National Essential Diagnostics List

2025

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National Essential Diagnostics List, 2025

2nd edition

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FOREWORD

Ensuring equitable access to quality diagnostics is a cornerstone for achieving universal health coverage. The diagnostic gap in the health care system is being recognised as major bottle neck in providing effective health care services at all levels of health care. The World Health Organisation (WHO) published its Model List of Essential In Vitro Diagnostics (EDL) in 2018, following which India was the first country to publish the National Essential Diagnostics List (NEDL) in 2019, a significant initiative to bridge diagnostic gaps at the primary healthcare level and strengthen healthcare delivery.

The NEDL was designed to address the needs of healthcare facilities across all levels, ensuring access to essential diagnostic tests. However, with the dynamic nature of healthcare demands and updates to key guidance documents such as the Indian Public Health Standards (IPHS), Integrated Public Health Laboratories (IPHLs) at district hospitals, a revision of the NEDL was both timely and necessary. The revised NEDL builds upon the first edition, incorporating updated guidance and aligning seamlessly with national health programs. This revised NEDL offers comprehensive recommendations for diagnostic tests across a wide spectrum of healthcare facilities, from village-level health facilities to Ayushman Arogya Mandirs Sub-Centres, Primary Health Centres, Community Health Centres, and Sub-District - District Hospitals. Notably, the revised edition emphasizes the inclusion of Rapid Diagnostic Tests to enable Point-of-Care diagnostic services ensuring timely and efficient management of patients.

This initiative would not have been possible without the unwavering support and expertise of numerous stakeholders. I deeply appreciate the contributions of national health programs -National Health System Resource Centre (NHSRC), National AIDS Control Organization (NACO), Revised National Tuberculosis Control Program (RNTCP), National Viral Hepatitis Control Program (NVHCP), National Center for Vector Borne Diseases Control (NCVBDC) and National Centre for Disease Control (NCDC), technical experts, and other partners who participated in the extensive consultations to refine and improve the NEDL.

It is anticipated that the NEDL will play a pivotal role in improving access to safe, effective, and affordable quality diagnostics. By reducing direct healthcare costs and out-of-pocket expenditures, it will contribute to better patient care and reinforce India's healthcare infrastructure.

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Abbreviations and acronyms

AAM	Ayushman Arogya Mandir
AFB	Acid Fast Bacilli
ALT	Alanine aminotransferase
ANM	Auxiliary Nurse-Midwife
APTT	Activated partial thromboplastin time
ART	Antiretroviral therapy
ASHA	Accredited Social Health Activist
AST	Aspartate aminotransferase
ASTM	American Standard Test Method
BIS	Bureau of Indian Standards
CBC	Complete Blood Count
CDSCO	Central Drugs Standards Control Organization
CFSL	Central Forensic Science Laboratory
CHC	Community Health Centre
CHO	Community Health Officer
CK-MB	Creatine Kinase-muscle/brain
CMDTL	Central Medical Device Testing Laboratory
COA	Certificate of analysis
CPK	Creatine phosphokinase
CRP	C-Reactive Protein
DBS	Dried blood spot
DHs	District Hospitals
DRT	Drug resistance testing
DST	Drug susceptibility testing
EDL	Essential Diagnostics List
ELISA	Enzyme-Linked Immunosorbent Assay
FDSI	Free Diagnostics Service Initiative
FTS	Filaria Test Strip
GDMO	General duty medical officer
GHTF	Global Harmonization Task Force on Medical Devices
GTT	Glucose tolerance test
HPLC	High performance liquid chromatography
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Programme
IEC	International Electro Technical Commission
IFU	Instructions for Use
IMDRF	International Medical Device Regulators Forum
IPC	Indian Pharmacopoeia Commission
IPHS	Indian Public Health Standards
IPHL	Integrated Public Health Laboratory
ISO	International Organization for Standardization
IRL	Intermediate Reference Laboratories

IVD	In Vitro Diagnostics
LDH	Lactate dehydrogenase
LFT	Lipid Function Tests
LPAs	Line Probe Assays
MDR	Medical device rule
MDAE	Medical Device Adverse Event
MDMC	Medical Device Monitoring Centres
MO	Medical Officer
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
NCDC	National Centre for Disease Control
NEDL	National Essential Diagnostics List
NHM	National Health Mission
NHSRC	National Health System Resource Centre
NIB	National Institute of Biologicals
NPV	Negative Predictive Number
NRL	National Reference Laboratory
NCVBDC	National Center for Vector Borne Diseases Control Programme
NVHCP	National Viral Hepatitis Control Program
OPG	Orthopantomogram
PER	Performance Evaluation Report
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Centre
PPV	Positive Predictive Number
PSA	Prostate-specific antigen
QMS	Quality management standard
RDT	Rapid Diagnostic Test
RNTCP	Revised National Tuberculosis Control Program
SC	Sub-Centre
SDHs	Sub-District Hospitals
SFCL	State Forensic Science Laboratory
TST	Tuberculosis skin test
UHC	Universal Health Coverage
WHO	World Health Organization

National Essential Diagnostics List: 2nd edition

Introduction

Ensuring equitable access to diagnostics is a critical need to achieve our goals of Universal Health Coverage (UHC). The diagnostic gap in the health care system is being recognised as major bottle neck in providing effective health care services at all levels of health care. India published the National Essential Diagnostics List (NEDL) in 2019.[1] Recognizing diagnostics to be a major bottle neck in providing health care services, the first edition of the National Essential Diagnostics List (NEDL) utilised the evidence from Global Burden of Disease data published in 2016. It also built upon the recommendations of Free Diagnostic Service Initiative (FDSI), launched in July 2015 under the National Health Mission (NHM)[2] and Indian Public Health Standards (IPHS) published in 2012, which are a set of uniform benchmarks. The adoption and implementation of the NEDL across the States was facilitated by National Health System Resource Centre (NHSRC) through the revised FDSI launched in 2019.[3]

Continuing with a focus on strengthening health care system in the country, the IPHS have been revised to incorporate new initiatives such as Ayushman Bharat Health & Wellness Centres and Urban Primary Health Centres. These centres now act as comprehensive primary care hubs covering preventive, promotive, curative, palliative, and rehabilitative services under the Ayushman Bharat initiative.[4] Additionally, the Ministry of Health and Family Welfare (MoHFW) has established Integrated Public Health Laboratories (IPHLs) to strengthen the diagnostic capacity at the district and state levels.[5] In light of these developments, the NEDL has been revised to address the new nomenclature of healthcare facilities with Sub-Centres now referred to as Ayushman Arogya Mandirs. The revised list builds upon the first NEDL and provides recommendations for diagnostic tests across various levels of healthcare facilities, including village-level facilities, Ayushman Arogya Mandirs (Sub-Centres), Primary Health Centres (PHCs), Community Health Centres (CHCs) and Sub-District Hospitals (SDHs)-District Hospitals (DHs). The update also incorporates guidance on the human resources and equipment required to deliver diagnostic services in alignment with the IPHS 2022.

Process followed in developing the 2nd edition of NEDL

The revision of the National Essential Diagnostics List (NEDL) was undertaken through extensive engagement with a wide range of stakeholders. The process began with an open call on the ICMR website inviting suggestions on the existing Essential Diagnostics List. This was followed by four rounds of consultations to discuss the suggestions received with the relevant experts and stakeholders.

Subsequently, the draft revised list was deliberated with representatives from State NHM and the Ministry of Health and Family Welfare. The final list incorporated the feedback and recommendations received in all consultations.

Key highlights

a. **Updated nomenclature for healthcare facilities:** In line with the GoI recommendation of renaming Sub-Centres as Ayushman Arogya Mandirs, the same is amended in the revised list.

b. **Integration of diagnostic test lists for Sub-District and District Hospitals:** The diagnostic test menu for Sub-District Hospitals (SDHs) has been merged with that of District Hospitals (DHs). This change aligns with the centrally sponsored scheme to upgrade district hospitals into medical colleges, and ensuring that SDHs provide equivalent diagnostic services as DHs.

c. **Expanding the test panel at Primary Healthcare Centres:** Certain diagnostic tests were previously listed under the "hub-and-spoke" model at PHCs. In view of revised equipment's list being provided under IPHS at PHCs, these tests can now be undertaken at PHCs. This will do away with the need of sample transfer to hubs thereby making it possible to diagnose and treat a wider array of conditions at the lower level.

d. **Inclusion of rapid diagnostic tests (RDTs) at the Point-of-Care (POC):** A key revision in this edition of NEDL is the inclusion of RDTs at lower levels of healthcare, such as Ayushman Arogya Mandirs Sub-Centres and primary health centres. This revision responds to the feedback received from national programs and other subject experts, who highlighted the growing importance of providing rapid diagnostic tools at these levels. Availability of RDTs for diseases like syphilis, sickle cell anemia and Hepatitis B at Ayushman Arogya Mandir Sub-Centre level will ensure early detection and timely treatment for patients in the rural areas. The inclusion of RDTs in the NEDL has been guided by program-specific protocols. Many RDTs available in the market have not been included for the want of robust evidence. These tests can be reconsidered for inclusion in NEDL once the required data is comprehensively assessed and verified.

Format of the National EDL

The second edition of the NEDL follows the same format as outlined in the first edition

a. Separate lists have been prepared for each type of facility – With the integration of diagnostic test lists for sub-district and district hospitals, tables are now provided for five levels: Village level, Ayushman Arogya Mandir Sub-Centre, Primary Health Centre, Community Health Centre, Sub-District -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. 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 and test for endemic areas**.** Tests related to radiology are included under the Radiology category, while other tests that are not IVDs are classified under the 'Other Tests' category
- **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.

List of diagnostic tests

Table 1: List of diagnostic tests at village level

S.No	Diagnostic test	Specimen type	Equipment
Clinical pathology			
1.	Urine albumin and glucose	Urine	Dipstick
2.	Urine pregnancy test	Urine	RDT
Biochemistry			
3.	Blood glucose	Capillary blood	Glucometer
Specific diseases			
4.	Malaria	Capillary/whole blood	RDT (Antigen based bivalent)
5.	Peripheral blood smear (thick smear for Filariasis*)	Capillary blood	Sample (prepared slide) to be collected and sent to PHC for microscopy
6.	Sputum for Acid Fast Bacilli (AFB)	Sputum collection in disposable sterile containers	Sample to be collected and sent to nearest microscopy center for follow up of TB treatment.

*For endemic areas

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

Table 2: List of diagnostic tests at Ayushman Arogya Mandir Sub-Centre

S.No	Diagnostic test	Specimen type	Equipment
Haematology			
1.	Haemoglobin	Capillary blood	Digital haemoglobinometer
2.	Test for sickle cell anemia and Thalassemia*	Capillary blood/DBS	RDT/POCT Sample to be sent to DH for confirmatory test by HPLC
Clinical pathology			
3.	Urine pregnancy test	Urine	RDT
4.	Urine albumin and glucose and Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity and reaction (pH)	Urine	Dipstick (2-para/ (multiparameter urine strip)
5.	Visual inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
Microbiology			
6.	Test for syphilis[@]	Whole blood	RDT/Through dual kit for Syphilis and HIV
Biochemistry			
7.	Blood glucose	Capillary blood	Glucometer
Specific Diseases			
8.	Malaria	Capillary/whole blood	RDT (Antigen based bivalent)
9.	Peripheral blood smear (thick smear) for filariasis*	Capillary blood	Sample (prepared slide) to be collected and sent to PHC for microscopy
10.	Sputum for TB-NAAT/ Acid Fast Bacilli (AFB)	Sputum collection in disposable sterile containers	Sample to be collected and sent to nearest NAAT center or to nearest microscopy center for AFB
11.	HIV test (Antibodies 1/2)[^@]	Serum/Plasma/Whole blood [@@]	RDT/ Through dual kit for Syphilis and HIV or single specific kit (HIV/Syphilis)
12.	HBs Ag test for Hepatitis B	Whole blood	RDT
13.	Dengue	Whole blood /Serum**	Sample to be collected and sent to CHC/DH for ELISA

Water quality testing			
14.	Water testing for faecal contamination	Water	H_2S strip test method
15.	Water testing for chlorination	water	Strip method/kit

*For endemic areas
^ Test to be done for HIV screening after pre-test counselling
@Dual or combined test kit can be used
@@ Serum/Plasma: RPR kits for Syphilis; Whole blood: Dual kit for HIV and Syphilis
**Serum should be separated soon after from blood collection

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

Table 3: List of diagnostic tests at Primary Health Centre (PHC)

S.No	Diagnostic test	Specimen type	Equipment
Haematology			
1.	Haemoglobin	Capillary blood	Digital haemoglobinometer
2.	Peripheral blood smear	Capillary blood	Microscopy
3.	Total RBC count[#]	EDTA whole blood	Microscopy
4.	Reticulocyte count[#]	EDTA whole blood	Microscopy
5.	Absolute eosinophil count[#]	EDTA whole blood	Microscopy
6.	Total leucocyte count[#]	EDTA whole blood	Microscopy
7.	Differential leucocyte count[#]	EDTA whole blood	Microscopy
8.	Platelet count[#]	EDTA whole blood	Microscopy
9.	CBC[#]	EDTA whole blood	3-part Hematology analyzer
10.	ESR[#]	EDTA whole blood	Manual/ ESR analyser
11.	Bleeding time and clotting time	Whole blood	Manual
12.	Blood grouping and Rh typing	EDTA whole blood	Manual
13.	Test for sickle cell anemia and Thalassemia*	Capillary blood/ EDTA whole blood/DBS	RDT/POCT Confirmation: Sample to be collected & sent to DH for HPLC and electrophoresis
14.	Reduction test for screening G6PD deficiency*	EDTA whole blood	Sample to be collected and sent to DH for qualitative visual method
Clinical pathology			
15.	Urine pregnancy test	Urine	RDT
16.	Urine albumin and glucose/ Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity and reaction (pH)	Urine	Dipstick (2-para/ (multiparameter urine strip)
17.	Urine microscopy	Urine	Microscopy
18.	Urine for microalbumin	Urine	Sample to be sent to CHC and DH for analyzer
19.	Urine for creatinine and Albumin to creatinine ratio (ACR)	Urine	Sample to be sent to CHC and DH for analyzer
20.	Visual inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum

21.	Pap smear	Cervical smear	Sample to be sent to DH for microscopy
Biochemistry			
22.	Blood glucose[#]	Capillary blood	Glucometer Semi-autoanalyzer**
23.	Glucose tolerance test (GTT)[#]	Plasma (Fluoride Tube)	Semi-autoanalyzer
24.	**LFT**: Serum Bilirubin (Total, direct, indirect) [#]	Serum	Semi-autoanalyzer
25.	Serum ALT[#]	Serum	Semi-autoanalyzer
26.	Serum AST[#]	Serum	Semi-autoanalyzer
27.	Serum alkaline phosphatase[#]	Serum	Semi-autoanalyzer
28.	Serum total protein [#]	Serum	Semi-autoanalyzer
29.	Serum albumin and AG ratio[#]	Serum	Semi-autoanalyzer
30.	Blood urea[#]	Serum	Semi-autoanalyzer
31.	Serum creatinine[#]	Serum	Semi-autoanalyzer
32.	Serum uric acid[#]	Serum	Semi-autoanalyzer
33.	**Lipid Profile:** S. Total Cholesterol[#]	Serum	Semi-autoanalyzer
34.	S. Triglycerides[#]	Serum	Semi-autoanalyzer
35.	S.HDL-C[#]	Serum	Semi-autoanalyzer
36.	S.LDL-C [#]	Serum	Semi-autoanalyzer
37.	Serum sodium[#]	Serum	Sample to be sent to Hub (CHC/DH) for electrolyte analyser
38.	Serum potassium[#]	Serum	Sample to be sent to Hub (CHC/DH) for electrolyte analyser
39.	Serum calcium[#]	Serum	Sample to be sent to Hub (CHC/DH) for electrolyte analyser
40.	Total T3	Serum	Sample to be collected and sent to DH for chemiluminescence analyzer
41.	Total T4/Free T4	Serum	Sample to be collected and sent to DH for chemiluminescence analyzer
42.	TSH (including for newborn screening)	Serum	Sample to be collected and sent to DH for chemiluminescence analyzer
43.	Glycosylated haemoglobin (HbA1C)	EDTA Whole blood	Sample to be collected and sent to DH for fully automated biochemistry analyser/HPLC
44.	Stool for occult blood	Stool	Manual
Microbiology			
45.	Smear for RTI/STDs[&]	Representative sample	Wet mounting, gram staining-microscope

46.	Urine M/E for pus cells	Urine	Microscopy
47.	Gram staining	Pus, body fluids	Microscopy
48.	Throat swab for diphtheria	Throat swab	Gram and Albert's stain, Microscopy
49.	Stool routine examination including ova and cyst	Stool	Microscopy
50.	Stool, pus, throat, blood and body fluids culture, and antimicrobial sensitivity	Respective sample	Sample collection and transport to DH
51.	Test for syphilis[@]	Serum/Plasma/Whole blood	RDT/Through dual kit for Syphilis and HIV
52.	rK39 test for Kala-Azar*	Serum	RDT
53.	CRP(including new born) (semiquantitative)	Serum	Semiquantitative analyzer Sample to be collected and sent to DH for turbidimetric based analyzer
Serology			
54.	RA factor (semiquantitative)	Serum	Semiquantitative analyzer Sample to be collected and sent to DH for turbidimetric based/ fully automated biochemistry analyzer
Specific Diseases			
55.	Peripheral blood smear for malaria parasite detection	Capillary/whole blood	Microscopy
56.	Malaria	Capillary/whole blood	RDT (Antigen based bivalent)
57.	Peripheral blood smear (thick smear) for filariasis*	Capillary blood	Microscopy
58.	Dengue	Serum	Sample to be collected and sent to DH for ELISA
59.	Japanese encephalitis*	Serum	Sample to be collected and sent to DH for ELISA
60.	Scrub Typhus IgM*	Serum	Sample to be collected and sent to DH for ELISA
61.	Sputum for TB-NAAT	Sputum collection in disposable sterile containers	Sample to be collected and sent to nearest NAAT center
62.	Sputum for Acid Fast Bacilli (AFB)	Sputum	Microscopy for follow up of TB treatment
63.	HIV test (Antibodies 1/2)[^@]	Serum/Plasma/Whole blood[@@]	RDT/ Through dual kit for Syphilis and HIV or single specific kit (HIV/Syphilis)
64.	HBs Antigen test for Hepatitis B	Whole blood	RDT
65.	Hepatitis C antibody test	Whole blood	RDT
Water quality testing			
66.	Water testing for faecal contamination	Water	H_2S strip test method

67.	Water testing for chlorination	water	Strip method/kit
Radiology			
68.	X-Ray		
Other tests			
69.	ECG		

*For endemic areas

#These tests may follow a hub-and-spoke model where analyzers are unavailable or for confirmation using fully automated analyser/indirect ion selective electrode analyzer. The nearest hub lab could be CHC and DH

**Blood glucose by semi-autoanalyser specifically for women with gestational diabetes

^ Test to be done for HIV screening after pre-test counselling

@Dual or combined test kit can be used

&*Neisseria gonorrhoeae,* Bacterial Vaginosis (*Gardnerella vaginalis*, *Mobiluncus mulieris,* etc.), *Haemophilus ducreyi,* Candida spp.; Wet mount - *Trichomonas vagnilis*

@@ Serum/Plasma: RPR kits for Syphilis; Whole blood: Dual kit for HIV and Syphilis

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	Diagnostic test	Specimen type	Equipment
Haematology			
1.	Haemoglobin	Capillary blood	Digital haemoglobinometer
2.	Peripheral blood smear	Capillary blood	Microscopy
3.	Total RBC count	EDTA whole blood	Microscopy/ Fully automated hematology analyzer
4.	Reticulocyte count	EDTA whole blood	Microscopy/ Fully automated hematology analyzer
5.	Absolute eosinophil count	EDTA whole blood	Microscopy/ Fully automated hematology analyzer
6.	Total leucocyte count	EDTA whole blood	Microscopy/ Fully automated hematology analyzer
7.	Differential leucocyte count	EDTA whole blood	Microscopy/ Fully automated hematology analyzer
8.	Platelet count	EDTA whole blood	Microscopy/ Fully automated hematology analyzer
9.	CBC	EDTA whole blood	Fully automated hematology analyzer
10.	ESR	EDTA whole blood	Manual/ ESR analyser
11.	Prothrombin time and INR	Plasma (citrate)	Automated coagulation analyser
12.	Bleeding time and clotting time	Whole blood	Manual
13.	Blood grouping and Rh typing	EDTA whole blood	Manual
14.	Blood cross matching	EDTA whole blood	Manual
15.	Packed Cell volume	EDTA whole blood	Fully automated haematology analyser
16.	Coomb's test-Direct with titre	EDTA whole blood	Sample to be collected and sent to DH for testing using manual method
17.	Coomb's test-Indirect with titre	EDTA whole blood	Sample to be collected and sent to DH for testing using manual method
18.	Activated partial thromboplastin time (APTT)	Plasma (citrate)	Sample to be collected and sent to DH for testing using automated coagulation analyser
19.	D-dimer	Plasma (citrate)	Sample to be collected and sent to DH for testing using coagulometer
20.	Plasma fibrinogen test	Plasma (citrate)	Sample to be collected and sent to DH for testing using coagulometer
21.	Test for sickle cell anemia and Thalassemia*	Capillary blood/ EDTA whole blood/DBS	RDT/POCT Confirmation: Sample to be collected & sent to DH for HPLC

			and electrophoresis
22.	Reduction test for screening G6PD deficiency*	EDTA whole blood	Sample to be collected and sent to DH for qualitative visual method
23.	Haemoglobinopathies screening/testing (in high prevalence areas)	EDTA whole blood and serum	Sample to be collected and sent to DH for HPLC and analyzer
24.	Haemoglobin electrophoresis	EDTA whole blood and serum	Sample to be collected and sent to DH for HPLC
Clinical pathology			
25.	Urine pregnancy test	Urine	RDT
26.	Urine albumin and glucose/ Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity and reaction (pH)	Urine	Dipstick (2-para/ (multiparameter urine strip)
27.	Urine microscopy	Urine	Microscopy
28.	Urine for microalbumin	Urine	Manual/Analyzer/ Turbidometer
29.	Urine for creatinine and Albumin to creatinine ratio (ACR)	Urine	Analyzer
30.	24- hrs urinary protein	Urine	Manual
31.	Visual inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
32.	Pap smear	Cervical smear	Sample to be sent to DH for microscopy
Biochemistry			
33.	Blood glucose	Capillary blood	Glucometer Fully automated biochemistry autoanalyzer**
34.	Glucose tolerance test (GTT)	Plasma (Fluoride Tube)	Fully automated biochemistry autoanalyzer
35.	Stool for occult blood	Stool	Manual
36.	**LFT**: Serum bilirubin (Total, direct, indirect)	Serum	Fully automated biochemistry autoanalyzer
37.	Serum ALT	Serum	Fully automated biochemistry autoanalyzer
38.	Serum AST	Serum	Fully automated biochemistry autoanalyzer
39.	Serum alkaline phosphatase	Serum	Fully automated biochemistry autoanalyzer
40.	Serum total protein	Serum	Fully automated biochemistry autoanalyzer
41.	Serum albumin and AG ratio	Serum	Fully automated biochemistry

			autoanalyzer
42.	Serum globulin	Serum	Fully automated biochemistry autoanalyzer
43.	Blood urea	Serum	Fully automated biochemistry autoanalyzer
44.	Serum creatinine	Serum	Fully automated biochemistry autoanalyzer
45.	Serum uric acid	Serum	Fully automated biochemistry autoanalyzer
46.	**Lipid Profile:** S. Total cholesterol	Serum	Fully automated biochemistry autoanalyzer
47.	S. Triglycerides	Serum	Fully automated biochemistry autoanalyzer
48.	S.HDL-C	Serum	Fully automated biochemistry autoanalyzer
49.	S.LDL-C	Serum	Fully automated biochemistry autoanalyzer
50.	Serum sodium	Serum	Electrolyte analyser (Indirect ion selective electrode)
51.	Serum potassium	Serum	Electrolyte analyser (Indirect ion selective electrode)
52.	Serum calcium	Serum	Fully automated biochemistry autoanalyzer
53.	Serum amylase	Serum	Fully automated biochemistry autoanalyzer
54.	Serum iron	Serum	Fully automated biochemistry autoanalyzer
55.	Serum magnesium	Serum	Electrolyte Analyser (Indirect ion selective electrode)
56.	Serum chlorides	Serum	Electrolyte Analyser (Indirect ion selective electrode)
57.	Serum phosphorous	Serum	Fully automated biochemistry autoanalyzer
58.	Total iron binding capacity	Serum	Fully automated biochemistry autoanalyzer
59.	Serum prolactin	Serum	Sample to be collected and sent to DH for chemiluminescence analyzer
60.	Serum ferritin	Serum	Sample to be collected and sent to DH and above for ELISA
61.	Total T3	Serum	Sample to be collected and sent to DH for chemiluminescence analyzer
62.	Total T4/Free T4	Serum	Sample to be collected and sent to DH for chemiluminescence analyzer
63.	TSH (including for newborn screening)	Serum	Sample to be collected and sent to DH for chemiluminescence

			analyzer
64.	Troponin I	Serum	RDT (If a physician is available at the CHC, troponin I testing may be included)
65.	Troponin T	Serum	RDT (If a physician is available at the CHC, troponin T testing may be included)
66.	Glycosylated haemoglobin (HbA1C)	EDTA Whole blood	Sample to be collected and sent to DH for turbidimetric based/ Fully automated biochemistry analyser/HPLC
Microbiology			
67.	Smear for RTI/STDs[&]	Representative sample	Wet mounting, gram staining-microscope
68.	Urine M/E for pus cells	Urine	Microscopy
69.	Smear examination for *Mycobacterium leprae*	Slit skin smear	Microscopy
70.	Gram staining	Pus, body fluids	Microscopy
71.	Throat swab for diphtheria	Throat swab	Gram and Albert's stain, Microscopy
72.	Hanging drop test for *V. cholera*	Stool	Microscopy
73.	Stool routine examination including ova and cyst	Stool	Microscopy
74.	Stool, pus, throat, blood and body fluids culture, and antimicrobial sensitivity	Stool, pus, blood, throat swab, and body fluids	Samples to be collected and sent to DH for manual/ automated analyzer
75.	Test for syphilis[@]	Serum/Plasma/Whole blood	RDT/Through dual kit for Syphilis and HIV
76.	rK39 test for Kala-Azar*	Serum	RDT
77.	CRP(including new born) (quantitative)	Serum	Fully automated analyzer Sample to be collected and sent to DH for turbidimetric based analyzer
Serology			
78.	RA factor (quantitative)	Serum	Fully automated analyzer Sample to be collected and sent to DH for turbidimetric based/ Fully automated biochemistry analyzer
Specific Diseases			
79.	Peripheral blood smear for malaria detection	Capillary blood	Microscopy
80.	Malaria	Capillary/whole blood	RDT (antigen based bivalent)
81.	Peripheral blood smear (thick smear) for filariasis*	Capillary blood	Microscopy

82.	Dengue	Serum	Sample to be collected and sent to DH for ELISA
83.	Japanese encephalitis*	Serum	Sample to be collected and sent to DH for ELISA
84.	Scrub Typhus IgM*	Serum	Sample to be collected and sent to DH for ELISA
85.	TB infection testing		Tuberculosis skin test (TST)/ TB infection skin test using *M.tuberculosis*-specific antigen
86.	Sputum for Acid Fast Bacilli (AFB)	Sputum	Microscopy for follow up of TB treatment
87.	Sputum for TB-NAAT	Pulmonary and extra pulmonary fluid specimen[v]	NAAT
88.	HIV test (Antibodies 1/2)[^]	Serum/Plasma/Whole blood[@@]	RDT/ Through dual kit for Syphilis and HIV or single specific kit (HIV/Syphilis)
89.	HBs Ag test for Hepatitis B	Serum	RDT
90.	Hepatitis C (Anti HCV)	Serum	RDT
Water quality testing			
91.	Water testing for faecal contamination	Water	H_2S strip test method
92.	Water testing for chlorination	water	Strip method//kit
Radiology			
93.	X-Ray		
94.	USG with color Doppler (with Trans Vaginal Probe)		
Other tests			
95.	ECG		
96.	Dental X-ray/Intra Oral periapical IOPA X-Ray		
97.	Orthopantomogram (OPG)		

*For endemic areas

[@]Dual or combined test kit can be used

**Blood glucose by automated analyser specifically for women with gestational diabetes

^ Test to be done for HIV screening after pre-test counselling

[&]*Neisseria gonorrhoeae,* Bacterial Vaginosis (*Gardnerella vaginalis*, *Mobiluncus mulieris,* etc.), *Haemophilus ducreyi,* Candida spp.; Wet mount - *Trichomonas vagnilis*

[V]Biopsy specimen needing homogenization to be sent to nearest IRL/ State level laboratory

[@@] Serum/Plasma: RPR kits for Syphilis; Whole blood: Dual kit for HIV and Syphilis

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

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

S.No	Diagnostic test	Specimen type	Equipment
Haematology			
1.	Haemoglobin estimation	Capillary blood/ EDTA Whole blood	Digital haemoglobinometer/ Fully automated haematology analyser
2.	Peripheral blood smear	Capillary blood	Microscopy
3.	Reticulocyte count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
4.	Absolute eosinophil count	EDTA whole blood	Microscopy/ Fully automated haematology analyser
5.	CBC (Total RBC count, Total leucocyte count, Differential leucocyte count, Platelet count, Packed Cell volume etc)	EDTA whole blood	Fully automated haematology analyser
6.	ESR	EDTA whole blood	Manual /ESR analyser
7.	Prothrombin time and INR	Plasma (citrate)	Automated coagulation analyser
8.	Activated partial thromboplastin time (APTT)	Plasma (citrate)	Automated coagulation analyser
9.	D-dimer	Plasma (citrate)	Coagulometer
10.	Plasma fibrinogen test	Plasma (citrate)	Coagulometer
11.	Bleeding time and clotting time	Whole blood	Manual
12.	Blood grouping and Rh typing	EDTA whole blood	Manual
13.	Blood cross matching	EDTA whole blood	Manual
14.	Coomb's test-Direct with titre	EDTA whole blood	Manual
15.	Coomb's test-Indirect with titre	EDTA whole blood	Manual
16.	Bone marrow aspiration	Bone marrow Aspiration	Microscopy
17.	Sickle cell test*	EDTA whole blood and serum	Screening: RDT Confirmatory: Electrophoresis
18.	Reduction test for screening G6PD deficiency*	EDTA whole blood	Qualitative visual method
19.	Thalassemia	EDTA whole blood and serum	POCT/HPLC

20.	Mixing study and Factor VIII Assay for Hemophilia	Whole blood in sodium citrate (1:9)	Automated coagulation analyser
21.	Mixing study and Factor XI Assay for Hemophilia	Whole blood in sodium citrate (1:9)	Automated coagulation analyser
22.	Haemoglobinopathies screening/testing (in high prevalence areas)	EDTA whole blood and serum	HPLC
23.	Haemoglobin electrophoresis	EDTA Whole blood and serum	HPLC
Clinical pathology			
24.	Urine pregnancy test	Urine	RDT
25.	Urine albumin and glucose/ Haemoglobin, bile salts, bile pigments, ketone bodies, specific gravity and reaction (pH)	Urine	Dipstick (2-para/ (multiparameter urine strip)
26.	Urine microscopy	Urine	Microscopy
27.	24-hours urinary protein	Urine	Manual/Analyzer
28.	Urine for microalbumin	Urine	Analyzer
29.	Urine for creatinine and Albumin to creatinine ratio (ACR)	Urine	Analyzer
30.	Vaginal smear for presence of sperms (Medico Legal Case)	Vaginal smear	Microscopy (Samples to be sent to SFSL/CFSL as per guideline)[6]
31.	Visual inspection acetic acid	Visual examination using vaginal speculum	Vaginal speculum
32.	Pap smear	Cervical smear	Microscopy
33.	Sputum cytology	Sputum	Microscopy
34.	Histopathology	Tissue biopsy	Microscopy
35.	Cytology - FNAC	Aspirate	Microscopy
36.	Semen analysis (morphology, vitality, pH, fructose (Qualitative) and viscocity	Semen	Microscopy/10 micron depth chamber
37.	Fluid analysis (cell count, biochemistry and cytology)	Fluid	Fully automated biochemistry and haematology analyser, Microscopy
Biochemistry			
38.	Blood glucose	Capillary blood Plasma (Fluoride Tube)	Glucometer and fully automated biochemistry autoanalyzer

39.	Glucose tolerance test (GTT)	Plasma (Fluoride Tube)	Fully automated biochemistry autoanalyzer
40.	Stool for occult blood	Stool	Manual
41.	**LFT**: Bilirubin (Total, direct, indirect)	Serum	Fully automated biochemistry autoanalyzer
42.	Serum ALT	Serum	Fully automated biochemistry autoanalyzer
43.	Serum AST	Serum	Fully automated biochemistry autoanalyzer
44.	Alkaline phosphatase	Serum	Fully automated biochemistry autoanalyzer
45.	Serum total protein	Serum	Fully automated biochemistry autoanalyzer
46.	Serum albumin	Serum	Fully automated biochemistry analyser
47.	Serum globulin	Serum	Fully automated biochemistry autoanalyzer
48.	Serum albumin and AG ratio	Serum	Fully automated biochemistry autoanalyzer
49.	Blood urea	Serum	Fully automated biochemistry autoanalyzer
50.	Serum creatinine	Serum	Fully automated biochemistry autoanalyzer
51.	Serum uric acid	Serum	Fully automated biochemistry autoanalyzer
52.	**Lipid profile:** Total cholesterol	Serum	Fully automated biochemistry autoanalyzer
53.	Serum triglycerides	Serum	Fully automated biochemistry autoanalyzer
54.	S.HDL-C	Serum	Fully automated biochemistry autoanalyzer
55.	S.LDL-C	Serum	Fully automated biochemistry autoanalyzer
56.	Serum amylase	Serum	Fully automated biochemistry autoanalyzer
57.	Serum lipase	Serum	Fully automated biochemistry analyser
58.	Serum sodium	Serum	Electrolyte analyser (Indirect ion selective electrode)
59.	Serum potassium	Serum	Electrolyte analyser (Indirect ion selective electrode)
60.	Serum calcium	Serum	Fully automated biochemistry autoanalyzer
61.	Serum chlorides	Serum	Electrolyte analyser (Indirect ion selective electrode)
62.	Serum phosphorous	Serum	Fully automated biochemistry autoanalyzer
63.	Serum magnesium	Serum	Fully automated biochemistry autoanalyzer

64.	Serum iron	Serum	Fully automated biochemistry autoanalyzer
65.	Total iron binding capacity	Serum	Fully automated biochemistry autoanalyzer
66.	Serum ionized calcium	Serum	Electrolyte analyzer
67.	Blood gases analysis	Serum	Blood gas analyser
68.	LDH	Serum	Fully automated biochemistry analyser
69.	Serum ferritin	EDTA whole blood/Serum	Chemiluminescence analyzer
70.	Total T3	Serum	Chemiluminescence analyzer
71.	Total T4/Free T4	Serum	Chemiluminescence analyzer
72.	TSH (including for newborn screening)	Serum	Chemiluminescence analyzer
73.	Serum thyroid peroxidase antibody	Serum	Chemiluminescence analyzer
74.	Troponin I	Serum	Immunoassay analyser/RDT
75.	Troponin T	Serum	Immunoassay analyser/RDT
76.	Creatine phosphokinase (CPK)	Serum	Fully automated biochemistry analyser
77.	Procalcitonin	Serum/Plasma	RDT/Immunoassay
78.	CSF analysis (sugar, protein, cell count)	CSF	Fully automated biochemistry analyser
79.	Creatine Kinase-muscle/brain (CK-MB)	Serum	Fully automated biochemistry analyser
80.	Prostate-specific antigen (PSA)	Serum	ELISA/ Chemiluminescence analyser
81.	Serum lithium	Serum	Electrolyte analyzer/ Fully automated analyser
82.	Nt-ProBNP (N-terminal pro-brain natriuretic peptide)	Serum	Fully automated analyser/ Chemiluminescence analyser
83.	Serum beta HCG	Serum	Chemiluminescence analyzer
84.	Serum prolactin	Serum	Chemiluminescence analyzer
85.	Serum FSH	Serum	Chemiluminescence analyzer
86.	Serum LH	Serum	Chemiluminescence analyzer
87.	Serum estradiol	Serum	Chemiluminescence analyzer
88.	Serum total testosterone	Serum	Chemiluminescence analyzer
89.	S. Alfa feto protein	Serum	Chemiluminescence analyzer
90.	S. CA-125	Serum	Chemiluminescence analyzer
91.	S. CEA	Serum	Chemiluminescence analyzer
92.	S. Vitamin D (25 Hydroxy)	Serum	Chemiluminescence analyzer
93.	S. Vitamin B12	Serum	Chemiluminescence analyzer

94.	Total IgE	Serum	Fully automated analyser
95.	Glycosylated haemoglobin (HbA1C)	EDTA Whole blood	Fully automated biochemistry analyser/HPLC Machine
96.	Protein electrophoresis	Serum	Electrophoresis machine
Microbiology			
97.	Smear for RTI/STDs[&]	Representative sample	Wet mounting, gram staining-microscope
98.	Urine M/E for pus cells	Urine	Microscopy
99.	Smear examination for *Mycobacterium leprae*	Slit skin smear	Microscopy
100.	Gram staining	Pus, body fluids	Microscopy
101.	Throat swab for diphtheria	Throat swab	Gram and Albert's stain, Microscopy
102.	Hanging drop test for *V. cholera*	Stool	Microscopy
103.	Stool routine examination including ova and cyst	Stool	Microscopy
104.	Gram stain for meningococci	Fluid, CSF cell type, cell count	Microscopy
105.	Rapid antigen detection test for bacterial meningitis	CSF	RDT
106.	KOH study for fungus	Sputum, Tissue, Nail, Hair, CSF etc.	Fluorescent microscopy/Microscopy
107.	Blood culture and antimicrobial sensitivity	Whole Blood	Automated/Manual
108.	Urine, stool, pus, CSF and other sterile body fluids, throat swab-culture and antimicrobial sensitivity	Representative sample	Automated/Manual
109.	Stool culture for *Vibrio cholera* and other bacterial enteropathogens	Stool	Automated/Manual
110.	Culture for diphtheria	nose, throat, membrane or nasopharynx swab	Automated/Manual
111.	Fungal culture	Representative sample	Automated/Manual
112.	Cholera	Stool	RDT
113.	Test for syphilis[@]	Serum/Plasma/Whole blood	RDT
114.	rK39 test for Kala-Azar*	Serum	RDT
115.	IgM for measles	Serum	ELISA
116.	C-reactive protein (CRP)	Serum	Turbidimeter
117.	TORCH: Toxoplasma, Rubella, CMV and HSV 1 and 2. Antibody detection test (IgM and IgG)	Serum	ELISA
118.	Corneal scraping for microbial keratitis[$]	Corneal scraping	Binocular microscope

Serology			
119.	Rheumatoid factor quantitative	Serum	Turbidometer /Fully automated analyser
120.	Antistreptolysin O quantitative	Serum	Turbidometer /Fully automated analyser
Specific Diseases			
121.	Peripheral blood smear for malaria detection	Capillary blood	Microscopy
122.	Malaria	Capillary/whole blood	RDT (Antigen based bivalent)
123.	Peripheral blood smear (thick smear) for filariasis*	Capillary blood	Microscopy
124.	Dengue	Serum	ELISA
125.	Japanese encephalitis IgM, antibody test	CSF, Serum	ELISA
126.	Chikungunya IgM, antibody test	Serum	ELISA
127.	Scrub Typhus IgM*	Serum	ELISA
128.	Leptospirosis IgM, antibody test	Serum	RDT and ELISA
129.	TB infection testing		Tuberculosis skin test (TST)/ TB infection skin test using *M.tuberculosis*-specific antigen
130.	Sputum for Acid Fast Bacilli (AFB)	Sputum	Microscopy for follow up of Tb Treatment
131.	TB diagnosis	Pulmonary and extra pulmonary fluid specimen[v]	NAAT
132.	TB culture (liquid)	Sputum, fluid etc.	Sample to be collected and sent to nearest to nearest IRL/ State level laboratory
133.	TB DST	Sputum, fluid etc.	Sample to be collected and sent to nearest to nearest IRL/ State level laboratory
134.	Line Probe Assays (LPAs) for drug resistance testing (DRT)	Sputum for Pulmonary TB/Extrapulmonary sample for Extrapulmonary TB	Sample to be collected and sent to NTEP certified culture & DST laboratories located in Medical colleges at district level/ nearest IRL, where samples are transported from the linked NAAT sites.
135.	HIV test (Antibodies 1/2)^	Serum/Plasma/Whole blood[@@]	RDT/ Through dual kit for Syphilis and HIV or single specific kit (HIV/Syphilis) and ELISA

136.	HIV: CD4 count[#]	Capillary/venous whole blood	Flow cytometry
137.	HIV: Early infant diagnosis	Dried blood spot (DBS)/Plasma/Whole blood[&]	Sample to be collected and sent to tertiary care for molecular testing
138.	HIV: Quantitative virological nucleic acid test	Plasma/Whole blood[&]	Sample to be collected and sent to tertiary care for PCR
139.	Hepatitis A IgM detection test	Serum	ELISA
140.	Hepatitis B surface antigen test	Serum	RDT and ELISA
141.	Hepatitis B : Quantitative test for viral load detection	Whole blood	Sample to be collected and sent to tertiary care for PCR
142.	Hepatitis C: Anti HCV (Total)	Serum	ELISA
143.	Hepatitis C: Quantitative test for viral load detection	Whole blood	Sample to be sent to tertiary care for PCR
144.	Hepatitis E: IgM detection test	Serum	ELISA
145.	HBc (Core antibodies): IgM detection test to hepatitis B core antigen	Serum	ELISA
Radiology (as per IPHS)**			
146.	X-Ray (Digital)		
147.	CT scan (with angiography capability; Pressure Injector)		
148.	MRI		
149.	USG with Color doppler (with Trans Vaginal probe)		
Other tests (as per IPHS)			
150.	TB:visual acuity, color vision test (for introduction of BPaLM treatment regimen)		
151.	ECG		
152.	C –Arm		
153.	Dental X-ray/Intra Oral periapical IOPA X-Ray		
154.	Orthopantomogram (OPG)		
155.	Echocardiography		
156.	Mammography		
157.	EEG		
158.	NCV(Nerve Conduction Velocity)		
159.	EMG		
160.	TMT		
161.	PFT		
162.	Ocular Coherence Tomography		

163.	Perimetry (automated)
164.	Pachymetry
165.	Refraction

*: For endemic areas

[#]Only where ART centres are located

^ Test to be done for HIV screening after pre-test counselling

[&] For whole blood sample: Freshly drawn specimens (whole blood) may be held at 15 to 30°C for up to 6 hours or at 2 to 8°C for up to 24 hours, prior to centrifugation

[&]*Neisseria gonorrhoeae,* Bacterial vaginosis (*Gardnerella vaginalis*, *Mobiluncus mulieris,* etc.), *Haemophilus ducreyi,* Candida spp.; Wet mount - *Trichomonas vagnilis*

[V]Biopsy specimen needing homogenization to be sent to nearest IRL/ State level laboratory

**Radiology department should have PACS to support teleradiology

@@ Serum/Plasma: RPR kits for Syphilis; Whole blood: Dual kit for HIV and Syphilis

[$]As per specialist availability

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

The following tests may be conducted at district hospitals that have been converted into medical colleges, provided the necessary infrastructure and human resources are available to support them. In absence of the latter, services may be procured from regional or nearest medical institutes or private providers. The list is mentioned below

Biochemistry	**Microbiology**	**Clinical Pathology**
Therapeutic drug monitoring (TDM)	Molecular tests	Cytopathology
Adenosine deaminase (ADA) estimation	Automated ID system for bacteria	Immunohistochemistry
Inborn errors of metabolism	Anaerobic culture	Molecular onco-pathology
	Parasitology referral culture	
	Therapeutic drug monitoring: Antibacterial and antifungal drugs	

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 under the Drugs and Cosmetics Act, 1940 and Medical Device Rules, 2017.[7] All medical devices/*in vitro* diagnostics are required to conform to the standards: **(1)** The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time. **(2)** Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC) or American Standard Test Method (ASTM), or by any other pharmacopoeial standards. **(3)** In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), 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 Medical Device for Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus, Syphilis, Blood Grouping, RT-PCR Kits for Diagnosis of Covid-19, Ribonucleic acid (RNA) Extraction Kits for Diagnosis of Covid-19, Viral Transport Medium (VTM) for Diagnosis of Covid-19, RTLAMP Kit for diagnosis of Covid-19, Glucose Test Strip and Fully Automated Analyser Based Glucose Reagent and Glucometer. The institute has been designated as a National Reference Laboratory (NRL) of National AIDS Control Organization (NACO), India and is monitoring its two states, Uttar Pradesh and Uttarakhand for strengthening HIV testing. 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%.

The criteria for evaluation of RT-PCR COVID kits are Sn≥95% Sp≥99%. 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, Chikungunya, 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 samples from three consecutive batches of such IVD products should be forwarded to NIB (NOIDA) or other notified laboratory. The Performance Evaluation Report (PER) should be submitted to both CDSCO and the concerned State Drugs Control Authority. Typically, a 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.

To increase the IVD validation capacity and to streamline the process of Performance Evaluation of IVDs, CDSCO has made a MoU with ICMR to develop harmonized protocol and to identify testing laboratories of high risk IVDs. The Indian Council of Medical Research (ICMR), in collaboration with the Central Drugs Standard Control Organisation (CDSCO) and other relevant stakeholders, has recently published a comprehensive validation protocol for rapid diagnostic tests aimed at pathogen identification and antimicrobial

susceptibility testing (AST).[8] These protocols provide a clear, systematic approach for innovators and developers to evaluate the performance and efficacy of their diagnostic tools in line with regulatory standards.

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) launched in 2015 under the umbrella of PvPI.[9] There are 501 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 including IVDs.

References:

1. National Essential Diagnostics List. New Delhi: Indian Council of Medical Research; 2019. Available from: https://www.icmr.gov.in/icmrobject/custom_data/pdf/resource-guidelines/NEDL_2019.pdf
2. Free Diagnostic service initiative, National Health Mission. Available at https://nhsrcindia.org/sites/default/files/2021-05/Free-Diagnostics-Service-Initiative.pdf.
3. Free Diagnostic service initiative, National Health Mission. 2019. Guidance document for implementing laboratory services in States. https://nhsrcindia.org/sites/default/files/2021-07/Guidance_document_for_Free_Laboratory_Services.pdf
4. Indian Public Health Standards (IPHS) guidelines 2022. Available at https://nhsrcindia.org/IPHS2022/iphs-2022-guidelines.
5. Guidelines on Integrated Public Health Laboratory, 2021. Available at https://nhsrcindia.org/sites/default/files/Guidelines%20on%20integrated%20public%20health%20laboratories_dt%2007%20jan.pdf.
6. GUIDELINES & PROTOCOLS. 2014. Medico-legal care for survivors/victims of sexual violence. Ministry of Health and Family Welfare. Available at https://mohfw.gov.in/sites/default/files/953522324.pdf
7. Medical Device rule, 2017. Available at https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf
8. Guidance document validation of rapid diagnostics for pathogen identification and antimicrobial susceptibility testing (AST), 2025. Available at https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1736941384_guidancedocument_amrdiagnostics_revised.pdf
9. Medical Devices Adverse Event Reporting Tools. Available at https://ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/mvpi-toolkit.html

Annexure I

Recommended list of human resource for different levels of healthcare

S.No	Village level	AAM-SC	PHC	CHC	SDH-DH
1.	Auxiliary Nurse-Midwife (ANM)	Community Health Officer (CHO)	Medical Officer (MO) MBBS	Nursing In Charge (Administrative cum clinical staff)	Specialist (Pathologist, Microbiologist, Biochemist, Cardiologist, Oncologist. Gastroenterologist, Neonatologist, Nephrologist, Urologist, Neurologist, Obstetrician & Gynecologist, Paediatrician, Medicine, Ophthalmologist, Orthopaedician, ENT, Dentist, Radiologist
2.	Accredited Social Health Activist (ASHA)	Medical Officer*	MO Dental	Specialist (Physician/Family Medicine Specialist, Obstetrician &Gynaecologist, Paediatrician, Ophthalmologist, Orthopaedician, ENT, Microbiologists/ Pathologists/Biochemist	Psychiatrist and Community Nurse (NMHP)
3.	NGO	Staff Nurse	Staff nurse	MO Dental	Lab Technician
4.		Auxiliary Nurse-Midwife (ANM)	Lab Technician	GDMO	Technicians (ECG, EEG, dental, Cytology, ophthalmic, radiology)
5.		Accredited Social Health Activist (ASHA)	Optometrist/ Ophthalmic Assistant/ Vision Technician	Lab Technician	
6.		Multi Purpose Worker MPW Male/Female	Auxiliary Nurse-Midwife (ANM)	Radiology and Imaging Technologist/Radiology Technician	
7.		Auxiliary Nurse-Midwife (ANM)	Health Worker/ Health Assistant (Male and female)		

*Urban SC

NMHP: National Mental Health Programme; NGO: Non-governmental organization

Annexure II

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

	Village level	AAM Sub-Centre	PHC	CHC	DH
1	Glucometer	Glucometer	Glucometer	Glucometer	Glucometer
2		Hemoglobinometer	Hemoglobinometer	Haemoglobinometer	Haemoglobinometer
			3-Part hematology analyzer	Fully automated hematology analyser	Fully automated hematology analyser
			ESR analyser	ESR analyzer	ESR analyser
3			Microscopy	Microscopy	-Microscope -Fluorescent microscope
4				Turbidometer	Turbidometer
5			Semi-automated biochemistry analyzer	Fully automated biochemistry analyzer	Fully automated biochemistry analyser
6				Automated coagulation analyser	Automated coagulation analyser
					Electrolyte analyzer (Indirect ion selective electrode)
					Urine analyser
7					ELISA reader (Fully automated)
10					Chemiluminescence analyser (Fully automated)
					Blood gas analyser
12					Electrophoresis machine/HPLC machine
13				Nucleic Acid Amplification Test (NAAT)	Nucleic Acid Amplification Test (NAAT)
14					Flow cytometry (where ART centres are located)

The other routine equipments to be made available at various levels of healthcare as per the guidance of Indian Public Health Standards (IPHS) 2022

Annexure III

Relevant guidance documents

A. Samples collection, transportation and waste management

a) Guidelines for bivalent RDT. https://ncvbdc.mohfw.gov.in/WriteReadData/l892s/guidelines-for-bivalent-rdt.pdf

b) National guidelines for HIV-1 viral load laboratory testing. (2018) https://www.naco.gov.in/sites/default/files/NationalGuidelinesForHIV-1ViralLoadLaboratoryTestingApril2018%20%282%29.pdf

c) National laboratory guidelines for testing of viral hepatitis. (2018) https://www.inasl.org.in/national-laboratory-guidelines.pdf

d) Guidelines for clinical management of *Japanese Encephalitis*. https://nvbdcp.gov.in/WriteReadData/l892s/Clinical_Management-JE.pdf

e) Biomedical waste management rules. (2016) https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Bio-medical_Waste_Management_Rules_2016.pdf

f) Biomedical waste management rules. (2016) (Amended) 2018 https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Amendment_BMWM_Rules2018.pdf

B. 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

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Leadership

Dr Rajiv Bahl, Secretary, Department of Health Research (DHR) & Director General, ICMR
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