECTION, CONFIDENTIALITY AND RECORD KEEPING

All details regarding data requirement etc. will be the same as mentioned in RFP with all the stipulated conditions with corrigendum; vide TE No _____ dated _____.

7. STAFFING

All staffing requirements will be the same as mentioned in RFP with all the stipulated conditions with corrigendum; vide TE No _____ dated _____.

8. PERFORMANCE SECURITY

The successful bidder shall furnish a performance security in the shape of a Bank Guarantee/FDR issued by a Scheduled bank in favor of Tender Inviting Authority for an amount as per the following formula of the total estimated contract value of 5 years. The performance security shall be as per proforma at **"Annexure G"** and remain valid for a period, which is six months beyond the date of expiry of the contract. This shall be submitted within 15 days (minimum) of receiving of Notice for Award of Contract, failing which the EMD may be forfeited and the notice is deemed to be withdrawn.

(*Formula: 5% of (Estimated number of tests of parameter 1 in one year multiplied by agreed per test rate of the parameter 1) + ...(Estimated number of tests of parameter n in one year multiplied by agreed per test rate of the parameter n) multiplied by total number of years of the contract duration will be for a period of 5 year & 6 months)

If the firm/contractor violate any of the terms and conditions of contract, the Performance Security shall be liable for forfeiture, wholly or partly, as decided by the Tender Inviting Authority (TIA) and the contract may also be cancelled.

The Tender Inviting Authority (TIA) will release the Performance Security without any interest to the firm/contractor on successful completion of contractual obligations.

9. VARIATIONS

11.1 This Service Level Agreement may not be varied unless a variation is agreed in writing and signed by all parties.

10. DISPUTES

The agreement shall be governed by and interpreted in accordance with the laws of India for the time being in force. The Court located at the place of issue of agreement shall have jurisdiction to decide any dispute arising out of in respect of the agreement. It is specifically agreed that no other Court shall have jurisdiction in the matter.

Both parties agree to make their best efforts to resolve any dispute between them by mutual consultations.

11. ARBITRATION

If the parties fail to resolve their dispute or difference by such mutual consultations within thirty days of commencement of consultations, then either the Service procuring agency or the Service provider may give notice to the other party of its intention to commence arbitration, as hereinafter provided. The applicable arbitration procedure will be as per the Arbitration and Conciliation Act 1996 of India.

In that event, the dispute or difference shall be referred to the sole arbitration of an officer as the arbitrator to be appointed by the <Name of the Contracting Authority>. If the arbitrator to whom the matter is initially referred is transferred or vacates his office or is unable to act for any reason, he/she shall be replaced by another person appointed by <Name of the Contracting Authority> to act as Arbitrator.

Work under the contract shall, notwithstanding the existence of any such dispute or difference, continue during arbitration proceedings and no payment due or payable by the Purchaser or the firm/contractor shall be withheld on account of such proceedings unless such payments are the direct subject of the arbitration.

Reference to arbitration shall be a condition precedent to any other action at law.

Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

12. TERMINATION

Either party may terminate this Agreement by giving not less than 3 months' notice in writing to the other. This notice shall include reasons as to why the Agreement is proposed to be terminated.

The contracting authority may terminate the Agreement, or terminate the provision of any part of the Services, by written notice to the Service provider with immediate effect if the Service Provider is in default of any obligation under the Agreement, where the default is capable of remedy and the Service Provider has not remedied the default to the satisfaction of the Contracting authority within 30 days of at least two written advice, or such other period as may be specified by the contracting authority after service of written notice specifying the default and requiring it to be remedied; or the default is not capable of remedy; or the default is a fundamental breach of the Agreement.

If the contracting authority terminates the agreement and then makes other arrangements for the provision of the Services, it shall be entitled to recover from the Service provider any loss that had to be incurred due to such sudden termination of agreement.

Both the parties agree that no further payment would be made to the Service provider, even if due till settlement of anticipated loss as a result of premature termination of the contract.

The contracting authority reserves the right to terminate the agreement without assigning any reason if services create serious adverse publicity in media and prima facie evidence emerge showing negligence of the Service provider.

The agreement with the Service Provider concerned may be treated as default services on any of the following grounds and will be treated as such:

i. There is a delay by the Service provider in roll out of full fledged services mentioned in the scope of services in the RFP to all assigned Government health facilities through laboratories of Service provider and through the empanelled laboratories. The maximum permissible delay will be one and a half years from the time of signing of Agreement beyond which the Contracting Authority will terminate the Agreement with the Service provider.. Any delay caused due to inability of the State Government to provide the designated support (as mentioned in the RFP) will not be considered as default by the Service provider.

ii. The Service Provider refuses services or is unable to provide services mentioned in the scope of services in the RFP/Agreement through its own laboratories for more than 10 consecutive working days for any test at any health facility. Any refusal or inability of provision of services by the Service provider which is caused due to inability of the State Government to provide the designated support (as mentioned in the RFP) will not be considered as default by the Service provider.

iii. The Service provider fails to follow Standard Operating Procedure (SOP) which adversely affect the quality, access or utilization of assigned laboratory services mentioned in the scope of services in the RFP/Agreement. If the Service provider is unable to follow the SoPs due to inability of the State Government to provide the designated support (as mentioned in the RFP), then it will not be considered as default by the Service provider.

iv. The service provider overcharges on the specified charges mentioned herein to the Contracting Authority for provision of laboratory services mentioned in the scope of services in the RFP/Agreement.

v. The Service provider over bills the Contracting Authority by inflating the number of patients/ samples/tests serviced by the Service Provider under the Agreement

vi. The Service provider is notcompliant to statutory requirements

vii. The Service provider is charged with Criminal indictment.

viii. The Service provider engages unqualified technical resource persons for providing services under the Agreement.

ix. The Service provider fails to get all laboratories NABL accredited for all designated tests within 3 years of signing of Contract. If the Service provider is unable to receive the NABL accreditation due to inability of the State Government to provide the designated support (as mentioned in the RFP), then it will not be considered as default by the Service provider.

13. INDEMNITY

By this agreement, the Service provider indemnifies the contracting authority against damages of any kind or for any mishap/injury/accident caused to any personnel/property of the Service provider while performing duty.

The Service provider agrees that all liabilities, legal or monetary, arising in any eventuality shall be borne by the Service provider.

14. FORCE MAJEURE

As used in this Agreement, the expression “Force Majeure” or “Force Majeure Event” shall mean occurrence in India of any or all of Non-Political Event, Indirect Political Event and Political Event, as defined in the Clauses mentioned below, if it affects the performance by the Party claiming the benefit of Force Majeure (the “Affected Party”) of its obligations under this Agreement and which act or event (i) is beyond the reasonable control of the Affected Party, and (ii) the Affected Party could not have prevented or overcome by exercise of due diligence and following Good Industry Practice, and (iii) has Material Adverse Effect on the Affected Party.

Non-Political Event

A Non-Political Event shall mean one or more of the following acts or events:

a. Act of God, epidemic, extremely adverse weather conditions, lightning, earthquake, landslide, cyclone, flood, volcanic eruption, chemical or radioactive contamination or ionizing radiation, fire or explosion (to the extent of contamination or radiation);

b. Strikes or boycotts or arson or theft (other than those involving the Service Provider or their respective Personnel/representatives, or attributable to any act or omission of any of them) interrupting the maintenance services for a continuous period of 24 (twenty-four) hours and an aggregate period exceeding 7 (seven) days in an Accounting Year, and not being an Indirect Political Event set forth in appropriate Clause.

c. Any failure or delay of a Service Provider but only to the extent caused by another Non-Political Event and which does not result in any offsetting compensation being payable to the Service Provider by or on behalf of such Service Provider;

d. Any judgement or order of any court of competent jurisdiction or statutory Authority made against the Service Provider in any proceedings for reasons other than (i) failure of the Service

Provider to comply with any Applicable Law or Applicable Permit, or (ii) on account of breach of any Applicable Law or Applicable Permit or of any contract, or (iii) enforcement of this Agreement, or (iv) exercise of any of its rights under this Agreement by the Authority;

e. Any failure unforeseeable by the Service Provider on account of unavoidable breach of cyber security; and

f. Any event or circumstances of a nature analogous to any of the foregoing.

Indirect Political Event

An Indirect Political Event shall mean one or more of the following acts or events:

a. An act of war (whether declared or undeclared), invasion, armed conflict or act of foreign enemy, blockade, embargo, riot, insurrection, terrorist or military action, civil commotion or politically motivated sabotage;

b. industry-wide or State-wide strikes or industrial action for a continuous period of 24 (twenty-four) hours and exceeding an aggregate period of 7 (seven) days in an Accounting Year;

c. Any failure or delay of a Service Provider to the extent caused by any Indirect Political Event and which does not result in any offsetting compensation being payable to the Service Provider by or on behalf of such Service Provider;

d. Any Indirect Political Event that causes a Non-Political Event; or

e. Any event or circumstances of a nature analogous to any of the foregoing.

Political Event

A Political Event shall mean one or more of the following acts or events by or on account of any Government Instrumentality:

a. Compulsory acquisition in national interest or expropriation of rights of the Service Provider;

b. Unlawful or unauthorized or without jurisdiction revocation of, or refusal to renew or grant without valid cause, any clearance, license, permit, authorization, no objection certificate, consent, approval or exemption required by the Service Provider to perform its obligations under this Agreement; provided that such delay, modification, denial, refusal or revocation did not result from the Service Provider's inability or failure to comply with any condition relating to grant, maintenance or renewal of such clearance, license, authorization, no objection certificate, exemption, consent, approval or permit;

c. Any failure or delay on part of a third party but only to the extent caused by another Political Event and which does not result in any offsetting compensation being payable to the Service Provider by or on behalf of such third party; or

d. Any event or circumstance of a nature analogous to any of the foregoing.

Duty to Report Force Majeure Event

Upon occurrence of a Force Majeure Event, the Affected Party shall by notice report such occurrence to the other Party forthwith. Any notice pursuant hereto shall include full particulars of:

a. The nature and extent of each Force Majeure Event which is the subject of any claim for relief with evidence in support thereof;

b. The estimated duration and the effect or probable effect which such Force Majeure Event is having or will have on the Affected Party's performance of its obligations under this Agreement;

c. The measures which the Affected Party is taking or proposes to take for alleviating the impact of such Force Majeure Event; and

d. Any other information relevant to the Affected Party's claim.

The Affected Party shall not be entitled to any relief for or in respect of a Force Majeure Event unless it shall have notified the other Party of the occurrence of the Force Majeure Event as soon as reasonably practicable, and in any event not later than 7 (seven) days after the Affected Party knew, or ought reasonably to have known, of its occurrence, and shall have given particulars of the probable material effect that the Force Majeure Event is likely to have on the performance of its obligations under this Agreement.

For so long as the Affected Party continues to claim to be materially affected by such Force Majeure Event, it shall provide the other Party with regular (and not less than weekly) reports containing information as required by the Authority, and such other information as the other Party may reasonably request the Affected Party to provide.

Effect of Force Majeure Event on the Agreement Upon the occurrence of any Force Majeure Event prior to the Appointed Date, the Conditions Precedent period as set forth in Article 4 shall be extended by a period equal in length to the duration of the Force Majeure Event.

At any time after the Appointed Date, if any Force Majeure Event occurs whereupon the Service Provider is unable to provide the Services during the period for which Force Majeure exists, no Service Fee shall be paid by the Authority to the Service Provider for those days. However, the Service Provider shall not be liable to pay any damages to the Authority in case it is unable to provide the diagnostic lab Services on account of any Force Majeure Event.

Allocation of costs arising out of Force Majeure Upon occurrence of any Force Majeure Event prior to the Completion Date and during the License Period, the Parties shall bear their respective costs and no Party shall be required to pay to the other Party any costs thereof.

Save and except as expressly provided in this Article 10, neither Party shall be liable in any manner whatsoever to the other Party in respect of any loss, damage, cost, expense, claims, demands and proceedings relating to or arising out of occurrence or existence of any Force Majeure Event or exercise of any right pursuant hereto.

15. PAYMENT AND PENALTIES

The consideration provided in this Agreement will be the full and comprehensive consideration for all the services to be performed and the obligations undertaken by the Service Provider under this Agreement.

Payment

Service Provider will submit the invoice by the 7th day of every month for the laboratory services (under the scope of services in RFP/Agreement) provided in the previous month to the Contracting Authority.

The payment will be made on per test basis and only for those tests performed by the Service Provider for which test reports have been released by the Service Provider to the respective Government health

facilities. **The price of each test parameter will be as quoted by the Service provider in its Financial bid. For calculation of monthly payments to be made to the Service provider, the number of each of test parameters reported in the previous month will be multiplied by the price of the respective test parameter.**

The invoice should contain details of Government health facilities, names of prescribing doctor, demographics of patients, names of tests, test results. All the reports included in the invoices need to be certified/verified by the Nodal officers of respective Government health facilities (Chief Medical Superintendent/MO or equivalent of the hospital concerned). In his absence, the Medical Superintendent or any Medical Officer as assigned by the Superintendent may sign the documents.

Along with this, the service provider is bound to submit complete data on all KPIs to the Authority at the prescribed time intervals for deduction of any penalties.

The data on monitoring indicators also needs to be submitted on prescribed time intervals. In case the service provider fails to submit the complete data on monitoring indicators, the Authority will levy penalty on the service provider.

Penalties will be levied on the service provider from the beginning of the roll out of services for not meeting mutually agreed clauses mentioned in the Agreement including KPIs.

In the event that Authority identifies any error or mistake in the invoices or need clarity on any item in the invoice, a notice will be issued to the Service Provider for rectification/clarification within 15 days of receipt of the invoice. This rectification/clarification process will not take time of more than 7 days.

All the reports need to be certified/verified by the Nodal officers who will be Chief Medical Superintendent/ MO or equivalent of the hospital concerned. In his absence, the Medical Superintendent or any Medical Officer as assigned by the Superintendent may sign the documents.

Within 30 days of the receipt of the invoice, the Authority will release 90% of the payment. For Balance 10% payment, based on the analysis of the reports and damages and penalties calculated in accordance with the provisions provided in bidding documents, the Authority will release the net payment (net of any liquidated damages) within 45 days of the receipt of the invoice.

Penalties

Penalty on the following points will be imposed on the service provider by the Tender inviting Authority:

1. If there is a delay in Implementation of laboratory services as per the timelines defined in the RFP (6 months after signing of Agreement) . Service provider should have started its full-fledged services in 100 percent of assigned facilities (for DHs), 90 percent of assigned facilities (for SDHs) and 80 percent of assigned facilities (for CHCs and PHCs) for all designated tests within 6 months of signing the Agreement (as stipulated in RFP). Beyond 6 months, The Authority will penalise the Service Provider an amount of INR 1,00,000 (One lakh rupees) per month per DH for delays in rolling out full fledged services (where all tests have not been rolled out), Rs 25000 per month for each SDH and CHC and PHC. A maximum of one extra year could be provided to the service provider for initiation of services in the remaining 10 percent of SDHs and 20 percent of CHCs and PHCs without penalties levied for delay in rolling out full fledged services in these facilities. After one extra year over and above the prescribed limit of 6 months, the Contracting Authority will terminate the Agreement with the Service provider. This clause shall not include those facilities where services could not be started by the Service provider because of lack of support from State Government, same shall be duly signed by the Government.

2. Quality Assurance:

    a. The test for which EQAS or interlaboratory comparison is not carried out, a Penalty of Rs 10,000 per month for that test will be levied to each laboratory of service provider which is not getting the EQAS or interlaboratory comparison done.

    b. If deviation of EQAS or interlaboratory comparison is more than 3 SD for 3 times consecutively, then Rs 10,000 per test for that test will be levied to each of the laboratories.

3. Turn around time: For levying penalty on unmet turnaround time in per-test payment model, 50% amount should be deducted for tests that did not meet the prescribed turnaround time, when the percentage of tests not meeting turnaround time is more than 5% of total tests. If percentage of tests not meeting turnaround time is less than 5% of total tests, then 25% amount should be deducted for these tests. In per-patient payment model, the delay in turnaround time for even a single test of a patient should be counted as delayed turnaround time for the patient. If the turnaround time is delayed for more than 25% of patients, 50% amount should be deducted for all patients whose tests did not meet the prescribed turnaround time. For critical tests (Fluids, Troponin, Culture, CRP, Platelet count, Bilirubin and other tests decided by the State), 100% amount should be deducted for all patients whose tests did not meet the prescribed turnaround time. For non critical tests, if percentage of patients is less than 5% (in one month) from his invoice, then 25% amount should be deducted for all patients whose tests did not meet the prescribed turnaround time.

4. When there is breakdown of services which extends for more than 1 working day, the Service provider shall make alternative arrangements for testing and reporting all the cases within 1 day of breakdown of services, without any additional charges to the TIA. The alternative arrangement should not stretch beyond more than 10 days and the service provider should resume testing in its own laboratories within 10 days of breakdown of services. When there is breakdown of services which extends for more than 1 working day, the Service provider shall make alternative arrangements for testing and reporting all the cases within 1 day of breakdown of services, without any additional charges to the TIA. The alternative arrangement should not stretch beyond more than 10 days and the service provider should resume testing in its own laboratories within 10 days of breakdown of services.

    a. If sampling services unavailability exceeds a total of 3 working days in a month, at any facility then penalty of Rs 10,000 per month will be levied to the service provider for that facility for that month.

    b. If any test is not available for a total of 3 working days in a month at any facility, penaltywill be deducted.

5. If cold chain is damaged for more than 5 percent of samples, then a penalty of Rs 20 per sample will be levied.

6. NABL accreditation: 100% of laboratories of service provider should be accredited under NABL for all tests within 3 years of signing of contract. For each laboratory which is not NABL accredited after 3 years of signing the **Agreement, a penalty of Rs 1 lakh per year will be levied on the service provider** Non-complinace to the terms and condition defined in the RFP

16. PERIOD OF AGREEMENT

Five years, extendable by same terms and conditions subject to satisfactory services.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be signed in their respective names as of the day and year first above written.

For and on behalf of [Mission Director, Tender Inviting Authority (TIA), NHM, Name of the State]	For and on behalf of M/s Laboratory Service Provider
..... Tender Inviting Authority (TIA)	..... Director
Witness 1..... 2.....	Witness 1..... 2.....

Note

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Ministry of Health & Family Welfare
Government of India