National Essential Diagnostics List

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FOREWORD

Access to affordable, appropriate and good quality health care is the basic right of all citizens. India is now aiming for universal health coverage which effectively means strengthening health systems by making available good quality care including the diagnostics available at public health facilities. Build-up of an appropriate diagnostics system will ensure healthy lives, help in maximizing the impact of the essential medicines list and eventually for achieving the goal of providing universal healthcare.

Recognizing the fact that availability of high quality diagnostics in health care system is crucial for imparting good quality health services, Indian Council of Medical Research (ICMR) has developed the National Essential Diagnostic List (NEDL). Following the release of first edition of EDL by WHO in May, 2018, India is the first country to launch the National EDL (NEDL).

The NEDL builds upon the Free Diagnostics Service Initiative and other diagnostics initiatives of MoHFW. The list has been developed for all levels of health care – village level, Sub-centre/Heath & Wellness Centres (HWs), Primary Health Centres (PHC)/HWs, Community Health Centres (CHC), Sub-District Hospital (SDH), and District Hospital (DH). Tests for each level of care have been proposed based on the utility and requirement of test at that level and the availability of infrastructure and manpower. NEDL consists of general laboratory tests required for routine patient care and for diagnosis of a wide array of both communicable and non communicable diseases. In absence of suitable capacities, 'hub and spoke model' has been suggested for implementing certain testes in the NEDL. This will ensure availability of the required number of tests at different levels of facilities in a cost-efficient way.

I applaud the diligent efforts of all the programs and technical experts who gave us their unstinted support during the consultation meetings. I gratefully acknowledge the valuable engagement of all the experts who have contributed to the compilation of NEDL document as well as those who reviewed it.

It is hoped that NEDL would significantly strengthen easy access of safe, effective and affordable good quality diagnostics to reduce both direct costs, out of pocket expenditure on health and improve patient outcomes.

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List of acronyms

BIS	Bureau of Indian Standards
CBC	Complete Blood Count
CDSCO	Central Drugs Standard Control Organization
CHC	Community Health Centre
CMDTL	Central Medical Device Testing Laboratory
COA	Certificate Of Analysis
CRP	C-Reactive Protein
DHs	District Hospitals
EDL	Essential Diagnostics List
ELISA	Enzyme-Linked Immunosorbent Assay
EML	Essential Medicine List
EQA	External Quality Assessment
FAQ	Frequently Asked Questions
FDI	Free Diagnostics Service Initiative
FTS	Filaria Test Strip
GHTF	Global Harmonization Task Force on Medical Devices
HWCs	Health and Wellness Centres
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Programme
IEC	Information Education Communication
IEC	International Electro Technical Commission
IFU	Instructions for Use
IMDRF	International Medical Device Regulators Forum
IPHS	Indian Public Health Standards
ISO	International Organization for Standardization
IVD	In Vitro Diagnostics
LIMS	Laboratory Information Management Systems
LMICs	Low Middle Income Countries
MDR	Medical Device Rules
MDAE	Medical Device Adverse Event
MDMC	Medical Device Monitoring Centres
MoHFW	Ministry of Health and Family Welfare

NABL	National Accreditation Board for Testing and Calibration Laboratories
NACO	National AIDS Control Organization
NCDs	Non-Communicable Diseases
NEDL	National Essential Diagnostics List
NHM	National Health Mission
NHSRC	National Health System Resource Centre
NIB	The National Institute of Biologicals
NPN	Negative Predictive Number
NRHM	National Rural Health Mission
NRL	National Reference Laboratory
NVBDCP	National Vector Borne Disease Control Programme
PER	Performance Evaluation Report
PPN	Positive Predictive Number
PHC	Primary Health Centre
QC	Quality Control
QMS	Quality Management System
RDT	Rapid Diagnostic Test
RNTCP	Revised National Tuberculosis Control Program
SC	Sub-Centre
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology
SDG	Sustainable Development Goal
SDHs	Sub-District Hospitals
UHC	Universal Health Coverage
WHO	World Health Organization

I. Background

Diagnostics serve a key role in improving health and quality of life. Equitable accessibility, affordability and appropriate use of good quality diagnostics are integral to high quality health care. Accurate diagnostics are indispensable for effective management of diseases, leading to better patient care and clinical outcomes, increase affordability by reducing overall therapy cost and also reduce antimicrobial resistance. Availability of quality assured diagnostics would also be helpful in optimal utilization of Essential Medicine List (EML). India has had EML for more than 40 years; however the same importance was not given to diagnostics. The Sustainable Development Goal (SDG) 3.8 sets the following target for 2030: achieve universal health coverage (UHC), including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all. India is now aiming for UHC which essentially means removing barriers to seeking and receiving needed care like reducing out-of-pocket expenditures, distance to health care facility, and underequipped facilities with poorly skilled health workers. Improving access to diagnostic tests has to be a key component of this initiative. There is, thus, an urgent need of an Essential diagnostics list (EDL) in India to complement the essential medicines ensuring healthy lives and eventually for achieving the goal of providing universal healthcare.

Appreciating the urgent need to improve the availability of accessible and quality diagnostics in public health facilities, the Ministry of Health and Family Welfare (MoHFW), Government of India under the aegis of National Health Mission (NHM) launched the Free Diagnostics Service Initiative (FDI) in July 2015. Under this initiative, the NHM is supporting all states to provide essential diagnostics – laboratory and radiology at their public health facilities, free of cost. In addition, National Rural Health Mission (NRHM) was launched to strengthen Rural Public Health System. Under NRHM, Indian Public Health Standards (IPHS) provides optimal specialized care to the community and achieve and maintain an acceptable standard of quality of care. All these documents have been revised recently to fall in line with the futuristic vision of the quality health care delivery in the country.

WHO released first edition of essential diagnostics list (EDL) in May, 2018. Even though WHO EDL act as a reference point for development of national EDL, India's diagnostics list has been customized and prepared as per landscape of India's health care priorities. The National Essential Diagnostics List (NEDL) builds upon the Free Diagnostics Service Initiative and other diagnostics initiatives of MoHFW [IPHS, Health and Wellness Centres (HWCs) etc] to provide an expanded basket of tests at different levels of the public health system. Implementation of NEDL will enable improved health care delivery through evidence-based care, improved patient outcomes and reduction in out-of-pocket expenditure; effective utilization of public health facilities; effective assessment of disease burden, disease trends, surveillance, and outbreak identification; and address antimicrobial resistance crisis. The accessibility of quality diagnostics leads to deliver not only comprehensive care but also improve rationality of

care. EDL will also enable standardization of technology/diagnostic services and will aid in promotion of R&D for new appropriate and effective diagnostics which in turn will lead to reduction in costs. It will also foster improved regulation in procurement, strengthened capacity of laboratories including their accreditation, establishment of nation-wide quality control systems etc. EDL will complement the national EML which has been successful in facilitating access to treatment and promoting affordable drug prices. Indian Council of Medical research (ICMR) has developed a framework of the first-ever standardized treatment workflows for over 100 diseases. The treatment workflows will provide guidance to clinicians on best way to treat a patient for a specific disease and provide secondary and tertiary care hospitalization services that fit in perspective of newly-launched Pradhan Mantri Jan Aarogya Yojana. This novel realistic and practical approach by ICMR can provide a framework to enhance the management and monitoring of disease through accurate and prompt diagnosis.

In absence of a stringent regulatory process for diagnostics in the past, various substandard poor quality diagnostics made their way into the Indian market. While affordability of diagnostics is a prime concern in low middle income countries (LMICs) like India, low cost, inaccurate diagnostics have no place in the quality health care system. Central Drugs Standard Control Organization (CDSCO), MOHFW has recently released a Medical Device Rules (MDR), 2017 to strengthen national regulatory capacity for diagnostics. A stringent national pre qualification specifications and processes are necessary to ensure availability of safe, effective, affordable tests of good quality as well as improving access to new diagnostics in resource –constrained settings.

II. The National EDL

1. Guiding principles

a. EDL as an opportunity to build over existing initiatives: MoHFW has formulated guidelines for strengthening diagnostic services in the country as part of FDI, IPHS, and National Health Programmes. EDL provides an expanded range of tests and complements these guidelines. Existing tests (In Vitro Diagnostics (IVD), radiology and others) have been reviewed and available basket of tests expanded based on inputs from experts. EDL has been developed for all levels of health care – village level, primary, secondary and tertiary care. Tests for each level of care have been proposed based on the utility and requirement of test at that level, infrastructure, training available or proposed to be made available through other initiatives.

b. The list also encompasses tests relevant for new programmes such as Health and Wellness Centres (HWCs) under Pradhan Mantri Jan Arogya Yojana. In addition to tests, corresponding IVD products have also been recommended.

c. Criteria for inclusion of tests in the EDL: Following criteria have been used for including tests in the EDL:

- Conditions with high disease burden/high public health relevance where diagnostics have a clear impact on the diagnosis and management of a disease:
  -Diseases with existing national programmes for diagnosis and management – maternal health complications, HIV, Tuberculosis, Malaria etc.
  -For priority conditions with weaker support programmes: NPCDCS (Diabetes, Hypertension, Cancers, Chronic kidney disease etc.)
- Tests that enable safe and rational use of EML medicines – For instance in case of HIV/AIDS - diagnosing the condition for which the medicine is indicated (Rapid card, ELISA, etc.), monitoring for medication efficacy (CD4 count, HIV RNA load assays), and monitoring for medication toxicity (Liver function tests).
- Conditions prone to outbreaks/epidemics (Dengue)
- Tests encompassing care pathways of diseases/conditions.
- Tests which are not mainstay of diagnosis but are critical supporting tests such as complete blood count (CBC) and C-reactive protein (CRP).

d. Lessons from developing the National EML: Best practices from process of development of the national EML have been used as guidance for developing the EDL.

2. Process of developing the National EDL(NEDL)

NEDL has been compiled and collated through a consultative process with all the stake holders (Figure 1). Two national consultations were organised with policy makers, clinicians, microbiologists, representatives from national health programmes and manufacturers & innovators**.** First consultation to discuss the EDL approach in India was jointly organized by ICMR and WHO in collaboration with Ministry of Health and Family Welfare on March 12, 2018. The second consultation held on August 20, 2018 focused on what additional tests are required in India with respect to Global WHO EDL; how the national EDL can be harmonized with other initiatives like Pradhan Mantri Jan Arogya Yojana, NHPS, IPHS and FDI; quality benchmarks/ standards for diagnostics in India; regulatory pathway for approval of new diagnostics; and industry and innovators' perspective on EDL. The consultations were attended by various stakeholders such as policymakers, clinicians, diagnosticians, manufacturers & innovators, and representatives from national health programmes.

National Consultation Meetings
The first consultation meet with nearly 50 stakeholders was held on March 12, 2018 at The Claridges Hotel, New Delhi
The second national consultation meet with participation of 40 stakeholders was held on August 20, 2018 at ICMR Headquarters, New Delhi
A roundtable with equipment manufacturers and laboratories was held on August 6, 2018 at WHO India Country Office, New Delhi
A consultation meeting with clinicians was held on December 7, 2018 at ICMR Headquarters, New Delhi.
A consultation meeting with national programs and technical experts to review the public comments received on draft NEDL was held on March 13, 2019 at ICMR Headquarters, New Delhi.

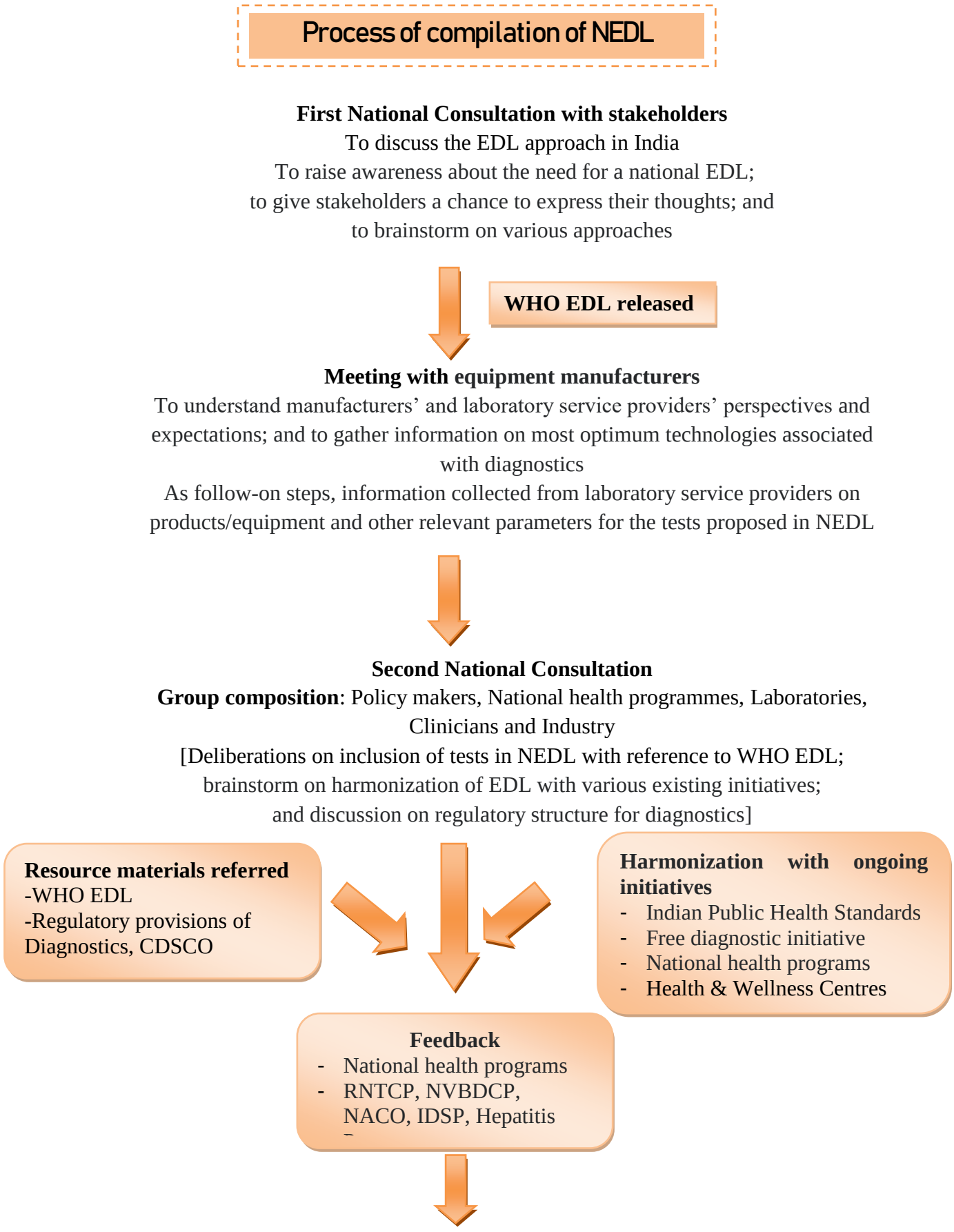

Figure 1: A flowchart illustrates the process of compiling NEDL

Feedback from the national consultations and the roundtable on NEDL are summarized below as key principles outlining the scope of the NEDL:

- National EDL should be strategic, realistic and address the key demands of our country.
- Ability to deliver at multiple levels of health care, with a focus on primary health care, is a very important criterion for the national EDL.
- The list should have tests for both communicable and non-communicable diseases (NCDs), complimenting the national vertical health programmes.
- NEDL should be small, simple, robust, relevant and affordable to society.
- It should provide guidance on logistics and infrastructure, maintaining quality and supply chain.
- There is a need to build capacities of service providers in guiding patients which facilities offer what diagnostics tests, collection of samples at spokes and transport of samples to hubs.
- National EDL should ensure minimal movement of patient across facilities and providers.
- An innovative research in diagnostics related to our priority healthcare conditions was emphasized.
- Assay formats need to be discussed for cost-effectiveness considerations.
- Innovations are needed to bridge gap between rapid test and central laboratory tests.
- The necessity of point-of-care tests for common pathogens was emphasized.
- Inclusion of culture facilities in the list specifically for quality of healthcare and antimicrobial resistance was highly recommended.
- There is a need to ensure quality of products and tests for diagnosis – a well defined in-house validation and evaluation criteria are important.

Following key enablers were identified to pave the way for effective implementation of the EDL in States:

- High political and administrative commitment and leadership and adequate budgetary allocations.
- Integration with existing diagnostics initiatives and national health programmes, wherever necessary.
- Provision of requisite equipment/technology, human resources, procurement and supply chain.
- Evidence-based and rational prescription of tests.
- Quality assurance and strengthening of laboratory capacity across the health system for diagnostic services.
- Robust monitoring mechanisms.
- Adequate Information Education Communication (IEC) for awareness generation about availability of tests.

3. Scope of NEDL

- Both in vitro diagnostics and other diagnostic tests like radiology have been included.
- Test category includes a group of general laboratory tests for routine patient care and for diagnosis of communicable and non- communicable diseases. These tests are grouped in categories (like Haematology; Clinical pathology; Biochemistry; Microbiology and Serology).
- Inclusion of the diagnostic test on specific diseases selected on the basis of disease burden: Vector borne diseases (Malaria, Dengue, Filariasis, Chikungunya, Japanese encephalitis); Leptospirosis, Brucellosis, Tuberculosis, Hepatitis A, B C and E, HIV, Syphilis.
- Desirable tests/Test for endemic areas: Certain tests have been put as desirable tests and should be included in regions or states with high disease burden of that disease.
- A guidance document on "Regulatory framework for diagnostics: National and International" has been included.
- Information on Human Resources has been included (Annexure I).
- Information on equipments required for delivery of diagnostic services has been included (Annexure II).

4. Content and format of the National EDL

a. Separate lists have been prepared for each type of facility – subcentre/HWC, primary health centre/HWC, community health centre, sub-district hospital, and district hospital.

b. A list of tests has been prepared with following description of each test:

    - **Test category:** The category/discipline to which the test belongs, e.g. haematology, microbiology etc.
    - **Specimen type:** The types of specimen (s) that can be used for the test.
    - **Product/equipment:** The product/equipment on which the test is best conducted.

Table 1: List of diagnostic tests at village level

S.No	Test category	Diagnostic test (ASHA/ANM/Health worker/NGO)	Specimen type	Equipment used
1	**Haematology**	Slide preparation for peripheral blood smear	Capillary blood	Sample (prepared slide) to be collected and sent to PHC for microscopy
2	**Clinical pathology**	Urine albumin and sugar	Urine	Dipstick
3	**Biochemistry**	Pregnancy test	Urine	RDT
		Blood sugar	Capillary blood	Glucometer
4	**Specific diseases**			
	Malaria	Antigen based bivalent RDT for malaria	Capillary/whole blood	RDT
	Filariasis*	Peripheral blood smear (thick smear)	Capillary blood	Sample (prepared slide) to be collected and sent to PHC for microscopy
	Tuberculosis	Sample collection for TB	Sputum collection in disposable sterile containers	Sample to be collected and sent to PHC for microscopy

*For endemic areas

PHC: Primary Health Centre

Hub and spoke, sample to be transferred to lab with available facility

Table 2: List of diagnostic tests at Sub-Centre /Health and Wellness Centres

S.No	Test category	Diagnostic test	Specimen type	Equipment used for test
1.	**Haematology**	Haemoglobin	Capillary blood /EDTA whole blood	Digital haemoglobinometer
		Slide preparation for peripheral blood smear	Capillary blood	Sample (prepared slide) to be collected and sent to PHC for microscopy
2.	**Clinical pathology**	Urine albumin and sugar	Urine	Dipstick
		Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity and reaction (pH)	Urine	Dipstick (multiparameter urine strip)
3.	**Biochemistry**	Pregnancy test	Urine	RDT
		Blood Sugar	Capillary blood	Glucometer
4.	**Specific Diseases**			
	Malaria	Antigen based bivalent RDT for malaria	Capillary/ venous whole blood	RDT
	Filariasis*	Peripheral blood smear (thick smear)	Capillary blood	Sample (prepared slide) to be collected and sent to PHC for microscopy
	Tuberculosis	Sample collection for TB	Sputum collection in disposable sterile containers	Sample to be collected and sent to PHC for microscopy
	HIV	Pre- test counselling for HIV screening		
		HIV test (Antibodies 1/2)	Serum/Plasma/Whole blood	RDT
5.	**Other tests**	Visual Inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
		Water quality testing	Water	H_2S strip test kit
		Estimation of residual chlorine in drinking water	Water	Kit based on ortho-toluidine reagent

*For endemic areas

PHC: Primary Health Centre

Hub and spoke, sample to be transferred to lab with available facility

Table 3: List of diagnostic tests at Primary Health Centre (PHC) /Health and Wellness Centres

S.No	Test Category	Diagnostic test	Specimen type	Equipment used for test
1	**Haematology**	Haemoglobin	Capillary blood/ EDTA Whole blood	Digital haemoglobinometer
		RBC count#	EDTA whole blood	Microscopy
		Reticulocyte count#	EDTA whole blood	Microscopy
		Absolute eosinophil count#	EDTA whole blood	Microscopy
		Total leucocyte count#	EDTA whole blood	Microscopy
		Differential leucocyte count#	EDTA whole blood	Microscopy
		Platelet count#	EDTA whole blood	Microscopy
		CBC	EDTA whole blood	Sample to be collected & sent to nearest hub lab for analyser
		ESR#	EDTA whole blood	Manual/ ESR analyser (sample to be sent to nearest hub lab)
		Peripheral blood smear	Capillary blood	Microscopy
		Bleeding time	Whole blood	Manual
		Clotting time	Whole blood	Manual
		Blood grouping and Rh typing	EDTA whole blood	Manual
		Sickle cell disease test*	EDTA whole blood	Screening: Sickling/solubility test; Confirmation: Sample to be collected & sent to DH for electrophoresis
		Reduction test for screening G6PD deficiency*	EDTA whole blood	Sample to be collected and sent to DH for qualitative visual method
2.	**Clinical Pathology**	Urine albumin and sugar	Urine	Strip method (Reading Manual or with a urine analyzer)
		Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity, Reaction (pH) and leucocyte esterase	Urine	Strip method (Reading Manual or with an analyser)
		Urine microscopy	Urine	Microscopy
		Vaginal smear for presence of sperms (Medico Legal Case)	Vaginal smear	Microscopy
		Pap smear	Cervical smear	Sample to be sent to DH and above for microscopy

3.	**Biochemistry**	Pregnancy test	Urine	RDT
		Blood Sugar	Capillary blood	Glucometer and for fully automated analyser (Hub and spoke)[@]
		Glucose tolerance test (GTT)	Plasma	Sample to be collected and sent for fully autoanalyzer[@]
		Bilirubin (Total, direct, indirect)	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		SGPT	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		SGOT	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		Alkaline phosphatase	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		Serum creatinine	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		Blood Urea	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		S. Total Cholesterol	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		S. Triglycerides	Serum	Sample to be collected and sent for fully autoanalyzer[@]
		Serum Sodium	Serum	Sample to be collected and sent indirect ion selective electrode analyser[@]
		Serum Potassium	Serum	Sample to be collected and sent to CHC for indirect ion selective electrode analyser
		Serum Calcium	Serum	Sample to be collected and sent for automated analyser[@]
		Free T3	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		Free T4	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		TSH (including for newborn screening)	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
4.	**Microbiology**	Smear for RTI/STDs	Representative sample	Wet mounting, gram staining-microscope
		Urine M/E for pus cells	Urine	Microscopy
		Smear examination for Leprosy	Slit skin smear	Microscopy
		Gram staining for clinical specimen	Pus	Microscopy
		Throat swab for Diphtheria	Throat swab	Microscopy
		Hanging drop test for *V. cholera*	Stool	Microscopy

		Stool routine examination including ova and parasite	Stool	Microscopy
		Stool for occult blood	Stool	Manual
		RPR Card test for syphilis	Serum	RDT
		rK39 test for Kala-Azar*	Serum	RDT
5	**Specific diseases**			
a)	Malaria	Peripheral smear for malaria parasite detection	Capillary blood	Microscopy
		Antigen based bivalent RDT for malaria	Whole blood	RDT
b)	Filariasis*	Peripheral blood smear for filarial parasite detection (Thick smear)	Capillary blood	Microscopy
c)	Dengue	NS1 antigen and IgM antibody based test	Serum	Sample to be collected and sent to DH for ELISA
d)	Japanese encephalitis*	Sample collection	Serum	Sample to be collected and sent to DH for ELISA
e)	Scrub typhus*	IgM detection test	Serum	Sample to be collected and sent to DH for ELISA
f)	Tuberculosis	Sputum for AFB	Sputum	Microscopy (ZN stain)
g)	HIV	Pre- test counselling for HIV screening	-	-
		HIV test (Antibodies 1/2)	Serum/Plasma/ Whole blood	RDT ELISA (sample to be sent to DH and above[&])
h)	Hepatitis B	HBs Ag	Serum	RDT
i)	Hepatitis C	Anti-HCV	Serum	RDT
8	**Other diagnostic tests**	Visual Inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
		Water quality testing	Water	H_2S strip test kit
		Estimation of residual chlorine in drinking water	Water	Kit based on ortho-toluidine reagent
9	**Radiology**	ECG		
		Mobile X-Ray		
		X-Ray for Tb detection	chest	Referral to nearest hub lab (CHC)

*For endemic areas

[#]All these tests will also be diagnosed by fully auto analyzer under hub and spoke model. The nearest hub lab could be CHC, SDH and DH

[@]The nearest hub lab could be CHC, SDH and DH

[&] Maintain the required cold chain and timelines for sample storage and transportation.

Hub and spoke, sample to be transferred to lab with available facility

Table 4: List of diagnostic tests at Community Health Centre (CHC)

S. No	Test Category	Diagnostic test	Specimen type	Equipment used for test
1	**Haematology**	Haemoglobin	Capillary blood / EDTA Whole blood	Digital haemoglobinometer/ Automated haematology analyser
		Total RBC count	EDTA whole blood	Microscopy/Fully automated haematology analyser
		Reticulocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Absolute eosinophil count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Total leucocyte count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		Differential leucocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Platelet count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		CBC	EDTA whole blood	Fully automated haematology analyser
		E.S.R	E DTA whole blood	Manual / ESR analyser
		Peripheral Blood Smear	Capillary blood	Microscopy
		Prothrombin time and INR	Plasma (citrate)	Automated coagulation analyser
		Bleeding time	Whole blood	Manual
		Clotting time	Whole blood	Manual
		Blood grouping and Rh typing	EDTA whole blood	Manual
		Blood cross matching	EDTA whole blood	Manual
		Packed Cell volume	EDTA whole blood	Automated haematology analyser
		Sickle cell disease test*	EDTA whole blood	Screening: Sickling/solubility test; Confirmation: Sample to be collected & sent to DH for electrophoresis
		Reduction test for screening G6PD deficiency*	EDTA whole blood	Sample to be collected and sent to DH for qualitative visual method
		Haemoglobinopathies screening/testing (in high prevalence areas)	EDTA whole blood and serum	Sample to be collected and sent to DH for HPLC and analyzer
2.	**Clinical Pathology**	Urine albumin and sugar	Urine	Strip method (Reading Manual or with a urine analyser)
		Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity, Reaction (pH) and leucocyte esterase	Urine	Strip method (Reading Manual or with an analyser)
		Urine microscopy	Urine	Microscopy

		Vaginal smear for sperms presence (Medico Legal Case)	Vaginal smear	Microscopy
		Pap smear	Cervical smear	Sample to be collected and sent to DH and above for microscopy
3.	**Biochemistry**	Pregnancy test	Urine	RDT
		Blood Sugar	Capillary blood	Glucometer/ Fully automated biochemistry analyser
		Glucose tolerance test (GTT)	Plasma	Fully automated biochemistry analyser
		Bilirubin (Total, Direct & Indirect)	Serum	Fully automated biochemistry analyser
		SGOT	Serum	Fully automated biochemistry analyser
		SGPT	Serum	Fully automated biochemistry analyser
		Alkaline phosphatase	Serum	Fully automated biochemistry analyser
		Serum creatinine	Serum	Fully automated biochemistry analyser
		Blood Urea	Serum	Fully automated biochemistry analyser
		Serum Total Cholesterol	Serum	Fully automated biochemistry analyser
		Serum Triglyceride	Serum	Fully automated biochemistry analyser
		Serum Sodium	Serum	Electrolyte analyser (Indirect ion selective electrode)
		Serum Potassium	Serum	Electrolyte analyser (Indirect ion selective electrode)
		Serum Calcium	Serum	Fully automated biochemistry analyser
		Free T3	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		Free T4	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		TSH	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		Serum Ferritin	Serum	Sample to be collected and sent to DH and above for ELISA
		Glycosylated haemoglobin (HbA1c)	EDTA Whole blood	Sample to be collected and sent to DH for Turbidimetric based/ Fully automated biochemistry analyser
3	**Microbiology**	Smear for RTI/STDs	Representative sample	Wet mounting, gram staining
		Urine M/E for pus cells	Urine	Microscopy
		Smear examination for Leprosy	Slit skin smear	Microscopy
		Throat swab for Diphtheria	Throat swab	Microscopy

		Hanging drop test for *V. cholera*	Stool	Microscopy
		Stool routine examination including ova and parasite	Stool	Microscopy
		Stool for occult blood	Stool	Manual
		Stool, pus, blood and body fluids culture, throat and antimicrobial sensitivity	Stool, pus, blood, throat swab, and body fluids	Samples to be collected and sent to DH for manual/ automated analyzer
		RPR card test for syphilis	Serum	RDT
		rK39 test for Kala-Azar*	Serum	RDT
4	**Specific diseases**			
a)	Malaria	Peripheral smear for malaria parasite detection	Capillary blood	Microscopy
		Antigen based bivalent RDT for detection of Malaria	Whole blood	RDT
b)	Filariasis*	Peripheral smear for parasite detection (Thick smear)	Whole blood	Microscopy
c)	Dengue	NS1 antigen and IgM antibody based test	Serum	Sample to be collected and sent to DH for ELISA
d)	Japanese encephalitis*	Sample collection	Serum	Sample to be collected and sent to DH for ELISA
e)	Scrub typhus*	IgM detection test	Serum	Sample to be collected and sent to DH for ELISA
f)	Tuberculosis	AFB test	Sputum, body fluids	Microscopy (ZN stain)
		Chip based Real time micro PCR test	Sputum	Micro PCR
		Sample collection	Sputum	Sample to be collected and sent to DH for NAAT
g)	HIV	Pre- test counselling for HIV screening	-	-
		HIV test (Antibodies 1/2)	Serum/Plasma/ Whole blood	RDT ELISA (sample to be sent to DH)[#]
h)	Hepatitis B	HBs Ag	Serum	RDT
i)	Hepatitis C	Anti-HCV	Serum	RDT
8	**Other diagnostic tests**	Visual Inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
		Water quality testing	Water	H_2S strip test kit
		Estimation of residual chlorine in drinking water	Water	Kit based on ortho toluidine reagent
9	**Radiology and other tests**	ECG		
		X-Ray		
		USG with colour doppler		

*: For endemic areas DH: District Hospital

[#] Maintain the required cold chain and timelines for sample storage and transportation.

Hub and spoke, sample to be transferred to lab with available facility

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

S. No	Test Category	Diagnostic test	Specimen type	Equipment used for test
1	**Haematology**	Haemoglobin	Capillary blood / EDTA Whole blood	Digital haemoglobinometer/ Automated haematology analyser
		Total RBC count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		Reticulocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Absolute eosinophil count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Total leucocyte count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		Differential leucocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Platelet count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		CBC	EDTA whole blood	Fully automated haematology analyser
		E.S.R	EDTA whole blood	Manual /ESR analyser
		Peripheral Blood Smear	Capillary blood	Microscopy
		Prothrombin time and INR	Plasma (citrate)	Automated coagulation analyser
		Bleeding time	Whole blood	Manual
		Clotting time	Whole blood	Manual
		Blood grouping and Rh typing	EDTA whole blood	Manual
		Blood cross matching	EDTA whole blood	Manual
		Packed Cell volume	EDTA whole blood	Fully automated haematology analyser
		Sickle cell disease test*	EDTA whole blood	Screening: Sickling/solubility test; Confirmation: Sample to be collected & sent to DH for electrophoresis
		Reduction test for screening G6PD deficiency*	EDTA whole blood	Sample to be collected and sent to DH for qualitative visual method
		Haemoglobinopathies screening/testing (in high prevalence areas)	EDTA whole blood and serum	Sample to be collected and sent to DH for HPLC and analyzer
2.	**Clinical Pathology**	Urine albumin and sugar	Urine	Strip method (Reading Manual or with a urine analyser)
		Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity,	Urine	Strip method (Reading Manual or with an analyser)

		Reaction (pH) and leucocyte esterase		
		Urine microscopy	Urine	Microscopy
		Vaginal smear for presence of sperms (Medico Legal Case)	Vaginal smear	Microscopy
		Pap smear	Cervical smear	Sample to be collected and sent to DH and above for microscopy
3	**Biochemistry**	Pregnancy test	Urine	RDT
		24-hours urinary protein	Urine	Manual/Analyser
		Blood Sugar	Capillary blood	Glucometer/ Fully automated biochemistry analyser
		Glucose tolerance test (GTT)	Plasma	Fully automated biochemistry analyser
		Bilirubin (Total, Direct & Indirect)	Serum	Fully automated biochemistry analyser
		SGOT	Serum	Fully automated biochemistry analyser
		SGPT	Serum	Fully automated biochemistry analyser
		Alkaline phosphatase	Serum	Fully automated biochemistry analyser
		Serum creatinine	Serum	Fully automated biochemistry analyser
		Blood Urea	Serum	Fully automated biochemistry analyser
		Serum Total Cholesterol	Serum	Fully automated biochemistry analyser
		Serum Triglyceride	Serum	Fully automated biochemistry analyser
		Serum Sodium	Serum	Electrolyte analyser (Indirect ion selective electrode)
		Serum Potassium	Serum	Electrolyte analyser (Indirect ion selective electrode)
		Serum Calcium	Serum	Fully automated biochemistry analyser
		Free T3	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		Free T4	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		TSH	Serum	Sample to be collected and sent to DH for Chemiluminescence analyzer
		Serum ferritin	Serum	Sample to be collected and sent to DH and above for

				ELISA
		Glycosylated haemoglobin (HbA1c)	EDTA Whole blood	Sample to be collected and sent to DH for Turbidimetric based/ Fully automated biochemistry analyser
		CSF analysis (Sugar, protein, cell count)	CSF	Sample to be collected and sent to DH and above for fully automated biochemistry analyser
4	**Microbiology**	Smear for RTI/STDs	Representative sample	Wet mounting, gram staining
		Urine M/E for pus cells	Urine	Microscopy
		Smear examination for Leprosy	Slit skin smear	Microscopy
		Throat swab for Diphtheria	Throat swab	Microscopy
		Hanging drop test for *V. cholera*	Stool	Microscopy
		Stool routine examination including ova and parasite	Stool	Microscopy
		Stool for occult blood	Stool	Manual
		Stool, pus, blood and body fluids culture, throat and antimicrobial sensitivity	Stool, pus, blood, throat swab, and body fluids	Samples to be collected and sent to DH for manual/automated analyzer
		Gram stain for Meningococci	Fluid, CSF cell type cell count	Microscopy
		KOH study for fungus	Sputum, Tissue, Nail, Hair, CSF etc	Light Microscopy
		RPR for syphilis	Serum	RDT
		rK39 test for Kala-Azar*	Serum	RDT
5	**Serology**	Rheumatoid Factor quantitative	Serum	Fully automated analyser
		Anti-Streptolysin O quantitative	Serum	Fully automated analyser
6	**Specific diseases**			
a)	Malaria	Peripheral smear for malaria parasite detection	Capillary blood	Microscopy
		Antigen based bivalent RDT for detection of Malaria	Whole blood	RDT
b)	Filariasis*	Peripheral smear for filarial parasite detection (Thick smear)	Capillary blood	Microscopy
c)	Dengue	NS1 antigen and IgM antibody based test	Serum	Sample to be collected and sent to DH for ELISA

d)	Japanese encephalitis*	Sample collection	Serum	Sample to be collected and sent to DH for ELISA
e)	Scrub typhus*	IgM detection test	Serum	Sample to be collected and sent to DH for ELISA
f)	Leptospirosis	Rapid test	Serum	Sample to be collected and sent to DH for RDT
g)	Tuberculosis	Sputum, pus for AFB	Sputum, body fluids	Microscopy (ZN stain)
		Chip based Real time micro PCR test	Sputum	Micro PCR
		Sample collection	Sputum	Sample to be collected and sent to DH for NAAT
h)	HIV	Pre- test counselling for HIV screening		
		HIV test (Antibodies 1/2)	Serum/Plasma/ Whole blood	RDT ELISA (sample to be sent to DH and above)[#]
i)	Hepatitis B	HBs Ag	Serum	RDT
j)	Hepatitis C	Anti-HCV	Serum	RDT
8	**Other diagnostic tests**	Visual Inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
		Water quality testing	Water	H_2S strip test kit
		Estimation of residual chlorine in drinking water	Water	Kit based on ortho-toluidine reagent
9	**Radiology and other diagnostic tests**	ECG		
		X-Ray	Chest, Skull, Spine, Abdomen, bones etc	
		USG with colour doppler		
		PFT		

*: For endemic areas DH: District hospital

[#] Maintain the required cold chain and timelines for sample storage and transportation.

Hub and spoke, sample to be transferred to lab with available facility

Table 6: List of diagnostic tests at District Hospital (DH)

S.No	Test Category	Diagnostic test	Specimen type	Equipment used for test
1	**Haematology**	Haemoglobin estimation	Capillary blood/ EDTA Whole blood	Digital haemoglobinometer/ Fully automated haematology analyser
		Total RBC count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		Reticulocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Absolute eosinophil count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Total leucocyte count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		Differential leucocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
		Platelet count	EDTA whole blood	Microscopy / Fully automated haematology analyser
		CBC	EDTA whole blood	Fully automated haematology analyser
		ESR	EDTA whole blood	Manual /ESR analyser
		Peripheral Blood Smear	Capillary blood	Microscopy
		Prothrombin time and INR	Plasma (citrate)	Automated coagulation analyser
		Activated partial thromboplastin time (APTT)	Plasma (citrate)	Automated coagulation analyser
		D-dimer	Plasma (citrate)	Coagulometer
		Plasma fibrinogen test	Plasma (citrate)	Coagulometer
		Bleeding time	Whole blood	Manual
		Clotting time	Whole blood	Manual
		Blood grouping and Rh typing	EDTA whole blood	Manual
		Blood cross matching	EDTA whole blood	Manual
		Packed Cell volume	EDTA whole blood	Fully automated haematology analyser
		Coomb's test-Direct with titre	EDTA whole blood	Manual
		Coomb's test-Indirect with titre	EDTA whole blood	Manual

		ANA/ANF	Serum	Immunofluorescence
		Bone Marrow Aspiration	Bone marrow Aspiration	Microscopy
		Sickle cell disease test*	EDTA whole blood and serum	Electrophoresis
		Reduction test for screening G6PD deficiency*	EDTA whole blood	Qualitative visual method
		Thalassemia	EDTA whole blood and serum	Haematology analyser and Electrophoresis
		Haemoglobinopathies screening/testing (in high prevalence areas)	EDTA whole blood and serum	HPLC and Haematology analyser
2	**Clinical Pathology**	Urine albumin and sugar	Urine	Strip method (Reading Manual or with a urine analyser)
		Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity, Reaction (pH) and leucocyte esterase	Urine	Strip method (Reading Manual or with a urine analyser)
		Urine microscopy	Urine	Microscopy
		Vaginal smear for presence of sperms (Medico Legal Case)	Vaginal smear	Microscopy
		Pap smear	Cervical smear	Microscopy
		Sputum cytology	Sputum	Microscopy
		Histopathology	Tissue biopsy	Microscopy
		Cytology - FNAC	Aspirate	Microscopy
		Bone marrow aspiration	Bone marrow aspirate	Microscopy
		Semen analysis (Morphology, Vitality, pH, fructose (Qualitative) and Viscocity	Semen	Microscopy/10 micron depth chamber
		Fluid analysis (Cell count, biochemistry and cytology)	Fluid	Fully automated biochemistry and haematology analyser, Microscopy
3	**Biochemistry**	Pregnancy test	Urine	RDT
		24-hours urinary protein	Urine	Manual/Analyser
		Blood Sugar	Capillary blood	Glucometer/ Fully automated biochemistry analyser
		Glucose tolerance test	plasma	Fully automated biochemistry analyser
		LFT: Total, Direct & Indirect bilirubin	Serum	Fully automated biochemistry analyser

		SGOT	Serum	Fully automated biochemistry analyser
		SGPT	Serum	Fully automated biochemistry analyser
		Alkaline phosphatase	Serum	Fully automated biochemistry analyser
		Total protein	Serum	Fully automated biochemistry analyser
		Albumin	Serum	Fully automated biochemistry analyser
		Albumin: Globulin ratio	Serum	Fully automated biochemistry analyser
		KFT: Urea	Serum	Fully automated biochemistry analyser
		Creatinine	Blood	Fully automated biochemistry analyser
		BUN	Serum	Fully automated biochemistry analyser
		Uric acid	Serum	Fully automated biochemistry analyser
		Lipid profile: Total Cholesterol	Serum	Fully automated biochemistry analyser
		Triglyceride	Serum	Fully automated biochemistry analyser
		VLDL	Serum	Fully automated biochemistry analyser
		HDL	Serum	Fully automated biochemistry analyser
		LDL	Serum	Fully automated biochemistry analyser
		Amylase	Serum	Fully automated biochemistry analyser
		Lipase	Serum	Fully automated biochemistry analyser
		Sodium	Serum	Electrolyte analyser (Indirect ion selective electrode)
		Potassium	Serum	Electrolyte analyser (Indirect ion selective electrode)
		Calcium	Serum	Fully automated biochemistry analyser
		Phosphorous	Serum	Fully automated biochemistry analyser
		Magnesium	Serum	Fully automated biochemistry analyser
		Chlorides	Serum	Fully automated biochemistry analyser
		Blood gases analysis	Serum	Blood gas analyser

		Creatine phosphokinase (CPK)	Serum	Fully automated biochemistry analyser
		LDH	Serum	Fully automated biochemistry analyser
		Free T3	Serum	Chemiluminescence analyzer
		Free T4	Serum	Chemiluminescence analyzer
		TSH	Serum	Chemiluminescence analyzer
		Serum Ferritin	EDTA whole blood and serum	Sample to be collected and sent to tertiary care for ELISA/ Chemiluminescence
		Glycosylated haemoglobin (HbA1c)	EDTA Whole blood	Turbidimetric based/ Fully automated biochemistry analyser
		CSF analysis (Sugar, protein, cell count)	CSF	Fully automated analyser
		Creatine Kinase-muscle/brain (CK-MB)	Serum	Fully automated biochemistry analyser
		Troponin I/T	Serum	Immunoassay analyser/RDT
		Prostate-specific antigen (PSA)	Peripheral blood	ELISA/ Chemiluminescence analyser
4	**Microbiology**	Smear for RTI/STDs	Representative sample	Wet mounting, gram staining
		Urine M/E for pus cells	Urine	Microscopy
		Smear examination for Leprosy	Slit skin smear	Microscopy
		Throat swab for Diphtheria	Throat swab	Microscopy
		Hanging drop test for *V. cholera*	Stool	Microscopy
		Stool routine examination including ova and parasite	Stool	Microscopy
		Stool for occult blood	Stool	Manual
		Gram stain for Meningococci	Fluid, CSF cell type, cell count	Microscopy
		KOH study for fungus	Sputum, Tissue, Nail, Hair, CSF etc.	Fluorescent microscopy/Microscopy
		Blood culture and antimicrobial sensitivity	Whole Blood	Automated/Manual
		Urine, stool, pus, fluid, throat swab, culture and antimicrobial sensitivity	Representative sample	Automated/Manual
		Stool culture for *Vibrio*	Stool	Automated/Manual

		cholera and other bacterial enteropathogens		
		RPR for Syphilis	Serum	RDT
		rK39 test for Kala-Azar*	Serum	RDT
		IgM for measles	Serum	ELISA
		Rapid antigen detection test for Bacterial meningitis	CSF	RDT
		C-reactive Protein quantitative	Serum	Turbidometer
		Procalcitonin	Serum/Plasma	RDT/Immunoassay
		TORCH: Toxoplasma, Rubella, CMV and HSV 1 and 2. Antibody detection test (IgM and IgG)	Serum	ELISA
5	**Serology**	Rheumatoid Factor quantitative	Serum	Turbidometer /Fully automated analyser
		Antistreptolysin O quantitative	Serum	Turbidometer /Fully automated analyser
6	**Specific diseases**			
a)	Malaria	Peripheral smear for malaria parasite detection	Capillary blood	Microscopy
		Antigen based bivalent RDT for detection of Malaria	Whole blood	RDT
b)	Filariasis*	Peripheral smear for filarial parasite detection	Capillary blood	Microscopy
c)	Dengue	NS1 antigen and IgM antibody based test	Serum	ELISA
d)	Japanese encephalitis*	IgM, Antibody test	CSF, serum	ELISA
e)	Chikungunya	IgM, Antibody test	Serum	ELISA
f)	Scrub typhus*	IgM detection test	Serum	ELISA
g)	Leptospirosis	Rapid test	Serum	RDT
		IgM, Antibody test	Serum	ELISA
h)	Brucellosis	Antigen based test	Serum	Standard tube agglutination test
i)	Tuberculosis	Sputum, pus for AFB	Sputum , body fluids Gram staining for body fluids	Fluorescent microscopy
		Nucleic Acid Amplification Test (NAAT)	Sputum	PCR based
		TB culture (liquid)	Sputum, fluid etc.	Sample to be collected and sent to nearest TB lab/State Tb lab

		TB DST (liquid)	Sputum, fluid etc.	Sample to be collected and sent to nearest TB lab/State Tb lab
j)	HIV	Pre- test counselling for HIV screening		
		HIV antibodies test	Serum/Plasma/ Whole blood	RDT , ELISA
		HIV screening in blood bank samples	Whole blood/Serum	RDT , ELISA
		CD4 count^	Capillary/venous whole blood	Flow cytometry
		Early infant diagnostic	Dried blood spot (DBS)/Plasma/Whole blood	Sample to be collected and sent to tertiary care for molecular testing
		Quantitative virological nucleic acid test	Whole blood	Sample to be collected and sent to tertiary care for PCR
k)	Hepatitis A	IgM detection test	Serum	ELISA
l)	Hepatitis B	HBs Ag	Serum	RDT and ELISA
		HBV screening in blood bank samples	Serum	RDT , ELISA
		Quantitative test for viral load detection	Whole blood	Sample to be collected and sent to tertiary care for PCR
m)	Hepatitis C	Anti HCV (Total)	Serum	ELISA
		Anti HCV screening in blood bank samples	Serum	RDT , ELISA
		Quantitative test for viral load detection	Whole blood	Sample to be sent to tertiary care for PCR
n)	Hepatitis E	IgM detection test	Serum	ELISA
o)	HBC (Core antibodies)	IgM detection test to hepatitis B core antigen	Serum	ELISA
8	**Other diagnostic tests**	Visual Inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
		Water quality testing	Water	H_2S strip test kit
		Estimation of residual chlorine in drinking water	Water	Kit based on ortho-toluidine reagent
		Urine for Iodine	Urine	
		Iodometry Titration	Salt	
		Blood bank	Services as per norms for the blood bank including services for self component separation	

9	**Radiology and other diagnostic tests**	X-ray	Chest, Skull, Spine, Abdomen, bones	
		C –Arm		
		Intra Oral periapical IOPA X-ray		
		Orthopantomogram (OPG)		
		Occlusal radiography and Bite wing radiography		
		TML Tomograms digital OPG		
		USG (with colour doppler)		
		Echocardiography		
		CT scan		
		ECG		
		Mammography		
		MRI (with service linkages)		
		EEG		
		NCV(Nerve Conduction Velocity)		
		EMG		
		TMT		
		PFT		
		Comprehensive Ophthalmic Diagnostic services	Ocular Coherence Tomography	
			Perimetry	
			Pachymetry	
			Eye Angiography	
			Refraction	
		Angiography		
		Endoscopy		

*: For endemic areas

^ Only where ART centres are located

Hub and spoke, sample to be transferred to lab with available facility

The following tests should be placed at DH, if there is infrastructure and human resource is available to support the same. In absence of the latter, services may be procured from tertiary medical institutes or private providers. The list is mentioned below:

Microbiology	Pathology	Biochemistry
Molecular tests	Cytopathology	Tests based on CLIA
Automated ID system for bacteria	Immunohistochemistry	FSH
Therapeutic Drug Monitoring: Antibacterial and antifungal drugs	Molecular onco-pathology	LH
Mycology (Fungal culture)		S.Prolactin
Anaerobic culture		S.Beta HCG
Parasitology referral culture		Estrogen
		Progesterone
		S. Alfa Feto protein
		S.CA 19.9
		S. CEA
		S.PSA
		S. Vitamin B12
		S. Folic acid
		S. Vitamin D
		S. CA 125
		Inborn errors of metabolism
		Protein electrophoresis

5. Implementation of the national EDL

Few points for consideration during and after implementation of the national EDL are summarized below:

a. The laboratories at government health facilities and availability of adequate and trained human resources will need to be ensured. Quality assurance protocols including External quality assessment (EQA) will need to be instituted. Laboratories should be encouraged to strive for accreditation and adequate funds should be allocated for laboratories that opt for National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation. In case of public-private partnerships for providing diagnostic services, it would be important to stipulate which all tests from the EDL should mandatorily be carried out in the in-house laboratories. This will enable effective utilization of in-house capacity.
b. An option of following a 'hub and spoke model' could be considered by the states for implementing the EDL. This will ensure availability of the required number of tests at different levels of facilities in a cost-efficient way. This model is already being used for implementing the free diagnostics initiative in Telangana (in-house modality) and in Andhra Pradesh, Maharashtra, Jharkhand, Rajasthan, Assam and Meghalaya (in PPP modality). Availability of comprehensive diagnostic services at

all levels will improve patient care and minimise referral of patients because of unavailability of tests. This has been shown to curtail patients' out-of-pocket expenditure on laboratory tests.

c. For EDL, equipment specifications should be general and generic, and at the same time robust. Storage and transportation will also need to be worked out. There should be a mechanism to see what all diagnostics are available at what level of health facility. It is important to ensure that reagents and equipment are compatible at the time of procurement. Validation of reagents is required before they go in the field through quality checks. Information on suboptimal tests needs to be made available.

Key challenges anticipated during implementation of the National EDL are as follows:

- Adoption by States and harmonization with local standard diagnostic protocols and treatment guidelines.
- Provision of requisite infrastructure, processes and human resources.
- Ensuring quality of tests including EQAS and quality control
- Adequate utilization of EDL tests for making informed decisions for treatment protocols.

Opportunities

1. An independent body/committee should look into minimum acceptable specifications/standards for diagnostic equipments, reagents and rapid test kits.
2. Cost-effectiveness of different technologies, equipment, reagents and rapid test kits should also be carried out and results from such studies should guide the availability/procurement of tests at various levels. This information should be widely disseminated to the states to enable good quality and cost-effective procurement for diagnostics.
3. Capacity for third party validation for diagnostic equipment, reagents and rapid test kits should be strengthened in the country.
4. EDL will be an opportunity to provide education and the list should be linked with clinical education.
5. Identify resource centres for sample collection in making panels representing different geographical locations within the country.
6. Indigenous stakeholders are facing logistic & economic issues with regard to availability of global panels, thus limiting their participation in WHO PQ Programme of In-Vitro Diagnostics for global tenders. This would need to be addressed for priority & new disease markers.
7. There is a need to ensure adaptation & implementation of Quality Management System (QMS). This would require capacity building workshops to be organized for lab strengthening, quality control (QC), validation, quality management systems, etc for stakeholders.
8. Laboratory Information Management Systems (LIMS)
    - Full integration of LIMS is essential to successful planning and execution.
    - Data Integrity

- Data generated should be described with a focus on quality attributed parameters.

9. Easy methods in adoption of high throughput automation platforms.
10. Identification of laboratories / institutions and participation in proficiency testing.
11. The mechanisms for capacity building of indigenous manufacturers in areas of QC testing and regulation by institutes such as NIB etc.
12. Guidance on post market surveillance risk based approach interfacing with quality control laboratories would need to be developed.

6. A regulatory framework for diagnostics: National and International

Various international and national authorities regulate medical devices including IVDs by assessing safety and efficacy of the products before providing approval for marketing.

List of international regulatory bodies
• CE Marking (European Union) • FDA (US) • International Organisation for Standardisation (ISO) • WHO's Pre qualifications • Expert Review Panel of Global Fund to Fight AIDS, Tuberculosis and Malaria

WHO's prequalification process, started in 2010 and primarily focuses on in vitro diagnostics for some major public health risk diseases like tests for malaria, HIV/AIDS, Hepatitis B and Hepatitis C. Till now more than 60 products have been prequalified and many more tests have now been covered like tests for glucose-6-phosphate dehydrogenase deficiency, screening for HPV, and emergency assessments in outbreak of diseases such as Ebola and Zika (http://www.who.int/diagnostics_laboratory/evaluations/en/). WHO pre-qualification process can be used by countries deprived of stringent regulatory systems allowing high-quality test to be more affordable and reducing the risk of marketing poor quality tests. The WHO pre-qualification process has three components required for the assessment of submitted IVDs (a) a review of the application and product dossier, (b) laboratory evaluation of the product and (c) manufacturing site inspection. The process of site inspections is directed as per quality management standard (QMS) International Organisation for Standardisation (ISO) 13485:2003, and by the Global Harmonization Task Force on Medical Devices (GHTF) and the International Medical Device Regulators Forum (IMDRF, now replacing GHTF) standards and guidelines whose purpose is to hasten international medical device regulatory harmonization.

The Global Fund Quality Assurance Policy for diagnostic products has created a list of diagnostic tests kits eligible for procurement based on many criteria's including WHO's recommendations (PQDs), accepted by regulatory authorities of the

Founding Members of Global Harmonization Task Force (GHTF): Australia, Canada, the European Union, Japan and the United States and also by using grant fund based on the advice of the WHO expert review panel. The Global Fund accepts CE Marking (European Union) (must meet ISO 13485 standard) and FDA (US) approval for IVDs dealing specifically with the safety quality and performance of IVDs. Other examples are the President's Emergency Plan for AIDS Relief (PEPFAR) which relies on the United States agency for international development's list of approved tests for HIV/AIDS. However, other than HIV, malaria and tuberculosis, very limited information/guidance is available for other neglected diseases. Thus more in vitro diagnostic tests are required to be endorsed or approved for use, by international agencies.

Regulatory requirements for manufacturing and testing of devices and IVDs in India

In India, diagnostics (medical devices and in vitro diagnostics) follow a regulatory framework based on the drug regulations under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules 1945. Diagnostics are regulated under the regulatory provisions of the Medical Device Rules, 2017. All medical devices/*in vitro* diagnostics are required to conform to the following Bureau of Indian Standards (BIS), in the same order of relevance: **(a).** A standard notified by central government for the medical device specifically or which has been laid down by the Bureau of Indian Standards ("BIS"). BIS is established under the BIS Act 1986 for the harmonious development of the activities of standardization, marking and quality certification of goods and for matters connected therewith or incidental thereto; or **(b).** Where (a) is absent, to a standard laid down by International Organisation for Standardisation ("ISO") or the International Electro Technical Commission ("IEC"), or by any other pharmacopoeial standards; or **(c).** Where both (a) and (b) are absent, the device shall conform to the validated manufacturer's standards.

The National Institute of Biologicals (NIB), NOIDA is designated as a Central Medical Device Testing Laboratory (CMDTL) by Government of India for in-vitro diagnostics for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C virus. MDTL has a Quality Management System in place and is NABL accredited in accordance with the standard ISO/IEC 17025:2005 for HIV-Ab, HCV-Ab, HBsAg and Syphilis serology. The institute has been designated as a National Reference Laboratory (NRL) of National AIDS Control Organisation (NACO), India and is monitoring its two states, Uttar Pradesh and Uttarakhand for strengthening HIV testing. It has also been designated as "Support cell for WHO- Prequalification program for in-vitro Diagnostics" in November, 2017. NIB has also enrolled and participated in External Quality Assurance Scheme (EQAS) for HIV, HBV, HCV and Syphilis serology organized by NRL, Australia since 2009 The laboratory is regularly participating in PT/EQAS.

The criteria for evaluation of Rapid & ELISA (HIV, HBsAg, HCV) Diagnostic kit adopted by NIB, Noida 1. Anti-HIV ELISA Sn100% Sp≥98%; Rapid Sn100% Sp≥98% 2. HBsAg ELISA Sn100% Sp≥98%; Rapid Sn100% Sp≥98% 3. HCV

ELISA Sn100% Sp≥98%; Rapid Sn≥99% Sp≥98%. All medical device testing laboratories shall follow the above specified criteria for Rapid, ELISA & CLIA based HIV, HBsAg & HCV diagnostic kits. There are also minimum criteria for evaluation of IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer and other Class B & C IVD kits. This complies with clinical sensitivity, specificity, repeatability, reproducibility, accuracy, Linearity, Variance etc. as claimed in the instructions for use (IFU)/ certificate of analysis (COA) /Product insert issued by the manufacturer. In India, it is noteworthy that many tests for disease relevance to public health have already been approved for use in various national programs by national authorities. Comprehensive manuals inclusive standard operating procedures for diagnosis of malaria, Kala Azar and other disease like HIV have been developed through the coordinated and concerted efforts of various organizations and are available for various settings in health care system. The details on the available guidance for diagnostics currently used and acceptable for the national programs may be seen in Annexure III.

Performance evaluation also needs to be conducted on the test batches of IVD before introduction in the market and it should be for three independent batches of IVDs, manufactured by using three different lots of key raw materials (e.g. Antigen, antibody). The prescribed number of sample from three consecutive batches of such IVD products should be forwarded to NIB (NOIDA) or other notified laboratory. The PER should be submitted to both CDSCO and the concerned State Drugs Control Authority. Typically, a Performance Evaluation Report (PER) should mention following details: Product name, lot / batch number, manufacturer name, importer name, import /test licenses number, number of samples tested, testing principle (ELISA/Rapid/NAAT etc.), information about reference used, testing procedure, specificity, sensitivity, Positive Predictive Number (PPN), Negative Predictive Number (NPN), report number, date of analysis, designation & signature of analyst and authorized signatory of the laboratory etc. Performance indicators for example sensitivity, specificity, PPN and NPN, repeatability, reproducibility and accuracy criteria should be accepted as applicable for any specific IVD product with rationale.

Monitoring of adverse events related to medical devices, including in vitro diagnostic products, is an important component of regulatory control, as their performance depends to a considerable extent on their appropriate use. A system is in place for this purpose through the Materio-vigilance Programme of India (MvPI) (http://ipc.nic.in/index1.asp?EncHid=&lang=1&linkid=82&lid=548) launched in 2015 under the umbrella of PvPI. There are 22 Medical Device Monitoring Centres (MDMCs). Adverse events are reported by a wide range of stakeholders supplying or handling CDSCO-notified medical devices. Reports are recorded on the Medical Device Adverse Event (MDAE) reporting form, which is forwarded by the MDMCs to the National Collaboration Centre. IPC receives technical support from the National Health System Resource Centre (NHSRC) and collaborates with the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) in providing advice to CDSCO on regulatory actions for medical devices.

Current regulatory challenges in diagnostics space in India

The current regulatory systems do not cover all the medical devices and IVD. The system is currently equipped to manage only the few notified devices. New products/ product segments need to be included in the notified list of devices. Utmost attention should be provided for the already marketed products. There is no set classification/ classification system in current device rules for both notified and non-notified devices category for innovative products/ technologies and needs guidance from regulators to bring clarity on the category.

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Annexure I

Recommended list of Human Resource for different levels of health care as per the proposed list of diagnostics

S.No	Village level	SC	PHC	CHC	SDH	DH
1	ANM	ANM	ANM	ANM	ANM	ANM
2	ASHA	ASHA	Lab Technician	Lab Technician	Lab Technician	Lab Technician
3	NGO	MLHP				Pathologist
4		MPW				Microbiologist
5						Radiologist

ANM: Auxiliary Nurse-Midwife

MLHP: Mid-level health care provider

ASHA: Accredited Social Health Activist

MPW: Multi Purpose Worker

Annexure II

Recommended list of equipments for different levels of health care as per the proposed list of diagnostics

	Village level	Sub-Centre	PHC	CHC	SDH	DH
1	Glucometer	Glucometer	Glucometer	Glucometer	Glucometer	Glucometer
2	Equipment for chlorine estimation	Equipment for chlorine estimation	Equipment for chlorine estimation	Equipment for chlorine estimation	Equipment for chlorine estimation	Equipment for chlorine estimation
		Digital Hemoglobin-ometer	Digital Hemoglobin-ometer	Digital Hemoglobinometer	Digital Hemoglobinometer	Digital Hemoglobinometer
3			Microscope	Microscope	Microscope	-Microscope -Fluorescent microscope
4				Fully automated Hematology analyser	Fully automated Hematology analyser	Fully automated Hematology analyser
5				Automated coagulation analyser	Automated coagulation analyser	Automated coagulation analyser
6				Fully automated biochemistry analyser	Fully automated biochemistry analyser	Fully automated biochemistry analyser
			Urine analyser	Urine analyser	Urine analyser	Urine analyser
7				Indirect ion selective electrode Electrolyte Analyser	Indirect ion selective electrode Electrolyte Analyser	Indirect ion selective electrode Electrolyte Analyser
				ESR analyser	ESR analyser	ESR analyser
8						Electrophoresis
9						ELISA reader (Fully automated)
10						Chemiluminescence analyser (Fully automated)
11						Turbidometer
						Blood gas analyser
						Automated blood culture/ Liquid Media System with Smart Rapid detection
12						HPLC
13						PCR for NAAT
14						Flow cytometry (where ART centres are located)
						Blood bank refrigerator

Radiology Diagnostics:						
1			ECG	ECG	ECG	ECG
2			Mobile X-ray	X-ray	X-ray	X-ray
3				USG with colour Doppler	USG with colour Doppler	USG with colour Doppler
4					Pulmonary function test (PFT)	C –Arm
5						Echocardiography
6						CT scan
7						ECG
8						Mammography
9						MRI (with service linkages)
10						EEG
11						NCV(Nerve Conduction Velocity)
12						EMG
13						TMT
14						Pulmonary function test (PFT)
15						Comprehensive Ophthalmic Diagnostic services
16						Angiography
17						Endoscopy

Recommended list of other equipments at District level (DH)

Histopathology equipment	**Cytology equipment**
Binocular Microscope LED	Improved neubauer chamber/Haemocytometer
Rotary microtome	Binocular Microscope LED
Knife sharpener	Liquid Based Cytology System
Block wax trimmer	
Paraffin dispenser	
Automated tissue processor	
Tissue floatation Bath with Digital Temperature Controller and display	
Antigen retrieval unit	
Hot Plate with Digital Temperature Controller	
Cryostat Instrument for Frozen Section	
Embedding Station	
Wax embel bath	
Bone cutter with saw	
Immunohistochemistry stainer	

The other routine equipments to be made available at various levels of heath care as per the guidance of IPHS

Annexure III

Information of various guidance documents

A. General guidance on samples collection, transportation and waste management

a) Guidelines on collection and transport of CSF samples and blood samples. https://www.cdc.gov/meningitis/lab-manual/chpt05-collect-transport-specimens.pdf

b) Specimen collection and transport for microbiological investigation. World Health Organization, Regional Office for the Eastern Mediterranean. (1995) https://apps.who.int/iris/bitstream/handle/10665/119529/dsa28.pdf?sequence=1&isAllowed=y

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i) Biomedical Waste Management Rules. (2016) (Amended) 2018 https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Amendment_BMWM_Rules2018.pdf

B. General guidance on regulatory framework of diagnostics

a) Detailed information on manufacturing, sale and distribution of In vitro diagnostic and medical devices; various processes and functionalities are available on CDSCO website (https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzMzNg==)

b) A brief about application processes and required document are mentioned below:

Processes

1. Approval Process for Application received in hard copy with respect to In Vitro Diagnostics.

2. Approval process for Application received Online Sugam Portal for grant of manufacturing licence with respect to In Vitro Diagnostics.
3. Approval process for Application received Online Sugam Portal for grant of Import licence / Permissions with respect to In Vitro Diagnostics

Guidelines Document

1. Classification of Medical devices and in Vitro diagnostic Medical devices under the provisions of the Medical Devices Rules 2017
2. Guidance Document on Common Submission Format for Import of Notified Diagnostic Kits in India (IVD's)
3. Guidance Document on Common Submission Format for Import of Non-Notified Diagnostic Kits in India (IVD's)
4. Guidance Document on Common Submission Format for Registration/ Re-Registration of Notified Diagnostic Kits in India (IVD's)
5. FAQ on IVD and Medical Device rule
6. FAQ in Vitro Diagnostic IVD Devices
7. Checklist/ Performa to be provided for verification of information on allergen IVD by applicant for grant of Form 10
8. Revised Pre-Screening checklist for acceptability of application of Medical Device and In-vitro Diagnostic

c) Web links for various guidance documents related to eligibility criteria for WHO prequalification of in vitro diagnostics, post-market surveillance of in vitro diagnostics, a risk based approach for the assessment of in vitro diagnostics along with tests approved by national authorities are also mentioned below:

i. http://apps.who.int/iris/bitstream/handle/10665/259170/WHO-EMP-RHT-PQT-2017.03-eng.pdf?sequence=1&ua=1
ii. http://www.who.int/diagnostics_laboratory/evaluations/140513_risk_based_assessment_approach_buffet.pdf?ua=1
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