TECHNICAL SPECIFICATIONS OF DIAGNOSTIC EQUIPMENT

Integrated Public Health Laboratory

TABLE OF CONTENTS

BACKGROUND

Ministry of Health and Family Welfare, after several rounds of discussion with the experts and also various concerned departments and Ministries took a policy decision for integrating all lab services running in the district under Integrated Public Health Laboratories (IPHL) which is also a component under recently rolled out Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM).

The concept of Integrated Public Health Laboratories contemplates setting up cost-effective laboratory systems that provide patient centric services, round the clock assured in-house functional quality lab services. The Integrated Public Health Laboratories will strengthen the diagnostic services comprehensively in a district with defined upward and assured downward linkages.

Presently, the multiple laboratories functioning within the district hospitals under various programs functioning in silos needs integration for synergised health outcome. This type of integration is critical for improving laboratory efficiency and reducing duplication of resources particularly infrastructure, equipment, human resources, as well as equipping laboratories for improved readiness and responsiveness to emerging diseases.

An effective IPHL will integrate clinical and public health requirements, with a scope of collecting and testing clinical specimens of human origin as well as samples of water, food and environment during outbreaks and, reporting the information in real time as part of public health surveillance systems and bringing all the programmes under one umbrella.

The type of tests and the equipment requirement for establishing the IPHL are explained in detail in the guidelines on Integrated Public Health Laboratories, access-https://nhsrcindia.org/sites/default/files/Guidelines%20on%20integrated%20public%20health%20laboratories_dt%2007%20jan.pdf

Purpose of the Document

This document on technical specifications of IPHL diagnostic laboratory equipment will serve as a reference for the state and district officials in organizing and setting up district IPHLs across the country. The document will also provide guidance to the state and district level committees for procuring quality laboratory equipment and accessories in compliance to the Indian Standards (IS) and thereby ensuring safety in operations.

Methodology

In light of the recent advancements and availability of plethora of vendors supplying various types of equipment, standard technical specifications for the diagnostic equipment under IPHL was urgently required. HCT division a WHO Collaborating Centre for priority medical devices at National Health Systems Resource Centre New Delhi conceived the first draft technical specifications based on WHO technical specification template for all the laboratory diagnostic equipment required for functioning of the IPHL. Development partners (CDC, PATH, JHPIEGO, FIND, etc) collaborated with NHSRC and held various consultative meetings before finalising the draft technical specifications.

Development partners (CDC, PATH, JHPIEGO, FIND, etc) supported the initiative and shared valuable inputs on the draft specifications with their respective field experience in working with states. An expert group consisting of subject experts, development partners under the chairpersonship of Advisor, HCT, NHSRC assembled virtually and physically to formulate the technical specifications of the 37 key diagnostic equipment. The consultative meeting with the expert group consisting of bio-medical engineers, pathologists, microbiologists, and public health experts evaluated the draft technical specifications considering the recent advances made in the diagnostic sector with valuable inputs from IDSP, NCDC, academic institutions like PGI Rohtak, AIIMS Bathinda, Sri Lal bahadur Shastri GMC.

EQUIPMENT MAINTENANCE

Technical specifications play an important role in identification, selection and procurement of appropriate and cost-effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment.

In the consultative meeting experts has mentioned the following activities which needs to be considered wisely while procuring any medical device.

(1) The public health facility that intend to house medical devices (especially electrical/electronic based) must ensure before installation:

(a) Proper earthing of electrical sockets

(b) Voltage stabilizer/surge protector is recommended with equipment operations for preventing malfunction due to voltage fluctuations.

(c) Well ventilated and illuminated workstation with heavy duty exhaust fans or Air conditioner (HVAC) is recommended for optimal equipment functionality.

(d) DOs & DONTs for safe operations of the equipment (as per manufacturers recommendations) must be affixed over each equipment.

(2) Appropriate filtering mechanism to be housed at public facility to ensure maximum useful life of medical devices for improved health outcomes.

(3) Ensure compliance for medical devices which are regulated under various laws/regulatory body like CDSCO, AERB, Pollution control Board, PC PNDT, PESO etc.

(4) Equipment calibration and preventive maintenance (incl. replacement of parts that are expected to be worn out after certain operation) as recommended in medical device manufactures operational/service manual must be ensured periodically.

(5) Warning/safety information must be placed on the medical devices for safe operation.

(6) User/In-house service training to be ensured while installation of any new equipment for its extended useful life of the equipment.

(7) Public health facility may actively engage with Post market surveillance under Materiovigilance program of India initiative under MoHFW for reporting adverse events related to use of medical devices in the prescribed Medical Device Adverse Event (MDAE) Form.

CLASS-II BIOLOGICAL SAFETY CABINET

Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Class-II Biological Safety Cabinet
GMDNS code(s)		20653
GENERAL		
1. USE		
1.1	**Clinical purpose**	A furniture-like device designed as a partial or total enclosure to provide a class II biosafety level (BSL) to the operator, the product, and the environment during the manipulation of microorganisms and other biological hazardous materials (usually up to category 3 pathogens). It is used for handling cell cultures and human pathogens (e.g., bacteria, viruses, parasites) and other biohazardous materials, extremely toxic agents (e.g., chemotherapy drugs), and also for tissue culture and tumour virus work.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Type: BIOSAFETY CABINET, CLASS II A2 (As per NSF guidelines) • The HEPA filter should have rated efficiency of more than 99% at 0.3 microns. • It should provide laminar airflow descending vertically downwards. • The motor for the air flow should have automated setting for the air flow speed to ensure continuous safe working condition. Air flow should be as per NSF regulation (Class II A2) • Fluorescent lamp for lighting of the interior of the cabinet. Light Intensity: 650 lux or more over the entire work surface. • Construction: Main body, side and rear panel: Electro - galvanized Steel or Mild Steel, oven baked epoxy powder coated finish. The internal cabinet material should be 300-series stainless steel and should provide a seamless and scratch free worksurface. • Front panels construction: Removable laminated safety and tempered glass for protection against leakage of UV rays and potential hazards materials. • The front sash opening should range between 8-12 inches and should be specified on the cabinet. Incase UV lamp is inbuilt, the closing/opening of the door

		should automatically be switched off if the front door is open. • Alarm system: Audio visual Safety alarms/safety display for low air velocity, faulted exhaust fan and incorrect sash height shall be required to indicate within 15 seconds. • Fluorescent lamp for lighting of the interior of the cabinet. Light intensity: 650 lux or more over the entire work surface. • Switches and indicators: Individual switches and indicator lamps for blower motor, florescent lamp, and UV lamp. • Differential pressure gauge (scale display in Pascals). The cabinet should use a pressure sensor to detect pressure drop across the supply filter. • Other fittings required for Attaching auxiliary services: Electrical outlet socket (5 ampere rating) qty: 2 numbers • Pre Filters: Filtration efficiency of 98% for all types of particle sizes 8 micron and larger. • The equipment should provide product, operator and environmental protection and must be certified to NSF/ANSI 49. The cabinet must have a data plate and NSF certification label. • A data plate(s) indicating the following shall be readily visible on the front of the cabinet: o Manufacturer's name and address o Cabinet model o Cabinet serial number o Type classification o Voltage requirements o Dimensions of cabinet o Method of field certification o Allowable ranges for Downflow Velocity Inflow • The minimum average inflow velocity should be 100ft/min and downflow velocity 50-80ft/min, it may vary according to model. • Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) certification and calibration- at the time of installation and annually during warranty period.
2.2	**User's interface**	Display for various indicators
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	4 feet width
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise level: < 60 dBA.

3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS with a minimum backup time of one hour
4.3	**Protection**	1. Resettable overcurrent breaker shall be fitted for protection 2. Voltage corrector/stabilizer of appropriate ratings.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	• Exterior exhaust filter guard • Spare fluorescent lamp.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		

9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

CELL COUNTER AUTOMATIC (5 PART)		
Version no. :		Ver._1
Date:		
Done By (Name/Institution		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological Cell Analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, red cell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Five-part differential with reticulocyte count based on the principle of flow cytometry including minimum 24 parameters with two histograms and scattergrams for RBC and PLT: BASO, WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, RBC, HCT,MCV, RDW-SD, RDW-CV, HGB, MCH, MCHC, PLT, PCT, MPV, PDW-SD, PDW-CV. • Advanced, integrated self-cleaning system. • Stores minimum 25,000 test results with histograms and scattergrams. • Sample Material - EDTA blood with atleast pre-diluted mode and whole blood mode. • Integrates with common practice management systems including cleaning of apertures, tube systems and calibration. • Should be able to perform all parameters on variable sample volume for adult and pediatric patients. • Should be able to avoid micro-RBCs interference in platelet count. • System must have throughput of atleast 60 or more samples per hour. • Should be equipped with automatic sample loading, mixing and testing. Also have manual mode and STAT modes along with Random access for individual samples. • Open system • Pre-diluted mode and whole blood mode • QC Mode LJ, SD, CV, QC histogram. • Provision for bi-directional LIS interface should be

		available. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	Touch screen and PC
2.3	**Software and/or standard of communication (wherever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS System with minimum back up time of one hour.
4.6	**Protection**	N/A
4.7	**Power consumption**	As specified by the manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	• 2D-Barcode/QR Code Scanner. • PC, Keyboard, Printer • Reagents: All the reagents required for 1000 tests should be supplied with the equipment along with one set of tri level control.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical,paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landlinenumber)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

CELL COUNTER SEMI-AUTOMATIC (3 PART)

Version no.:		Ver._1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological cell analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, red cell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The system should have End point, kinetic, fixed time and turbidimetric mode. • The system should be capable of 3 part WBC differential, estimating minimum 18 parameters with linearity (WBC, TC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW- SD/RDW-CV, PLT, MPV, Pt Crit, PDW, PLCR optional). • The system should have memory of minimum 10000 patient samples. • The system should have high intensity LED source for Hb estimation. • The system should have dual mode – flow cell and cuvette. Non-cyanide based is preferable. • External keyboard. • Automated standby and wake up. • Auto probe cleaning and sample dilution preferable. • System must have throughput of at least 60 samples per hour. • QC Mode: LJ, SD, CV, QC histogram • Provision for Bar Code/QR code reading should be available • Built-in voltage stabilizer and test results printing facility. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Touch screen (Coloured) • Provision for bi-directional LIS/HIS interface should be available.

2.3	**Software and/or standard of communication (wherever required)**	To be provided by manufacturer
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	N/A
3.2	**Weight (lbs, kg)**	N/A
3.4	**Noise (in dBA)**	N/A
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary laboratory Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS system with minimum 1 hour back up
4.7	**Protection**	Internal electrical protection
4.8	**Power consumption**	To be specified by vendor
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	• 2D-Barcode/ QR code Scanner. • Built-in Thermal printer and provision for external printer. • All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. • Online UPS for minimum 1 hour back up.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	As specified by manufacturer and compatible electrical accessories as per standard Indian set-up.

8.2	**Requirements for sign-off**	• Supplier to perform installation, safety and operation checks before handover. • Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical,paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. • Preventive maintenance visits atleast one in each quarter.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost should be quoted
	11. NOTES	
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to beprovided;
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed;

FULLY AUTOMATED BIOCHEMISTRY ANALYSER

Version no.:		Ver._1
Date:		
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyser IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and/or cardiac function test analytes.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The equipment should be capable of all Routine STAT and special Biochemical tests including specific protein, therapeutics, and user defined applications in clinical sample like whole blood, serum, plasma, urine and body fluids. • Throughput: minimum 200 tests/hour. • Measurement principle: photometric analysis. • Optical System should have Wavelength range from 340 to 700 nm. • Should have built in Cooled reagent Compartment with sample volume 2- 40 µl. • Auto diagnosis of machine errors with message and correction steps. • Must have on board capacity for permanent and numbered cuvettes. • Separate probe for reagents and sample. • Laundry System with minimum 5 step washing. • Minimum carryover of not more than 0.05 ppm. • The system should be having the facility of both auto-calibration and manual. • Should have solid state light source (LED Technology) with a split reference beam with working life of more than 10000 hrs. • Should have minimum 50,000 Patient Result memory Storage • Online QC Tracking with Levy and Jennings Chart for upto 30 different points, SD and CV.

		• Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	• Digital display • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration,control, patient sample results on daily basis.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system with minimum one hour back up
4.4	**Protection**	NA
4.5	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	1. Suitable Water plant/Purification System on RO or any latest technology. 2. External printer. 3. UPS online pure sine wave for back up of system with PC and ITperipherals for one hour. 4. One light source.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical,paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits at least one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a tollfree/landline number)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed

SEMI-AUTOMATED BIOCHEMISTRY ANALYSER

Version no.:		Ver._1
Date:		
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyser IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	A semi-automated laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and cardiac function test analytes.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Analyzer should have ability to use external cuvettes and integrated flow cell. • Analyzer should have more than 200 programmable channels. • Open Ended system preferably. • Analyzer should have 5 assay types: End point, Fixed time, Kinetic, absorbance and 1-point calibration with option for extended keyboard. • Analyzer should have calibration types: Linear factor, multi-point, point to point and Log-Log out • Facility for kinetic assay measurement with multiple standard mode. • Should have minimum 10,000 Patient Result memory Storage • Should have light source with working life of more than 10000 hrs. • Should have complete visual range. • 3 levels control with day-to-day Levey Jennings chart stored and displayed. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Facility for integration with PC • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication**	NA

	(wherever required)	
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary lab Installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system for backup of minimum one hour
4.4	**Protection**	NA
4.5	**Power consumption**	To be specified by manufacturer/supplier
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	1. Light source/Lamp-1 no. 2. Micro pipettes (5 No.) - 2 variable (5-50), (100-1000) 3. Tips 500 - small and 500- big.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in idealcircumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contactwith the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.

8.3	**Training of staff (medical,paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landlinenumber)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed

CHEMILUMINESCENT IMMUNOASSAY ANALYSER IVD

Version no.:	Ver_1
Date:	
Done by: (Name/institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
GMDNS name	Chemiluminescent immunoassay analyser IVD
GMDNS code(s)	56701
GENERAL	
1. USE	
1.1 **Clinical purpose**	An automated laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of chemical and biological markers (e.g., protein, drug, hormone, microbial toxin) in a clinical specimen.
1.2 **Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1 **Technical characteristics (specific to this type of device)**	• Fully Automated multi-channel analyzer based on chemiluminescence technology. • The instrument should provide comprehensive process check that performs, monitors, and verifies each step throughput sample and assay processing. • Continuous loading capacity of 30 or more samples. • Throughput of atleast 60 test per hour or more • The system should be able to read multiple barcode types or QR code. • It should have capability to do the assay in continuous, random, batch & stat mode. • Serum, plasma, urine, whole blood (assay-dependent) type of samples handling system. • System to use latest mixing probe technology to mix the samples and reagents to have complete uniformity with clot detection facility. • It should have the facility for bubble detection, check viscosity, sample level and short samples to ensure accuracy preventing erroneous results due to improper samples. • It should have an ability to do on board dilution and reflex dilution for high and abnormal samples. • It should have facility for automated probe cleaning or disposable tips system to avoid reagent carryover. • Should have onboard liquid waste container (4 litre), direct drain optional. • Should be a microprocessor-controlled device with digital display. • 2-point re-calibration facility, switched mode power supply, automated instrument calibration, user friendly

		and intelligent software • System should have software that automatically generates LJ charts for QC and have appropriate alerts. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility. • External USB storage available
2.2	**User's interface**	• Digital display • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required)**	Built - in/Automatic/compatible, windows based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	System should have on-board cooling facility to maintain the temperature of the reagents.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Online UPS with minimum one hour back up
4.3	**Protection**	Internal electrical protection.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	• External Printer to take printout of patient results and QC reports. • Online UPS with minimum one hour backup
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

CENTRIFUGE 16 TUBE

Version no.:		1
Date:		
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		General-Purpose Centrifuge IVD
GMDN code(s)		36465
GENERAL		
1. USE		
1.1	**Clinical purpose**	A device intended to be used to separate the components of multiple types and various volumes of clinical suspensions using centrifugal force. It is typically used to centrifuge various types of clinical specimens, either alone or after addition of reagents or other additives, for subsequent in vitro diagnostic analysis.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Speed: Range 0-6000 RPM. • Minimum Capacity-16 tubes (5-15 ml) • Digital Timer and speed control panel. • Safety features like certified biocontainment lid, rotor imbalance detection, automated lid interlock to prevent opening while running centrifuge with emergency lid lock release. • Microprocessor with digital display. • Dynamic brake for quick deceleration. • Stainless steel Chamber easy to clean. • Hinges to prevent door falling. • Rotor should be corrosion resistant. • Rotors should be autoclavable.
2.2	**User's interface**	Digital display for time and speed
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		

4.1	Power Requirements	220 +/- 10% VAC, 50Hz.
4.2	Battery operated	No
4.3	Protection	Internal electrical safety
4.4	Power consumption	To be specified by manufacturer/supplier
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables/ reagents (open, closed system)	Rubber adapter should be provider for the use of vacutainer for 3ml and 5ml.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements:nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM.

		2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, servicemanuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	Other accompanying documents	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed

COAGULATION ANALYZER IVD		
Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Coagulation analyser IVD, laboratory
GMDNS code(s)		56689
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of one or multiple coagulation components involved in haemostasis in a clinical specimen (e.g., performs tests such as prothrombin time (PT), partial thromboplastin time (PTT))
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Blood Coagulation analyzer should be a fully automated (It should automatically aspirate, dispense, incubate and measure) with random access. • The system must be open for essential reagents. • Should have option for clotting, Chromogenic, turbidimetric, fluorogenic or immune assays as well. • Instrument should be able to detect automatically positive sample and reagent positions. • Possibility of auto rerun and auto redilution of samples should be available, positive sample and reagents level detection should be provided. • It should support a wide range of parameters including PT, APTT, Factor Assay, Protein C, Protein S, Fibrinogen, and Thrombin Time, ATIII, Heparin, PLG, LP(a), APCR, DDI, FDP, vWf. Factor VIII quantification. • Throughput: Must perform at least 20 tests (for APTT and PT) per hour. • Storage: It should have capacity of storing 1000 test results in its memory. • System should have on-board cooling facility to maintain the temperature of the reagents. • Machine should provide patient analysis curve.

		• Instrument should have in-built Barcode reader for identification of sample and reagents i.e. name, stability, volume, position etc. • System should have software that automatically generates LJ charts for QC and have appropriate alerts. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	• LCD Display • Provision for bi-directional LIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required)**	In built – to be provided by the manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS of suitable kVA with at least 1 hour backup.
4.3	**Protection**	Internal electrical protection.
4.4	**Power consumption**	To be specified by manufacturer/vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	1. All the consumables, controls and calibrators and any other reagents or items required for conducting 500 tests should be mentioned and supplied with the equipment. 2. Barcode/QR code Scanner 3. Built-in Thermal printer or provision for external printer 4. Online UPS for minimum 1 hour back up
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C (minimum range) and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. • Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided. 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

ISE BASED ELECTROLYTE ANALYSER IVD		
Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Ion-selective Analyser IVD
GMDN code(s)		56682
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of electrolytes and other ions in a clinical specimen using ion-specific membranes to selectively measure electrical potential against a reference electrode to determine the target ion concentration.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Should be able to measure sodium [Na+], potassium [K+], chloride [Cl-]). • Should be based on measuring method of Ion Selective Electrode (ISE) (Direct Potentiometer). • Should have individual electrodes for the electrolytes. • Should have automatic calibration. • Should have a throughput of minimum 40 samples per hour. • Should have a memory of at least 100 samples. • QC should be based on test parameters. • The equipment should have in-built digital display unit, PC interface facility and provision for printing of reports • Should have provision for barcode/ QR code reader.
2.2	**User's interface**	• Touchscreen Display • Provision for bi-directional LIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required**	Inbuilt-To be provided by manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab installation

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Online UPS for minimum one hour back up
4.3	**Protection**	Internal electrical protection
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. 2D-Barcode/QR code Scanner. 2. Built-in Thermal printer or provision for external printer. 3. All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. 4. Online UPS for minimum one hour back up
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C (minimum range) and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast once in each quarter

10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

LABORATORY SHAKER IVD

Version no. :		Ver_1
Date:		
Done by: (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Laboratory Shaker IVD
GMDNS code(s)		65432
GENERAL		
1. USE		
1.1	**Clinical purpose**	An electromechanical in vitro diagnostic device designed to shake/stir samples or mixtures with a rapid and forceful movement. It is used to provide a rapid mixing or to prevent substances comprised of different components from separation or sedimentation because of their different densities.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Non-slip Platform size- minimum 300x300 mm with adjustable roller to accommodate ample in test test tubes, VDRL plates/slides, blood bottles and flasks by clamp and spring holder. • Should have rotation in horizontal plane. • Knob for selecting operation. • Acceleration circuit to prevent sudden start and stop should be available • Timer adjustable from 0 to 99 min or continuous mode with digital display of RPM and timer desirable. • Noiseless operation • Uniform shaking variable speed upto 180 rpm or more with ± 2 rpm accuracy, heavy duty motor and timer
2.2	**User's interface**	Digital display for RPM and timer
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noiseless operation
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		

4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Test tube racks.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,);** **Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

BINOCULAR MICROSCOPE

Version no.:		Ver_1
Date:		
Done by: (name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	A microscope is a laboratory instrument used to examine objects that are too small to be seen by the naked eye. Microscopic analysis of specimens helps diagnose diseases by looking at cellular morphology and presence of infectious agents and other microscopic structures. Binocular microscope is a microscope that lets the viewer use both eyes as it has 2 eye lenses.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Body-Single mold sturdy stand inclined Binocular body 30 °, 360º rotatable head without adjusting screws with inter-pupillary distance of 50-75mm. • It should have LED light source with rechargeable battery system. • Eyepieces-Paired high quality 10X/20mm wide angle anti fungus field eyepiece. one with pointer. Diopter adjustment must be present on both eye pieces. • Objectives-Parfocal, antifungal coated 4x, 10x, 40x and 100x having numerical aperture 0.1, 0.25, 0.60-0.65 and 1.25-1.65 respectively. Oil immersion objective (40x and 100x) should be spring loaded. All objectives should be plan achromatic, antifungal coated infinity and color corrected. Objective should be well centered even if their position on turret is changed. • Mechanical stag- ceramic coated surface with vernier scale on X-Y axis and slide holder. • Condenser, numerical aperture (NA) 1.25 focusable with rack and pinion arrangement incorporating spherical lens and iris diaphragm. It should have filter holder and swing in/out blue filter. • Should have inbuilt protective safety device which can withstand fluctuations of voltage from 140 V-280V. • LED illumination 3W with intensity control knob > 10,000 Hrs bulb lifespan with battery backup of 1 hrs and charging indication. • Focusing knob should have coaxial coarse and fine focusing knobs. Fine focusing movements should have

		sensitivity of 2 micron or less, coarse focus with torque adjustment, focusing stop for slide safety should be there.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer/vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should be provided with wooden storage box, dust cover, immersion oil.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements:**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.

	nature, values, quality, tolerance	
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

FLUORESCENCE LIGHT MICROSCOPE		
Version no.:		1
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Fluorescence light microscope
GMDN Code		35796
GENERAL		
1. USE		
1.1	Clinical Purpose	A magnification instrument in which light (typically ultraviolet) that has been absorbed by the specimen and re-emitted at a longer wavelength is observed (as visible light) so that the specimen is visible through the eyepiece. This device is typically used in the laboratory for histopathology and microbiology, commonly in conjunction with fluorescent dyes.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• The body shall be epoxy powder coated durable metal. • Should have Integrated Illumination, Koehler illumination. Illumination source: LED • LED light source with a minimum lifetime of 20,000 hrs. • Optical system must be infinity corrected for maximum S/N ratio and best optical performance from UV to near-infrared. • Fluorescence with minimum 5 or more position built in filter Cube Turret. 120/130 metal Halide / Mercury light illuminator • Filters should be DAPI/Hoechst, FITC/GFP, TRITC/ Rhodamine & Texas Red dyes, CY5. • Plan Achromat 4X Objective, plan semi apochromat 10X Objective, Universal plan semi apochromat objective 40X, and Universal Plan semi apochromat 100X objective oil for better resolution. • Should have CCD Monochrome scientific camera suited with both low light Fluorescence and bright field imaging with color reproduction. • Software for fully automated acquisition and device control. • The microscope should have an X-Y scanning stage with slide holder and lock down holders. • Paired widefield 10X eyepiece, with diopter adjustment facility for both eyes and with field of view 22 mm or higher.

		• Swingout/switchable condenser with colour coding for fast and easy adjustment of aperture.
2.2	Software and/or standard of communication (wherever required)	Software for fully automated acquisition and device control.
3. PHYSICAL CHARACTERISTIC		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	NA
3.5	Mobility/Portability	Lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Power consumption	As specified by Manufacturer/Supplier
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. Spare Lamp/Light source- 2 nos. 2. Lens cleaning paper (objectives, condenser, eye piece), 100 packs should be provided. 3. Immersion oil
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover 2. Lab In-Charge to affirm completion of installation.

8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Comprehensive Maintenance Contract for minimum 5 years after warranty. 3. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

ELISA READER AND WASHER

Version no.:		1
Date:		
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		NA
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory technique that uses antibodies linked to enzymes to detect and measure the amount of a substance in a solution, such as serum. The assay uses a solid-phase type of enzyme immunoassay to detect the presence of a ligand in a liquid sample using antibodies directed against the protein to be measured.
1.2	**Used by clinical department/ ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The device should be fully automated and easy to operate with 8 and 12 channel manifold. • It should be capable to wash flat, round and V bottom plates and strips. • Reader should be capable to read variety of different types of ELISA plates and strips. • It should have large display along with more than 40- 50 program storage facility. • System should have calibration facility. • System should have warning/alarm for full waste container and empty wash bottle. • Residual volume after washing should be < 2ul. • It should have specially designed peristaltic pump to dispense 50 - 400 µl. • It should be supplied with waste container, wash bottle and rinse bottle of capacity 2 liters with tubings. • It should have option of programming wash cycles with capacity for storing at least 50 wash protocols. • Cross wise aspiration, overflow washing and bottom washing. • Bichromatic/Optics with six standard wavelengths for ELISA kits. • Trichromatic Light source. • Internal Printer with port for external printer. • Should read ELISA Plate Horizontally A to H and vertically 1 to 12. • Photometric Accuracy should be ±3%.

		• Should have a resolution of 0.001 Abs. • Print out of whole plate in Matrix Format. • Linear measurement range 0 to 4 Absorbance unit. • 8 filter wheel capacity with Interference. • Filters of 405, 450, 492, 620 nm with at least 4 extra positions within the range of 400-750 nm.
2.2	**User Interface**	Compatibility with external Printer
2.3	**Software and/or standard of communication (wherever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Online UPS with minimum one hour back up
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables/ reagents (open, closed system)**	.) Paper rolls for printer- 10 nos. 2) Online UPS for minimum one hour back up
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C (minimum range) and relative humidity of up to 90% in ideal circumstance
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
	7. STANDARDS AND SAFETY	

7.1	**Certificates (pre-market, sanitary, ...); Performance andsafety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	Compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical,paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost should be quoted.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to beprovided;
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

LABORATORY REFRIGERATOR, BASIC

Version no.:		Ver_1
Date:		
Done by: (name, institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Laboratory refrigerator, basic
GMDN code(s)		17157
GENERAL		
1. USE		
1.1	**Clinical purpose**	A refrigerator specially designed to maintain the cold temperatures required for the storage of samples, specimens, cultures, and other laboratory preparations.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should be Vertical and single door. 2. Internal volume capacity minimum 500L with minimum 5 shelves. 3. Temperature range: adjustable range between 2°C- 8°C ± 1°C. 4. Digital temperature indicator cum controller. 5. Audio & Visual alarm for temperature excursions. 6. Should be CFC free.
2.2	**User's interface**	Digital display for temperature
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	No
4.3	**Protection**	Should be provided with a voltage stabilizer (external or inbuilt) of appropriate ratings.
4.4	**Power consumption**	To be specified by vendor.

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should be provided with a voltage stabilizer (external or inbuilt) of appropriate ratings.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast once in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

DEEP FREEZER (-20 DEG C)		
Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Ultralow-temperature laboratory freezer
GMDNS code(s)		40513
GENERAL		
1. USE		
1.1	**Clinical purpose**	A freezer designed for the storage of laboratory products and sample materials [e.g., in vitro diagnostic (IVD) reagents, cryo-preserved tissue/body fluid samples] that require extremely low temperatures.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Type of Insulation: PUF/polystyrene, • Rust-free heavy-duty casing with one compressor and preferably vertical. • Type of Cooling: Direct with inverter technology • Castor: Heavy Duty Lockable • Capacity: 300 L or higher • Shelves/ Drawers: Sealed 5-7 pullout drawers / shelves of different sizes that can be adjusted for storage flexibility • Material of Chamber Interior: Stainless steel, preferably 304 grades • Material of Chamber Exterior: Stainless steel, preferably 304 grades • Door Material: Stainless steel, preferably 304 grades • Finish: Powder coated exterior finish • Temperature Range: - 20 °C to -40°C • Temperature Uniformity in Degree Celsius: ±3°C or less • High Quality Door Seals • Lockable Outer and Inner Lids • Fully programmable microprocessor controlled with membrane keypad and eye level control panel • Easy to read, LED/LCD control panel and alarm status with integrated diagnostics • **Acoustic Safety alarms:** Should be equipped with for High/low temperature, door ajar and malfunction alarms, sudden power failure, system failure and battery low • **Temperature History:** Data logger for temperature and temperature history which can be downloaded via a USB port • CFC-Free, HCFC-Free non-inflammable refrigerants.

2.2	**User's interface**	LED/LCD control panel
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	Voltage stabilizer
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.

8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection; 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

DEEP FREEZER (-80 DEG C)

Version no.:	Ver_1
Date:	
Done by: (Name/Institution)	HCT/NHSRC

NAME, CATEGORY AND CODING

GMDNS name	Ultralow-temperature laboratory freezer
GMDNS code(s)	40513

GENERAL

1. USE

1.1	**Clinical purpose**	A mains electricity (AC-powered) freezer designed for the storage of laboratory products and sample materials [e.g., in vitro diagnostic (IVD) reagents, cryo-preserved tissue/body fluid samples] that require extremely low temperatures.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	**Construction** • Solid cabinet casing with phosphated cold rolled sheet, steel to prevent corrosion Acrylic Varnishing of high quality and lockable castor. It should have minimum 2 compressors and inverter technology. • Capacity: 300 L or higher • It should have 5 or 6 shelves of stainless steel. **Control system** • Micro-processor-based temperature controller with digital temperature display LED-LCD with seven days graphic inkless temperature recorder with rechargeable battery back-up including charger maintenance free and insensitive to vibration. **Refrigeration System** • Heavy Duty refrigeration system, maintenance free, below -80C cascaded connection with hermetically sealed refrigeration compressors and reliable refrigeration to minimise noise and vibration, air cooled with security lock to prevent unintentional switch off shall be supplied. It should have short cooling time of 4 to 5 hours. The equipment should be of continuous duty. Access port for CO2 back up for refrigeration system in case of machine failure. **Alarm** • It should also have audio visual Electronic Alarm System independent of power supply. **Insulation** • About 17.5 cm high density polyurethane or equivalent Gaskets - Double seal silicon.

2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	1. Resettable overcurrent breaker shall be fitted for protection 2. Suitable Servo controlled Stabilizer/CVT
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.

8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

VERTICAL AUTOCLAVE

Version no. :		1
Date:		
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		NA
GMDN code(s)		NA
GENERAL		
1 USE		
1.1	**Clinical purpose**	An airtight vessel used for sterilizing laboratory equipment, culture media and decontaminating biohazardous waste with moist heat at high temperatures and pressure.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2 TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specificto this type of device)**	• Rust-proof 304 grade stainless steel. Triple walled construction. • Minimum chamber Capacity :100 L • Adjustable pressure range- 15-20 psi with accuracy +/- 1 to 3 psi. • Hydrostatically tested to withstand 2.5 times the working pressure. • Sealed with Neoprene/Silicon long-lasting and durable gasket. • Mounted on 304 stainless steel frame with ground leveling flanges • Display for temperature, pressure, and time. • Temperature and pressure cut-off device. • Auto cut-off at low water level • Cylindrical construction. • Equipment should have separate steam release valve and drainage system. • Minimum of two safety valves with auto-release.
2.2	**User's interface**	Display for temperature, pressure and time
2.3	**Software and/ or standard of communication (wherever required)**	NA
3 PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism

3.5	**Mobility, portability**	Portable
4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2)		
4.1	**Power Requirements**	Power Supply: 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by Manufacturer
5 ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard,optional); Spare parts (main ones); Consumables / reagents (open, closedsystem)**	• Automatic Pressure Control Switch -2 no. • Automatic Water Cut-off Device -2 no. • Micro Processor PID Controller with Timer & Auto Stop Facility • Digital Pressure Indicator-2 no. • Perforate basket (rust-free stainless steel) • Cord-plug-2 no.
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity,dust ...)**	Operating condition: Capable of operating continuously in ambienttemperature of 10 to 50 deg C and relative humidity of up to 90% inideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable ofeasy disinfection or be protected by a single use/disposable cover.
7 STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the devicetype);Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8 TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature,values, quality, tolerance**	As specified my manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9 WARRANTY AND MAINTENANCE		

9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10 DOCUMENTATION		
10.1	**Operating manuals, service manuals, othermanuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers andcost;
11 NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed

VORTEX MIXER IVD		
Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Vortex mixer IVD
GMDN code(s)		64819
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used to mix small volumes of liquid or solution, or to resuspend sediment, in a container (e.g., test tube, microplate) using a vortex during the processing of a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have speed range of 0-300 rpm 2. Should have orbital type movement 3. Should have a heavy metal base with rubber feet 4. Should have variable speed control regulator. 5. Should have choice of continuous operation and touch activated operation. 6. Low speed operation should be possible in touch activated operation. 7. Should have attachments for flask, test tube and 1.5ml tubes.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise pressure level: ≤60 dbA.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection,

		5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

URINE ANALYSER IVD, LABORATORY

Version no.:		1
Date:		
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Urine Analyser IVD, Laboratory
GMDN code		35918
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen, which typically include bilirubin, glucose, haemoglobin, ketones, nitrites, pH, protein, urobilinogen, specific gravity, blood, red cells, white cells, casts, crystals, sperm, and/or microorganisms (e.g., bacteria).
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should be able to analyse multiple Parameters: Leucocytes, Nitrite, Urobilinogen, Protein, pH, Specific gravity, microalbumins, Ketones, Bilirubin, Glucose etc. • Should be portable, fully automated integrated urine analyzer. • Should have a throughput of minimum 100 samples / hour. • Random access for individual samples • Memory: patient test results minimum 1000 and QC test results: 50. • Provision for report printing • QC should be based on test parameters. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Display: touch-screen LCD • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	Inbuilt

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary Lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	Power Supply: 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Yes
4.4	**Protection**	Internal electrical safety
4.5	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables/ reagents (open, closed system)**	1) Thermal Paper 10 rolls. 2) 1000 test strips to be provided. 3) Calibration strip 2.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical,paramedical, technicians)**	1. Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.

		2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

ELECTRONIC ANALYTICAL BALANCE

Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Electronic analytical balance
GMDN code(s)		45513
GENERAL		
1. USE		
1.1	**Clinical purpose**	An electronic laboratory instrument designed for weighing with a high degree of accuracy and precision.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have automatic calibration program. 2. Should have automatic zero setting. 3. Should have stability indicator. 4. Should have single weighing mode. 5. Should have capacity range from 0.1 mg to 100g (Minimum). 6. Should have readability 0.00001g. 7. Should have repeatability (std dev) 0.000015g. 8. Should have linearity +/- 0.00002g. 9. Should have stabilization time 3 seconds. 10.Leveling should be Automatic.
2.2	**User's interface**	Digital display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220 + - 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. Balance table with vibration bumpers, preferably granite isolator. 2. Protective dust cover. 3. Optional: Weighing scoop, 90 mm, stainless steel.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	As indicated by Manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and standard electrical accessories as per Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

FORCED-AIR LABORATORY OVEN

Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Forced-air laboratory oven
GMDN code(s)		21087
GENERAL		
1. USE		
1.1	**Clinical purpose**	A mains electricity (AC-powered) device with a heating chamber designed to provide fan-assisted convection to ensure a homogenous temperature profile in the chamber. It is used for laboratory procedures that involve drying, heating, and sterilizing objects.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Thermostatically controlled, temperature range ambient to 250°C with fine and coarse adjustment, with fan, digital display. • Volume of interior housing: Approx.- 180-400 liters • Housing: preferably stainless steel • Heat and Corrosion resistant, good quality, durable • Metal housing care • Stainless steel (SS-304) interiors with supports on three sides, adjustable slots and removable three shelves. • Fan convection to ensure uniform temperature, fitted with load indicator and safety thermostat take over indicator lamp. • Built-in timer with temperature control for to set the sterilization cycle. • Temperature variation +/-1 deg C, LCD/LED indicator.
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Stationary Installation

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	Internal Electrical Safety
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Racks with different sizes, Gloves different sizes, Digital temperature controller and indicator.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Not applicable.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	As specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

HOT PLATES

Version no.:	Ver_1
Date:	
Done by: (Name/Institution)	HCT/NHSRC

NAME, CATEGORY AND CODING

GMDN name	NA
GMDN code(s)	NA

GENERAL

1. USE

1.1	**Clinical purpose**	Tabletop devices designed to heat substances (i.e., solid, liquids) in containers placed on them. These devices typically consist of a flat surface that is heated by electrically powered heating.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	1. Heating range 40-110 degree C, 220 volt with temperature controller. 2. Top plate should be either ceramic or aluminum, chemical and scratch resistance 3. Heating Surface area should be at least 400 cm^2 4. Spill trough to deflect spills away from electronic and control knobs with LCD/LED indicator, hot indicator light whenever hot plate is above 50 degrees.
2.2	**User's interface**	Control knobs with LCD/LED indicators
2.3	**Software and/ or standard of communication (wherever required)**	NA

3. PHYSICAL CHARACTERISTICS

3.1	**Dimensions(metric)**	1ft x 1ft
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)

4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor

5. ACCESSORIES, SPARE PARTS, CONSUMABLES

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Set of Heating & cooling element (Two in number)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Standard electrical accessories as per Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection,

		6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

INCUBATOR		
Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		NA
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Incubators are designed to provide the appropriate environmental conditions (e.g., temperature, humidity, gas concentration) necessary for certain laboratory tests or procedures e.g., bacterial and fungal culture, incubation of ELISA plates etc.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Inner chamber made up of Stainless steel make of SS-304 grade, full length inner acrylic security glass door. • Inner Chamber Capacity: Minimum 120 L • Heat and Corrosion resistant, good quality durable metal housing care. • Triple wall with special grade glass wool insulation. • Temperature range, ambient to 80°C, ±1°C resolution. • Controller/Digital indicator for Temperature and time. • Adjustable over-temperature protection controller to ensure that the Incubator does not go beyond the set temperature and maintains the desired temperature. Should have auto-cut off facility. • Programs stored on power failure so that when power is restored, equipment continues to function on the previous program.
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	Inner Chamber Capacity: Minimum 120 L
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism

3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	Internal Electrical Safety
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Gloves different sizes. 2 or 3 shelves made of stainless steel
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPAR TMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter

10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY ANALYSER IVD		
Version no.:		01
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		High performance liquid chromatography analyser IVD
GMDN Code		57845
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered laboratory instrument designed for the qualitative and/or quantitative in vitro determination of chemical and biological markers in a clinical specimen.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• It should be able to screen and quantitate Hb A2, Hb A, Hb F, and Hb A1c hemoglobin, in addition to that it should also be able to identify prevalent abnormal hemoglobin's like Hb S, Hb D, Hb E, Hb C, Hb Q-India etc. and other rare abnormal hemoglobin. • System should be able to load a minimum of 10 samples at a time. • Should provide two level controls for Hb A2, Hb F and Hb S and provide quality control program to help compare results with similar users. • The system should have a feature of rack & sample position identification to avoid error in case of faulty barcode/QR code reader. • The system should have a visible alarm system for low buffer level in mobile phase reservoirs, low level of cartridge injection and overfill of the waste tank, and a built-in calibration failure alarm. • The waste tank should be sufficiently large, to reduce frequent user interference • The System should be NGSP (National Glycohemoglobin Standardization Program) Certified and verifiable to IFCC reference method. • The system should offer both NGSP & IFCC value reporting on the same patient report, control & calibrator report. • QC should be based on test parameters. • Provision for bi-directional LIS interface should be available. • Provision for Bar Code/QR code reading should be available.

		• The equipment should have in-built digital display unit and PC interface facility.
2.2	User Interface	Digital Display
2.3	Software and/or standard of communication (wherever required)	1. Graphical and user-friendly design of the software. 2. Software should be able to control all modules of the HPLC system
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility/Portability	Stationary lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Battery Operated	Online UPS with minimum one-hour backup.
4.3	Protection	Internal Electrical Protection
4.4	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. Equipment should be provided with Online UPS with at least one-hour backup. 2. Basic required repair tools and spare parts for regular maintenance needs to be provided. 3. Color Laser Jet Printer with Scanner 4. A Computer system with latest configuration (i5 processor with 3.2 GHz processor, 8 Gb RAM, 1 Tb hard disc, or better) and with operating system compatible with the dedicated software should be provided along with the system. 5. All consumables including controls, calibrators, regents etc. required for testing of 100 HbA1C & 100Hb Variants analysis. Consumables should be of HPLC grade.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating Condition: Capable of operating continuously in ambient temperature of 10-50°C and relative humidity of up to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards.

	type); Local and/or international	4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided
11.2	Recommendations or warnings	Any warning sign should be adequately displayed

GLYCATED HAEMOGLOBIN (HBA1C) ANALYSER IVD

Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Glycated haemoglobin (HbA1C) analyser IVD
GMDN code(s)		35968
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of glycated haemoglobin (HbA1c), also known as glycohaemoglobin, glycosylated haemoglobin or glucosylated haemoglobin, in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Automated integrated system for HbA1c testing. • Should have automatic calibration system. • Should provide NGSP/IFCC certificate for equipment at the time of installation. • System should have a throughput of 20 test/hour. • Measuring range: HbA1c 3-20%. • High precision, CV ≤5% • Should have inbuilt battery backup • The system should have provision of bi-directional data flow. • The equipment should have digital display unit and PC interface facility. • The system should be equipped with an automated barcode/QR code reading facility
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		

4.1	**Power requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Should have inbuilt battery backup
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should provide Sample rack – 1 No, Pipette rack – 1 No, Printer rolls – 2 Nos, necessary pipettes and any other additional accessories required to perform the HbA1C test.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

MECHANICAL MICROPIPETTE IVD

Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Mechanical micropipette IVD
GMDN code(s)		65710
GENERAL		
1. USE		
1.1	**Clinical purpose**	A manually operated in vitro diagnostic device designed to withdraw, transfer, and inject minute volumes of fluid materials (e.g., microlitres or smaller).
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Single channel microliter pipettes. 2. Fully autoclavable (121 °C); UV-resistant material. 3. Three defined stops (single-button operation preferred): - take-up from the first stop - dispensing and blow out - tip ejection. 4. Should have volume range of 1 µl to 50 µl. 5. Easy and safe tip ejection mechanism. 6. Fixation of adjusted volume. 7. Slim pipette shaft.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**NA**
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Disposable Tips (different volume comparator)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Sterilization required.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		

11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

pH METER IVD		
Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		pH meter IVD
GMDN code(s)		15164
GENERAL		
1. USE		
1.1	**Clinical purpose**	An instrument intended to be used for the qualitative and quantitative in vitro determination of the pH of a clinical specimen (i.e., its degree of acidity or alkalinity) by measuring hydrogen ion concentration.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Portable light weight pen type instrument battery/electrically operated with 5ml capacity. • pH range 0-14 with digital display and stand by and calibration mode. • Temperature compensation should be provided • Calibration with at least three standard calibration buffers (pH 4.0, 7.0, 10.0) • Resolution: up to 3 decimal places • Accuracy: ±0.01 pH units. • Should provide simultaneous read-out of pH and temperature, preferably in an LCD display • Automatic and manual buffer selection
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor.

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Provision of spare electrode.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	As specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection,

		6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

ERYTHROCYTE SEDIMENTATION RATE (ESR) ANALYSER IVD		
Version no.:		01
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Erythrocyte Sedimentation rate (ESR) analyser IVD
GMDN Code		56691
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics (Specific to this type of device)	• The instrument should carry out automated ESR analysis using the principle of sedimentation of red blood cells (Westergren Method). • Should be able to load minimum 10 samples at a time. Both batch and continuous. • Measuring range in mm: 1-140 using optical sensor. • ESR controls should have at least 06 month shelf life. • Should have an inbuilt Bar code Reader and printer. • Should have auto mixing facility as per ICSH & CLSI requirements. • Have provision for internal temperature correction at 18°C or 37° C • Should have feature of haemocrit HCT correction • Should offer random access testing • Data storage capacity: upto 1000 test results. • Internal Quality Control Management with minimum two level of controls should be provided. • Should have facility for calibration and should comply with National/International quality standards • Provision for bi-directional LIS interface should be available. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	User's Interface	Microcontroller based LCD/LED Display Unit

2.3	Software and/or standard of communication (Wherever required)	All software installations or updates should be done free of cost during warranty period.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.5	Heat Dissipation	NA
3.6	Mobility/Portability	Stationary Lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Battery Operated	Yes
4.3	Protection	Internal Electrical Safety
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (mainones) Consumable/reagents (Open, closed system)	1. Reagents and consumables to carry out minimum 200 tests 2. One additional set of RS 232 cables 3. Other Standard accessories.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating Condition: Capable of operating continuously in ambient temperature of 10-50°C and relative humidity of up to 90 % in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS & SAFETY		

7.1	Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

10.2	Other accompanying documents	List of all the important spares and accessories, with their part numbers and cost needs to be submitted.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided.
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned.

AUTOMATED AGAROSE GEL – ELECTROPHORESIS SYSTEM IVD		
Version no.:		01
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Electrophoresis analyser IVD
GMDN Code		57837
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratory instrument or system intended to be used for the qualitative and quantitative in vitro determination of various molecules (e.g., nucleic acid, proteins etc) in a clinical specimen based on their size, ionic charge and/or rate of migration through an electrically charged field.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• Should be able to analyze in vitro of various molecules (nucleic acid, proteins etc.) in a clinical specimen or tissue body fluid. • Automated sample application and sequential processing of each step of electrophoresis with disposable applicators • Gel imaging, interpretation and reporting software should be available with the system • The system should use deuterium lamp with optical fibers for emission and reception. • The system needs to have in built tube mixer. • System should have ability to add samples in between the cycle. • Should have provision for automatic recycling of Buffer and Stainer. • System should have in built reading capacity. • The instrument should be capable of quality control measures • The through put of the system should be, at least i. Hemoglobin – 8 samples/ hour ii. Protein – 20 samples/ hour • Automatically able to manage the reagents and automatic washing cycle before the switch-off of the unit. • System should be capable to restart from point where process is interrupted due to electrical failure/other factors. • The system should have the facility of automatically wash out after completion of every process.

		• Provision for bi-directional LIS interface should be available.
2.2	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	NA
3.5	Mobility/Portability	NA
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Battery Operated	Online UPS system with minimum one hour back up.
4.3	Protection	Internal electrical safety
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. To be supplied with computer (minimum i5 processor, 500 GB HDD and 4 GB RAM), A4 size laser printer and appropriate bar code reader 2. Start-up kit for at least 200 tests should be provided. 3. Online UPS system with minimum one hour back up
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating Condition: Capable of operating continuously in ambient temperature of 10-50°C and relative humidity of up to 90 % in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		

8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned

RT-PCR SYSTEM		
Version no.:		01
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		NA
GMDN Code		NA
GENERAL		
1. USE		
1.1	Clinical Purpose	RT-PCR is a laboratory technique combining reverse transcription of RNA into DNA (in this context called complementary DNA or cDNA) and amplification of specific DNA targets using polymerase chain reaction (PCR). This is achieved by monitoring the amplification reaction using fluorescence a technique called real-time PCR or quantitative PCR (qPCR). Combined RT-PCR and qPCR are routinely used for analysis of gene expression and quantification of viral RNA in research and clinical settings.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• Tabletop model. • Open system to accommodate TaqMan, SYBR green and all other fluorescent dye-based chemistries. • The system should be flexible to use micro well plates, individual PCR tubes and PCR tube strips. • Peltier based atleast 48 well block/Rotor or better system. • It should have excellent thermal (Temperature range: 4 to 99 deg C; Temperature accuracy: ± 0.25 Deg C) and optical performance. • Sensitivity: Detection of 1 copy of template and differences as small as 1.5-fold in target. • It should have a fast ramp rate for heating and cooling. • The system should be easily calibrated with new dyes without any change filter or hardware. (Should have pre-calibrated for minimum 7 dyes). • CCD camera with halogen/LED/Photodiode/CMOS and at least six excitation and six emission filters to perform multiplex assays. • Option for melt curve analysis using high resolution software.

		• The system should facilitate for calibration of multiple dyes at installation. • It should have 5 channels (5plex) for optical detection: Green channel (Excitation: 470 ± 10 nm, Detection: 510 ± 5 nm), Yellow channel (Excitation: 530 ± 5 nm, Detection: 557 ± 5 nm), Orange channel (Excitation: 585 ± 5 nm, Detection: 610 ± 5 nm), Red channel (Excitation: 625 ± 5 nm, Detection: 660 ± 10 nm), and crimson channel (Excitation: 680 ± 5 nm, Detection: 712 high pass nm). In addition, the software should allow creation of new excitation/detection wavelength combinations, as per requirement. • The system should be flexible and compatible with reagents, chemistries and plastic ware. • The system should have online UPS system with minimum 2-hour backup. • HRM analysis should be supported by thermal resolution of 0.02°C, high data-acquisition rates, and appropriate HRM software. • It should support multiple PCR tube formats and strips as per standards. • It should have digital display. • It should have a small footprint (Width: <40 cm; Height: <30 cm; Depth: <45 cm and Depth (door open): <55 cm). • Software: Software should be latest, compatible with window OS system and should be compliant or matching with the hardware. • Should be able to generate reports and analysis reports in both excel or pdf format. • A quick and automated temperature accuracy testing provision should be available.
2.2	Software and/or standard of communication (wherever required)	1. Unlimited user licenses and individual user management provision should be available for the software. 2. Analysis workstation should be of latest configuration with a color printer.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	As per the manufacturer
3.2	Weight	As per the manufacturer
3.3	Noise	NA
3.4	Heat Dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility/Portability	Portable
4. ENERGY SOURCE		
4.1	Power input	220 + - 10% VAC, 50 Hz
4.2	Battery Backup	Should be compatible with online UPS (2KV).

4.3	Protection	Internal electrical safety
4.4	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. A laptop with latest configuration and with operating system compatible with the dedicated software should be provided along with the system. 2. The system should come with – a. RT-PCR instrument, b. Rotors stand/holder, c. USB and RS-232 serial cable d. PCR tubes (1000 Nos.) and strip tubes with caps (1000 Nos.). e. Dyes should be provided with the system. f. Reagents for 500 reactions should be provided with the instrument.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating Condition: Capable of operating continuously in ambient temperature of 10-50°C and relative humidity of up to 90 % in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As per manufacturer's recommendation
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		

10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning signs should be adequately displayed.

REFRIGERATED MICROCENTRIFUGE		
Version no.:		Ver_1
Date:		
Done by:		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Microsample centrifuge IVD
GMDNS code(s)		17452
GENERAL		
1. USE		
1.1	**Clinical purpose**	An electrically powered device intended to be used mainly in the clinical laboratory to centrifuge small sample volumes through centrifugal force.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Speed – upto 16000 rpm, adjustable in increments of 10. • Programmable and noise free operations. • Temperature range (-4 deg C to 25 deg C) approx. • Fixed angle rotors for 1.5 ml and 2 ml tubes. • Should have acceleration and deceleration time in range of 11 to 16 seconds and 12 to 18 sec respectively. • Should have separate short spin/pulse button for quick centrifugation. • Should be microprocessor based with digital display and regulation for speed (rpm and RCF) and run time. • Should have soft touch one finger lid closure for ergonomic operation. • Should have alarm system for imbalance. • Should incorporate Safety Features for Imbalance detection, lid interlock, over temperature, rotor over speed, etc.
2.2	**User's interface**	Digital display and regulation for speed and time
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.

3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection from the manufacturer
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

PCR WORKSTATION		
Version no. :		Ver_1
Date:		
Done by: (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	The workstation is used to prepare reagents and set up the PCR reaction mixture under clean conditions to avoid contamination with DNA/RNA.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Class 100 vertical laminar flow air. • Exterior dimensions (H × W × D) should be minimum 30” x 32”x24”: • Interior working area (W × D) should be minimum 25”x22” • Average downflow 60fpm+/- 5 fpm at 10 cm above the work access opening with down flow velocity uniform across the work area • Continuous monitoring and digital display of down flow velocity is desirable. • Exterior: anti rust stainless steel (SS 304). • Interior: stabilized stainless steel. • Side panels transparent, able to absorb wavelengths below 400 nm. • Overhead UV light for DNA decontamination; two lamps, 25 W each. • Separate, switchable, UV air-sterilizing circulation unit; UV lamp (25 W) with minimum life span of 9000 hrs. • Timer and key lock for UV lamp; timer operates only when key lock is on. • Overhead white light; 15 W; at least 800 lux. • At least two power socket outlets built into the chamber; AC 230 ± 10 V; 50 Hz; 5A fuse. • Sterile air through HEPA filter having rated efficiency of more than 99% at 0.3 microns.
2.2	**User's interface**	Digital display
2.3	**Software and/ or standard of communication (wherever required)**	NA

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	• Each workstation to be accompanied by an authorized list of accessories and spare parts. • Set of fuses for the workstation. • Two UV lamps.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

BLOOD CULTURE ANALYSER IVD		
Version no.:		01
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Blood culture analyser IVD
GMDN Code		56739
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratory instrument intended to be used for the qualitative and/or quantitative in vitro determination of microorganism growth in a blood culture preparation or other clinical specimen, with or without subsequent identification of the organism.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• Fully automated modular system capable of culturing of blood, sterile body fluids for bacteria and fungi. • Capacity: Minimum 25 bottle positions. • System should have optimized recovery of organism with continuous agitation. • System should be based on sensitive fluorescence/colorimetric technology for interpretation of results. • The system should be modular with possibility of expansion on requirement. • The system should be capable of processing both adult and pediatric samples. • QC should be based on test parameters. • Provision for bi-directional LIS interface should be available. • System should have sample accession facility using bar code/ QR code reader. • Should have PC interface facility.
2.2	Software and/or standard of communication (wherever required)	Within the warranty period needs to cover free of cost upgradation and re-installation
3. PHYSICAL CHARACTERISTIC		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA

3.4	Heat Dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility/Portability	Stationary Lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	The system should be supplied in a complete system with all accessories, hardware's like computer, printer etc and the required software.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be

		supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of all the important spares and accessories, with their part numbers and cost needs to be submitted
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned.

MICROORGANISM IDENTIFICATION/ANTIMICROBIAL-SUSCEPTIBILITY ANALYSER IVD		
Version no. :		01
Date:		
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Microorganism identification/antimicrobial-susceptibility analyser IVD
GMDN Code		56747
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratory instrument intended to be used for the identification of bacteria and/or yeast isolated from clinical specimens and for the determination of their antimicrobial susceptibility profile using morphology, substrate utilization and/or biochemical reactivity and by monitoring growth rates and/or determining endpoint growth, against a range of antimicrobials.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• System should be fully automated for microbial identification and sensitivity (MIC values). • The system should have capacity of minimum 30 cartridges to be in position. • The system should have a bar code/QR code scanning device for test card identification and specimen number entry. • System should have susceptible panel for Gram Negative (GN), Gram Positive (GP), Fungal, yeast and bacteria. • The system should include customized cards containing antibiotics most frequently used and prescribed in Indian Hospitals. • The System should have database of at least 2000 reference phenotypes. • The system should use safe, self-contained closed card system versus open panels.

		• The software must have the following capabilities - Workflow management, Data storage, Test quality control management, Test result validation capability and ability to detect antibiotic resistant bacteria. • The system must have the ability to check the quality of test results and result comes with % confidence for the results reported. • The system should use CLSI guideline for AST/MIC interpretation. • The system software must have the ability to alert to any unusual resistance mechanism including emerging ones. • Should have Separate panels for ID & AST • The system should provide flexibility of auto-release of completed results to HIS (subject to fulfilment of set criteria).
2.2	Software and/or standard of communication (wherever required)	Software upgradation and installation needs to be free within warranty period
3. PHYSICAL CHARACTERISTIC		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility/Portability	Stationary lab installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	Suitable UPS power Backup for 4 hours
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As indicated by Manufacturer

7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by Manufacturer
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of all the important spares and accessories, with their part numbers and cost needs to be submitted
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

BLOOD GAS ANALYSER IVD, LABORATORY

Version no.:		Ver_1
Date:		
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Blood gas analyser IVD, laboratory
GMDN code(s)		56661
GENERAL		
1. USE		
1.1	**Clinical purpose**	An electrically powered laboratory instrument intended to be used for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters [e.g., bicarbonate (HCO3-), base excess, arterial-alveolar gradient] in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Essential Measured parameters; pH, pCO2, pO2, tHb, Barometric Pressure, Na+, K+, Ca++, Cl-. All these parameters should be measured simultaneously • Should have minimum 15 calculated parameters including SaO2, Bi carbonate (HCO3), Standard HCO3, Base Excess of Blood (BE), Base Excess of extra cellular fluid. • Sample volume-less than 100ul. • Should have minimum process time (less than 5 min). • Warm up time should be less than 30 minutes. • Maintenance free electrodes • Fully automatic liquid calibration of all parameters at user-defined intervals. • Should be with numeric keypad, graphic / LCD display, and inbuilt printer. Should have interface for PC compatibility. • QC should be based on test parameters • Automatic result processing, test ordering and provision for bi-directional LIS interface should be available. • Automatic data archiving and customizable layout. • Should have provision for data backup.
2.2	**User's interface**	LCD/Graphical Display
2.3	**Software and/ or standard of communication (wherever required)**	Inbuilt

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise pressure level: ≤60 dbA.
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	220 +- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes at least 30 minutes backup
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Reagents for minimum 200 tests should be provided along with the machine. Electrodes for all the parameters specified -01 set Quality control tools/reagents for minimum 200 tests or as per requirement.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		

9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

FLOW CYTOMETRY ANALYSER IVD		
Version no.:		Ver_1
Date:		
Done by:		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Flow cytometry analyser IVD
GMDNS code(s)		57839
GENERAL		
1. USE		
1.1	**Clinical purpose**	An electrically powered laboratory instrument intended to be used to count, examine and sort cells or microscopic particles in a clinical specimen (e.g., blood, urine).
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Pre-configured flow cytometer equipped with minimum dual laser system with inbuilt cell sorting system • Capability of minimum 4 fluorescent colors and 6 parameters. For each parameter the flow cytometer should be capable of measuring area, height and width. • Minimum detectable particle size should be 0.5 µm. • Forward and side scatter detector. • Should have single tube sample mode as well as multi tube loader capability with minimum of 24 tube loading capacity as well as 48 and 96-well plate loader. • Should be able to acquire at least upto 10,000 events per second. • Fluorescence Channel 1, Channel 2, Channel 3 and Channel 4 detectors. • Should have compensation capability between all fluorescence channels with online as well as post-acquisition manual and auto-compensation features. • Should have digital signal processing with linear and log modes and dynamic range of atleast 5 decades. • The cytometer should have bio-hazard containment system and proper waste collection and management system. • Dual fluorescence compensation network • Double Discrimination Module for area and width measurement (DNA Analysis) • Built in sort module for 3 sort mode (recovery, single cell and exclusion) • Data management system • Sorter cell cycle 200 cells per sec.

		• Compatible computer system: PC workstation with at least Core i7 or higher, 2 TB hard drive or more, DVD/CD ROM R/VV Combo Drive, at least 23-inch LCD monitor.
2.2	**User's interface**	LCD monitor
2.3	**Software and/ or standard of communication (wherever required)**	Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220 +- 10% VAC, 50Hz
4.2	**Battery operated**	UPS of suitable rating with voltage regulation and spike protection for one hour back up
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards

8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

NAAT MACHINE		
Version no.:		Ver_1
Date:		
Done by:		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is intended for amplification and real-time detection of target nucleic acid of human pathogens in a clinical specimens using polymerase chain reaction (PCR) principle.
1.2	**Used by clinical department/ward**	Clinical Diagnostic laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The System should be based on rapid Real Time PCR Technology with complete automated workflow including extraction, amplification, detection and result interpretation with minimal hands-on time and able to do rapid on-demand molecular tests as required by national guidelines/health programs. • The System should be based on Single use disposable Cartridge/chip capable of performing RNA/DNA extraction, reverse transcription and real time PCR. • The tests cartridge should include built-in internal controls for all test steps to ensure accurate test performance and for identification of microorganisms. • The system should be able to perform on-demand and random access. • The system should be easily connected to LIS/HIS. • The system should not require special (lab or PCR) environment to operate effectively. **Reaction site thermal controls:** 1. Each Active Module should have Solid State heater and forced air cooling. 2. Reaction chamber thermistors calibrated to ± 1.0°C using National Institute of Standards and Technology (NIST)-traceable standards 3. The System should have 4-16 active modules which are independently used and controlled for any test cartridge.
2.2	**User's interface**	Built-in/Automatic

2.3	**Software and/ or standard of communication (wherever required)**	Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Laptop/Desktop (if required to control the system) with software.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,);** **Performance and safety standards (specific to the device type); Local and/or international**	1. Should be BIS and CDSCO approved. 2. Should conform USFDA/ European CE, in case of non-availability of BIS Standards. 3. Should conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover.

		2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. State/UT to link with the existing Biomedical Equipment Management and Maintenance Program under NHM. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

LIST OF CONTRIBUTORS

S.No.	Name of Participants	Designation/ Organization
1	Ms. Roli Singh	Additional Secretary & Mission Director, MoHFW
2	Mr Vishal Chauhan	Joint Secretary (Policy), MoHFW
3	Maj Gen Atul Kotwal	Executive Director, NHSRC
4	Dr. Dhara Shah	DD, IDSP, National Centre for Disease Control
5	Dr. Sunite Ganju	Professor & Head, Department of Microbiology, SLBSMC, Mandi
6	Dr. Sanjay Kumar	Professor, Department of Pathology, PGI Rohtak
7	Dr. Kamala Kant	Assistant Professor, Department of Microbiology, AIIMS Bhatinda
8	Dr. Manoj Kr. Nandkeoliar	Professor, Dept. of Biochemistry, School of Medical Sciences & Research, Sharda Hospital, Gr. Noida,
9	Dr. Divya Sahay	Sr. Consultant, Microbiology, Jeevan Anmol Hospital, New Delhi,
10	Dr. Bhaskar Charan Kabi	Professor & Head, Dept. of Biochemistry, School of Medical Sciences & Research, Sharda Hospital, Gr. Noida,
NHSRC		
11	Dr. Himanshu Bhushan	Advisor, PHA, NHSRC
12	Dr. Ranjan Kumar Choudhury	Advisor, HCT, NHSRC
13	Dr. Prasanth KS	Sr. Consultant, PHA, NHSRC
14	Mr. Anjaney	Sr. Consultant, HCT, NHSRC
15	Ms. Vertika	Sr. Consultant, HCT, NHSRC
16	Ms. Ritu Malik	Consultant, HCT, NHSRC
17	Dr. Poonam	Consultant, PHA, NHSRC
18	Ms. Manisha	Consultant, HCT, NHSRC
19	Ms. Charu	Consultant, HCT, NHSRC
20	Mr. Prakamya Gupta	Consultant, HCT, NHSRC
21	Dr. Hari Om Sharma	Consultant, PHA, NHSRC
22	Dr. Aditi Joshi	Consultant, PHA, NHSRC
23	Dr Asutosh Kothari	Consultant, PHA, NHSRC
24	Ms Diksha	Consultant, PHA, NHSRC
25	Dr. Palak	Consultant, PHA, NHSRC
26	Dr Kushagr Duggal	Consultant PHA, NHSRC
27	Dr Syeda Tahseen Kulsum	Consultant PHA, NHSRC
28	Ms Chinmayee Pawar	Consultant HCT, NHSRC
29	Mr Priyobroto Basu	Fellow HCT, NHSRC
CDC		
30	Dr. Mayank Dwivedi	Public Health Specialist & Lab Advisor, CDC
31	Dr Indranil Roy	Public Health Specialist & Lab Advisor, CDC

32	Ms. Richa Kedia	Consultant, CDC
33	Ms. Archi Shukla	Consultant, CDC
FIND		
34	Dr. Sarabjit S. Chadha	FIND
JHPIEGO		
35	Dr. Neeraj Agrawal	Chief of Party, NISTHA
36	Dr. Vineet Srivastava	Chief of Party, RISE
37	Dr. Prashant Singh	Sr. Advisor Lab Strengthening, RISE
38	Dr. Vasundhara Razdan	Representative from JHPIEGO
39	Dr. Parvez Menon	Deputy Chief of Party, RISE
40	Dr. Himanshu Jha	Advisor Lab Strengthening & Diagnostics, NISTHA
PATH		
41	Mr. Ajit Kumar Singh	State Lead
42	Dr. Praveen G	Project Lead, Lab Strengthening
43	Dr. Priyanka Bajaj	Manager, Health and Innovation Impact Lab