National Accreditation Board for Testing and Calibration Laboratories (NABL)

Guidance document: Medical Laboratories

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AMENDMENT SHEET

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CONTENTS

1. Scope

This document provides guidance to medical testing laboratories for the following aspects:

- Operation of sample collection centres / facilities
- Sample format for the preparing the scope of accreditation
- Lot verification
- Algorithm for Automated Selection and Reporting of Results
- Sample format for competency assessment
- Examples for the type of sample and their stability for Clinical Biochemistry parameters

2. Guidance for operating sample collection centre/Facility (SCF) of the Medical Laboratory

Maintaining the integrity of the test sample at all stages of collection, handling, transportation to the main laboratory and processing plays a vital role to ensure reliability of test results. Therefore, it is important to ensure quality at the collection centres. The detailed procedure for recognition of sample collection centres/ facilities (SCF) declared by medical laboratory is mentioned in document NABL 111.

The following are the types of sample collection centres:

i. Ownership: Collection centres owned by the laboratory or its parent organization and personnel are employees of the laboratory.
ii. Management: Laboratory or its parent organization does not own the collection centre but is entirely responsible for day-to-day operations and its employees.
iii. Franchisee: Laboratory or its parent company does not own the collection centre but has an arrangement for sample collection under an agreement e.g., hospitals, Nursing home.

Apart from the above, laboratory shall declare details of all other source(s) of sample collection other than the medical laboratory or sample collection centre/ facility. Laboratory shall ensure integrity of samples from these sources. They shall be assessed on a random basis by NABL, however, claim of recognition under Recognized sample collection centre/ facility cannot be made by laboratory/ sources.

The collection centres/facilities shall meet the following guidelines:

i. All issues related to the operation of collection centres and maintenance of quality shall be addressed by the laboratory in the quality system of the laboratory. Specific instructions for proper collection and handling of primary samples at the collection centre and transportation of these samples to the laboratory shall be documented in a primary sample collection manual, which shall be a part of the quality system of the laboratory and the collection centre.

ii. Laboratory shall document policies and procedures to ensure maintenance of proper hygiene, lighting, environmental conditions and privacy in its collection centres. Collection centres should have adequate space to avoid any cross contamination. During the sample collection in collection centres, laboratory shall ensure the safety, comfort and privacy of the patients.

iii. The laboratory shall have policies and procedures that integrity of the samples is not affected during collection, storage and transportation. Collection centres shall ensure maintenance of required temperature during transport as mentioned below:

a. Temperature monitoring:

Integrity of temperature sensitive parameters / analytes during transport of samples is a major concern in a distant testing scenario. Use of appropriate packaging material, of suitable and well insulated containers, of coolants (4 to 8°C) and dry ice (for ultra cold temperature) are measures that help in maintaining stability of such samples.

The following guidelines will be helpful in this direction:

i. The laboratory may run pilot studies to determine the time taken for samples to reach the laboratory by the route and mode of transport that it plans to use to transport of patients' samples for testing. The nature and type of measures required to maintain the samples in the temperature range recommended for the specific parameter / analyte will depend on information gathered from such trial runs. Accordingly, the laboratory should use appropriate packaging and cooling / freezing material for transporting samples. Most parameters / analytes, except some, are stable at ambient temperature for up to 2 - 4 hours from collection. Hence, if the test is carried out within this time frame, special packaging for transporting of samples might not be necessary.

ii. It is the laboratory's responsibility to ensure that samples are continuously maintained at the temperature recommended for preservation and transport of samples for the tests to be performed. Monitoring of the temperature of samples during transit using electronic

data loggers is encouraged to achieve this objective. The laboratory can include such a device inside the package containing the samples, download and examine the data at the time of receiving the samples in the laboratory. Appropriate corrective measures should be taken by the laboratory if temperature inside the package goes above or below that recommended for the tests to be performed. Samples not maintained at the desirable temperature during transit shall not be accepted for testing.

iii. All acceptable samples that are not going to be processed immediately after accessioning shall be transferred to and preserved immediately at appropriate temperatures till testing. This is important for ensuring integrity of samples received from laboratory / collection centre (wherever samples are collected).

Laboratory shall ensure that its collection centres dispose waste as per the national laws (eg. Biomedical Waste Act) and the local regulations on waste disposal (e.g. the State Pollution Control Board).

For some tests the sample has to be separated & stored (e.g. platelet poor plasma for lupus inhibitors or separation of serum / plasma to be sent in frozen condition); the laboratory shall ensure that adequate training is imparted to the staff for this. Transport of microbiological specimens shall be as per the latest guidelines of Manual of Clinical Microbiology, ASM Press.

b. Staff:

The staff employed in collection centres shall be adequately trained. The training shall include but not be restricted to issues as:

i. Policies, procedures and guidelines
ii. Maintenance of proper hygiene and environmental conditions
iii. Methodology for collection of sample and the quantity required
iv. Processing of collected samples
v. Packaging of samples
vi. Proper transportation of the samples / specimen
vii. First aid measures to be taken, in case of abnormal events
viii. Safety and waste disposal

c. Spillage:

Treatment of spills - Any spill should be covered with a blotting paper / paper towel to reduce the volume of spill. Pour 1% hypochlorite over it and leave it for 30 mins. Discard this in the yellow / red bags as per the waste segregation guidelines.

d. Occupational safety:

Needle stick injury and the action taken to be recorded.

Laboratory shall ensure evaluation of the training imparted to staff in collection centres and maintain records.

Laboratory shall have a plan to conduct internal audit of its collection centres to ensure its compliance to the requirements of NABL111 . Laboratory shall conduct internal audit of each of its collection centre at least once a year. Management review of the laboratory shall also discuss the internal audit of its collection centres.

Only those collection centres which are declared to NABL shall be claimed by the laboratory as a part of its laboratory system. The laboratory shall include the name and address of its collection centre in the test reports. The sample collection centre can claim recognition in line with NABL 133.

Collection centre(s) of the laboratories will be assessed by NABL, these may or may not be assessed by the same assessor who has conducted assessment of the laboratory. Their assessment may be conducted separately by another assessor at a different time. Assessors shall assess the records maintained by the collection centres, including the internal audit records of collection centres. Competence of the staff especially the phlebotomist shall also be assessed.

If major non-conformities or a total system failure is observed during the assessment of a collection centre, the collection centre/facility will not get any recognition or will be derecognized, if it already holds recognition. In case the laboratory fails to take corrective actions or there is a gross system failure, an appropriate and proportionate action against the laboratory will be taken.

Only those collection centres/facilities which are declared to NABL shall be claimed as recognized sample collection centres/facilities of that laboratory during its valid accreditation cycle.

The checklist-3 of NABL 223 shall be used for assessing the collection centres which will be the additional requirements for accreditation of medical laboratories operating collection centres.

Records mentioned in the checklist-3 of NABL 223 shall be available at the collection centre during assessment.

3. Guidelines for scope preparation

The model scope for the various disciplines are given in the tables mentioned below. It is to be noted that %CV and MU where applicable has to be derived based on the IQC data generated within the laboratory. It is preferable to choose the highest %CV of the IQC data (I.e., at or near clinical decision limits as far as possible) obtained in the previous six months. Groups of test parameters referred to as profiles/function tests /analysis /routine examination e.g., Lipid profile, Liver function test, stool routine examination, semen analysis etc., should be segregated individually with their component parameter and relevant test methodology, range of testing and % CV as appropriate. When there is an enzymatic methodology, the enzyme should be specified

a) Histopathology

Sl.	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	Range of testing/ Limit of Detection	%CV/ MU
1.	Small, Medium & Large tissues in Formalin (Any other fixative	Grossing, Decalcification (where applicable)	Light Microscopy with Interpretation	Descriptive	NA

	needs to be mentioned)	Processing. Paraffin embedding Microtomy H& E Staining (Manual /Automated)			
2.	Biopsy with Immuno-fluorescence Renal / Skin etc	Grossing – Processing, Paraffin embedding Microtomy H& E Staining (Manual /Automated) + Cryosections Staining with FITC for IF	Light Microscopy + Fluorescent Microscopy with Interpretation	Descriptive	NA
3.	Paraffin Blocks/Slides for second opinion (Stained / Unstained slides)	Microtomy/ H & E Staining (Manual /Automated)	Light Microscopy with Interpretation	Descriptive	NA
4.	Cell block preparations for fluids / aspirates	Processing Microtomy H & E Staining (Manual /Automated)	Light Microscopy with Interpretation	Descriptive	NA
5.	Fresh biopsy/resection specimen with/without orientation without fixative	Grossing, freezing with OCT, Cryo sectioning. Staining: Rapid H & E / Toluidine blue	Light Microscopy with Interpretation	Descriptive	NA

6.	Tissue / Paraffin block / Unstained slide	PAS stain McManus method	Light Microscopy with Interpretation	Descriptive	NA
7.	Tissue/ Paraffin block/ Cytology slides/ Unstained slide on APES/ Polylysine coated/ charged slides	Anti Cyclin D1	Immunohistochemistry (Manual/automated Staining)	Qualitative and semi-quantitative	NA
8.	Tissue/ Paraffin block/ Cytology slides/ Unstained slide on APES/ Polylysine coated/ charged slides	Arginase	Immunohistochemistry (Manual/automated Staining)	Qualitative and semi-quantitative	NA
9.	Tissue/ Paraffin block/ Cytology slides/ Unstained slide on APES/ Polylysine coated/ charged slides	CD3	Immunohistochemistry (Manual/automated Staining)	Qualitative and semi-quantitative	NA
10.	Tissue/ Paraffin block/ Cytology slides/ Unstained slide on APES/ Polylysine coated/ charged slides	CD4	Immunohistochemistry (Manual/automated Staining)	Qualitative and semi-quantitative	NA
11.	Tissue/ Paraffin block/ Cytology slides/ Unstained slide on APES/ Polylysine coated/ charged slides	CD 35	Immunohistochemistry (Manual/automated Staining)	Qualitative and semi-quantitative	NA

12.	Tissue/ Paraffin block/ Cytology slides/ Unstained slide on APES/ Polylysine coated/ charged slides	NSE	Immunohistochemistry (Manual/automated Staining)	Qualitative and semi-quantitative	NA
13.	Tissue for TEM (tissue in glutaraldehyde or Formalin)	Processing as per standard protocol,	TEM with interpretation	Qualitative & Semi-quantitative	NA

b) <u>Cytopathology</u>

Sl.	**Materials or Products tested**	**Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed**	**Test Method Specification against which tests are performed and / or the techniques / equipment used**	**Range of testing/ Limit of Detection**	**%CV/ MU**
1.	Palpable or non palpable lesion involving any organ	Giemsa (any Romanowsky/ Staining with or without PAP/ H & E	FNA, smear preparation, Staining and Light Microscopy with Interpretation	Descriptive	NA
2.	Body fluids (Ascitic, Pleural, CSF, Synovial, Pus, BAL fluid, ET secretions, nipple discharge)	PAP, H & E and Giemsa or any Romanowsky staining	Smear preparation, Staining and Light Microscopy with Interpretation	Descriptive	NA
3.	Unstained smears (Air Dried / Fixed fixative to be mentioned)	Giemsa or any Romanowsky or without PAP/ H & E	Light Microscopy with Interpretation	Descriptive	NA

4.	Scrapings / brushings (GIT, bronchial, oral)	MGG staining with or without PAP/ H & E	Light Microscopy with Interpretation	Descriptive	NA
5.	Scraping from vesiculobullous lesions of skin	Tzanck Smear MGG Stain	Light Microscopy with Interpretation	Descriptive	NA
6.	Cervical and vaginal smears (Conventional / Liquid based,)	PAP stain	Light Microscopy with Interpretation	Descriptive	NA
7.	Whole slide Imaging a. Routine Histopathological examination b. Frozen Section c. Histochemistry d. Immunohistochemistry e. In situ Hybridization Cytopathology (Non Gynaec & Gynaec)	Digital Scanner, Image Viewing Software	Virtual Microscopy with Interpretation	Descriptive	NA

c) Microbiology & Infectious Disease Serology

Sl.	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	Range of testing/ Limit of Detection	%CV/ MU
1.	Sputum, CSF, Pleural Fluid, Ascitic Fluid, Synovial Fluid, Urine, Aspirate, Tissue Biopsy, Pus	Gram Staining	Light Microscopy	Descriptive Gram positive/Negative;Cocci/ bacilli;Epithelial/pus cells	NA
2.	Throat & Nasopharyngeal Swabs	Staining of Metachromatic Granules	Albert's Staining / Light microscopy	Descriptive present/ absent	NA
3.	Stool	Examination for Cryptosporidium, Cyclospora	Modified Acid fast (Ziehl Neelsen) Staining / Light microscopy	Descriptive present/ absent	NA
4.	Stool	Hanging drop for Cholera	Microscopy	Qualitative	NA
5.	Sputum, CSF, Pleural Fluid, Ascitic Fluid, Synovial Fluid, Urine, Aspirate, Tissue Biopsy, Pus	AFB staining for Nocardia, actinomyces	Modified Kinyoun's method & light microscopy	Descriptive present/ absents	NA

6.	Blood, Bone Marrow, CSF, Pleural Fluid, Ascitic Fluid, Synovial Fluid, Urine, Aspirate, Tissue Biopsy, Pus	Aerobic Culture	Culture – Aerobic by Automated method	Qualitative	NA
7.	Aspirate Fluid, Pleural Fluid, Ascitic Fluid, Peritoneal Dialysate and Bile	Aerobic Culture Identification & Antibiotic sensitivity	Routine Culture – Aerobic, ID by automated/ manual methods. AST by Disk Diffusion / MIC / E test	Qualitative	NA
8.	Stool, Bronchial Secretions	Adenovirus Antigen Detection	Immunochromatography	Qualitative	NA
9.	Throat Swab	Group A Streptococcus antigen detection	Latex Agglutination	Qualitative	NA
10.	Sputum, Pus, Pleural Fluid, Ascitic Fluid, Synovial Fluid, Urine, Aspirate, Tissue Biopsy	Detection of Acid Fast Bacilli	Direct and / or Concentration method / Ziehl Neelsen / Kinyoun's stain and Microscopy	Qualitative	NA
11.	Sputum, Pus, Pleural Fluid, Ascitic Fluid, Synovial Fluid, Urine, Aspirate, Tissue Biopsy	Detection of Acid Fast Bacilli	Fluorescent Microscopy by Auramine Staining	Qualitative	NA

12.	Serum	Anti Streptolysin-O Antibody	Latex Agglutination	Qualitative	NA
13.	Serum	Leptospira IgM	Immunochromatography	Qualitative	NA
14.	Serum	ANA (Anti Nuclear antibodies)	Immunofluorescence	Qualitative	NA
15.	Serum	Anti HBs Ag	ELISA	Semi – Quantitative (Reactive / Non-reactive)	7.3

d) <u>Clinical Biochemistry</u>

Sl.	**Materials or Products tested**	**Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed**	**Test Method Specification against which tests are performed and / or the techniques / equipment used**	**Range of testing/ Limit of Detection**	**%CV/ MU**
1.	Serum	Albumin	Bromocresol Green	1.5 to 6 g/dL	3.1
2.	Serum	Alkaline phosphatase	IFCC / AMP Buffer	5 to 1500UL	6.5
3.	Serum	Aspartate aminotransferase (AST/SGOT)	IFCC with P5P	3 to 1000 U/L	4.2
4.	Serum	AST/ALT Ratio (DeRitis ratio)	Calculated	NA	NA
5.	Serum	Cholesterol	CHOD -POD	20 to 700 mg/dL	3.5

6.	Serum	HDL Cholesterol	Sulphated alpha-cyclodextrin blocking apoB /PEG coupled CE & CO	2 to 180 mg/dL	4.2
7.	Serum	LDL Cholesterol	Calculated	NA	NA
8.	Serum	LDL Cholesterol	Homogeneous assay, alpha-cyclodextrin blocking /polyoxyethylene-polyoxypropylene masking couple with CE & CO	10 to 400 mg/dL	4.6
9.	Serum	Iron	TPTZ	10 to 1000 µg/dL	7.5
10.	Serum	TIBC	Calculated	NA	NA
11.	Serum	UIBC	Nitroso PSAP	55 to 450 µg/dL	7.8
12.	Serum	Total PSA	CMIA	0.008 to 100 ng/mL	9.8
13.	Serum	Troponin I	CLIA	0.01 to 100 ng/mL	6.9
14.	Serum	Creatinine	Creatinine aminohydrolase/ sarcosine oxidase	0.61 to 100 mg/dL	5.3
15.	Serum	Potassium	Indirect ISE	1 to 10.0 mmol/L	2.2
16.	Serum	Amylase	CNP G3	10 to 2000 U/L	3.7
17.	Serum	Protein Electrophoresis-Albumin	Capillary Electrophoresis	0.103 to 5.2 g/dL	4.2

18.	Serum	Protein Electrophoresis-Alpha 1	Capillary Electrophoresis	NA	7.1
19.	Serum	Protein Electrophoresis-Alpha 2	Capillary Electrophoresis	NA	9.8
20.	Serum	Protein Electrophoresis-Beta	Capillary Electrophoresis	NA	7.6
21.	Serum	Protein Electrophoresis-gamma	Capillary Electrophoresis	0.103 to 3.1 g/dL	4.5
22.	Urine (random/24h)	Protein	Pyrogallol red	1 to 200 mg/dL	5.6
23.	Urine (random/24h)	Osmolality	Freezing point depression	10 to 2000 mOsmol/kg of H2O	3.3
24.	Urine (random/24h)	Creatinine	Modified Jaffe	1 to 400 mg/dL	7.4
25.	CSF	Human IgG	Agglutination on nephelometer	3.6 to 115 mg/L	8.9
26.	Serum	Human Kappa Chain	Immunoturbidimetry	6.6 to 165 mg/L	18
27.	Urine (random/24h)	Human Kappa Chain	Immunoturbidimetry	6.6 to 165 mg/L	13.5
28.	Urine (random/24h)	Human Lambda Chain	Immunoturbidimetry	6.6 to 162 mg/L	14
29.	Serum	FLC ratio	Calculated	NA	NA
30.	Whole Blood	Glucose-6-Phosphate Dehydrogenase	Oxidation of G6P to 6-phosphogluconate/ reduction of NADP, UV Kinetic-fluorometry	0.1 to 13.8 U/g Hb	13.6

31.	Whole Blood	Neonatal 17-OHP (17-hydroxyprogesterone)	DELFIA	1 to 700 ng/mL	9.6
32.	Whole Blood	Neonatal Phenylalanine (PKU)	DELFIA	0.1 to 14.5 mg/dL	9.4
33.	Whole Blood	GM1 Gangliosidosis (Beta Galactosidase enzyme)	Enzymatic, Fluorometry	2 to 400 nmol/h/mg	10.0
34.	Urine	Succinyl acetone	GC-MS	0.05 to 450 mmol/mol	10.5
35.	Serum	25-hydroxy vitamin D	LC-MSMS	20 to > 200 nmol/L	10.9
36.	Whole Blood	Acylcarnitine - C0	Tandem mass spectrometry	3 to 300 µmol/L	9.6
37.	Serum	Busulfan	Tandem Mass Spectrometry	0.03 to 4000 µmol/L	12.9
38.	Urine	Epinephrine	HPLC	2.6 to 1000 µg/L	7.2
39.	Whole Blood	Arsenic	ICPMS	0.1 to 100 µg/L	12
40.	Whole Blood	Lead	AAS	1 to 100 µg/L	11.3
41.	Stone	Gall / kidney stone	FTIR spectroscopy	5 to 100% of individual constituents	NA
42.	Whole Blood	pH	Potentiometry	6 to 8	0.01
43.	Whole Blood	pCO2	Potentiometry	0 to 250 mmHg	3.5
44.	Whole Blood	pO2	Amperometry	0 to 800 mm Hg	2.7

45.	Whole Blood	cBase(B)c	Calculated	NA	NA
46.	Whole Blood	Lactate	Amperometry	0.5 to 15 mmol/L	8.4
47.	Whole Blood	Ionised Calcium	Potentiometry	0.2 to 9.99 mmol/L	1.7
48.	Ascitic Fluid/ Pleural Fluid/ CSF	Amylase	CNP G3	10 to 2000 U/L	4.2
49.	Sweat	Sweat Chloride Estimation	Titration	NA	NA
50.	Urine	Glycosoaminoglycans (GAGs) Quantification	Spectrophotometry	NA	NA
51.	Urine	Glycosoaminoglycans (GAGs) Qualitative	Electrophoresis	NA	NA
52.	Serum	ADA2 enzyme assay (Adenosine De-aminase enzyme2) for Polyarteritis nodosa	Spectrophotometry	NA	NA
53.	Whole blood leukocytes/Dried Blood Spot/Chorionic villi	α- Mannosidase (Mannosidosis A)	Fluorometry	NA	NA
54.	Urine	Porphyria – Total porphyrin in urine (Quantitative)	Spectrophotometry	NA	NA
55.	Urine	Porphyria – Chromatography for coproporphyrin & uroporphyrin	Silica gel Chromatography	NA	NA

56.	Heparin/ EDTA blood (5-6 ml)/ Whole blood Leukocytes/ Chorionic villus sample (30 mg)	Acetyl- CoA : α-glucosaminide Nacetyl transferase Sanfillipo IIIC (MPS-3C)	Fluorometry	NA	NA
57.	Whole blood leukocytes/Dried Blood Spot/Chorionic villi	Total Hexosaminidase (A+B) enzyme assay for Sandhoff disease	Fluorometry	NA	NA
58.	Whole blood leukocytes/Dried Blood Spot/Chorionic villi	Aryl sulfatase A enzyme assay for Metachromatic leukodystrophy (Lysosomal Storage disorder)	Spectrophotometry	NA	NA
59.	Whole blood leukocytes/Dried Blood Spot/Chorionic villi	Palmitoyl protein thioesterase (PPT) enzyme assay for Infantile NCL1 disease	Fluorometry	NA	NA

NA: Not Available

Note:

1. All CV percentages are representative only.

2. Body fluid without matrix matched internal quality controls and proficiency testing programs need verification before being put in the scope.

3. All %CV/MU of calculated parameters only, they will be dependent on methods and the formula used. It is advisable to clearly state the formula while reporting the same.

Calculated Parameters:

Calculated parameters could be a simple arithmetic calculation like Indirect bilirubin when both total and direct bilirubin can be measured or could be ratio as in AST/ALT ratio or complex equation involving multiple parameters such as creatinine clearance. Some of the calculated parameters are offered by the machine such as base excess in blood gas analysis and MCHC as in haematology. However, components of calculated parameter i.e., their primary parameters should be a part of the scope of accreditation for it to be considered for inclusion into scope. Laboratory shall use recommended formula/equation with scientific justification for its use along with appropriate references. Laboratories shall provide a declaration of all primary parameters that is required for its calculated parameters. All calculated parameters shall be evaluated for its QC performance like primary parameter i.e., mean, SD and %CV.

e) <u>Clinical Pathology</u>

Sl.	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	Range of testing/ Limit of Detection	%CV/ MU
1.	Urine	Colour/Transparency	Visual Examination	NA	NA
2.	Urine	Glucose	GOD-POD	Neg - 4+	NA
3.	Urine	Bile Salt	Diazo Reaction/ Hay's Sulphur Test	Neg - 4+	NA
4.	Urine	Ketone	Sodium Nitroprusside Reaction/Rothera's Test	Neg - 4+	NA
5.	Urine	Specific gravity	pKa Change/Indicator	1.005 – 1.030	NA
6.	Urine	pH	Double Indicator	5.0 – 9.0	NA
7.	Urine	Protein	Protein error of indicator/ Sulphosalicylic Acid method	Neg - 4+	NA
8.	Urine	RBC, Pus Cells, Epithelial Cells, Cast, Crystals, Any Other Cells, Eosinophils	Microscopy	0 – Plenty / hpf	NA
9.	Urine	Reducing Substance	Benedict's method	Positive / Negative	NA

10.	Stool	Colour, Consistency, Mucus, Blood	Visual Examination	NA	NA
11.	Stool	RBC, Pus Cells, Vegetable Matter, Trophozoites, Ova, Cyst, Any Other Findings	Microscopy	0 – Plenty / hpf	NA
12.	Stool	Occult Blood	Standard Two Field Guaiac Method	Positive / Negative	NA
13.	Semen	Volume, Color, Liquefaction, Viscosity	Visual Examination	NA	NA
14.	Semen	pH	Indicator Method	5.0 – 9.0	NA
15.	Semen	Fructose	Seliwanoff's Method	Positive / Negative	NA
16.	Semen	Motility	Microscopy	NA	NA
17.	Semen	Morphology	PAP Staining and Microscopy	NA	NA
18.	Semen	Vitality	Eosin-Nigrosine Staining and Microscopy	NA	NA
19.	Semen	Sperm Count	Improved Neubauer chamber/Automated	0 – 50 x 10^6/ml	NA
20.	Semen	Sperm Count Per Ejaculate	Calculated	NA	NA
21.	Semen	Red Cells, Pus Cells, Epithelial Cells, Crystals, Amorphous, Deposit, Bacteria	Microscopy	NA	NA
22.	CSF	Colour/Appearance	Visual Examination	NA	NA
23.	CSF	Xanthochromasia	Visual Examination	NA	NA
24.	CSF	Total RBC Count Total WBC Count	Microscopy – Neubauer Chamber	Nil - Plenty	NA
25.	CSF	Differential Count/Any other findings	Microscopy-Romanowsky	0-100%	NA

f) Haematology & Immunohaematology

Sl.	Materials or Products tested	Component, Parameter or Characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	Range of testing/ Limit of Detection	%CV/MU
Hematology					
1.	EDTA Whole Blood	Haemoglobin	Modified Cyanmethemoglobin method	0.1 – 22.5 g/dl	2.3
2.	EDTA Whole Blood	Haemoglobin	Non-Cyanide	0-25 g/dl	3.2
3.	EDTA Whole Blood	Packed Cell Volume (PCV)	Calculated	NA	4.5
4.	EDTA Whole Blood	Mean Corpuscular Volume (MCV)	Optical Cytometer	0 – 200 fl	2.3
5.	EDTA Whole Blood	Mean Corpuscular Volume (MCV)	Derived from RBC histogram	50-150fl	3.4
6.	EDTA Whole Blood	Mean Corpuscular Haemoglobin (MCH)	Calculated- Automated Cell counter	NA	4.5
7.	EDTA Whole Blood	RBC Count	Flow Cytometry	0 – 7.0 x 10^6/µL	2.3
8.	EDTA Whole Blood	RBC Count	Electrical Impedance	0 – 7.0 x 10^6/µL	4.5
9.	EDTA Whole Blood	Platelet Count	Flow Cytometry	5.0 – 3500 x 10^3/µL	3.3
10.	EDTA Whole Blood	Platelet Count	Electrical Impedance	10.0 – 3500 x 10^3/µL	4.5
11.	EDTA Whole Blood	Red Cell Distribution Width (RDW – CV)	Calculated	10-40%	6.4

12.	EDTA Whole Blood	Total WBC Count	Flow Cytometry	0.02 – 400 x 10^3/µL	6.3
13.	EDTA Whole Blood	Total WBC Count	Electrical Impedance	0.05 – 400 x 10^3/µL	5.4
14.	EDTA Whole Blood	Neutrophil	Flow Cytometry/ Leishman Staining and Microscopy	0-100%	2.3
15.	EDTA Whole Blood	Neutrophil	VCS/Leishman Staining and Microscopy	0-100%	3.4
16.	EDTA Whole Blood	Neutrophil	Leishman Staining and Microscopy	0-100%	NA
17.	EDTA Whole Blood	Absolute Neutrophil Count	Calculated/ Leishman Staining and Microscopy	0- 400 x10^3cells/cumm	3.4
18.	EDTA Whole Blood	ESR	Automated Sedimentation method (Principle of detection to be specified)	0 – 140 mm/hr	8.9
19.	EDTA Whole Blood/ Citrated Whole Blood	ESR	Modified Westergren Method	0 – 140 mm/hr	NA
20.	EDTA Whole Blood	Malarial Parasite	Immunochromatography (pLDH and HRP II)	Positive / Negative	NA
21.	EDTA Whole Blood	Malarial Parasite	Leishman Staining and Microscopy (Thick and Thin Smear)	Interpretative	NA
22.	EDTA Whole Blood	Reticulocyte Count	New Methylene Blue or Brilliant Cresyl Blue Staining and Microscopy	0 – 100%	NA
23.	Bone Marrow Aspirate & Imprints	Bone marrow Examination	Giemsa, Wrights, Perl's Prussian Blue Staining and Microscopy	Interpretative	NA

24.	Bone Marrow Aspirate	PAS/Sudan B Black	Microscopy	Qualitative	NA
25.	Citrated Whole Blood	Prothrombin Time	Mechanical or Optical Clot detection method	5 - 170 sec	5.4
26.	Citrated Whole Blood	PT- INR	Calculated	NA	NA
27.	Citrated Whole Blood	aPTT	Optical Clot detection method	8 – 180 sec	2.3
28.	Citrated Whole Blood	Fibrinogen	Modified von Clauss method	30 – 1400 mg/dl	5.6
29.	Citrated Whole Blood	Factor VIII	One stage clot based method	0.4 – 480%	4.3
30.	Citrated Whole Blood	Factor XIII	Manual – Urea Solubility method	NA	NA
31.	Blood (Plain)	Clot Retraction	Manual	NA	NA
Immunohematology					
32.	EDTA Whole Blood and Serum	Blood Grouping & Rh Typing	Tube Agglutination (Forward & Reverse)	A/AB/B/O & Negative /Positive	NA
33.	EDTA Whole Blood	Blood Grouping & Rh Typing	Column Agglutination Technique (CAT) – Manual /Automated	A/AB/B/O & Negative/positive	NA
34.	EDTA Whole Blood	Direct Coombs Test	Tube Agglutination/ Column Agglutination Technique (CAT) – Manual /Automated	Qualitative	NA
35.	EDTA Whole Blood and Serum	Crossmatch Coombs	Column Agglutination Technique (CAT) – Manual /Automated	Qualitative	NA
36.	EDTA Whole Blood	Antibody Screen	Column Agglutination Technique (CAT) – Manual	Qualitative	NA

g) Molecular Diagnostics

Sl.	Materials or Products tested	Component, Parameter or Characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	Range of testing/ Limit of Detection	%CV/ MU
1.	EDTA Whole Blood or Bone Marrow	BCR-ABL qualitative	Multiplex RT PCR/Real-time PCR	10^{-3}-10^{-4}	NA
2.	EDTA Whole Blood or Bone Marrow	PML-RARA t (15:17) qualitative	Multiplex RT PCR/Real-time PCR	10^{-3}-10^{-4}	NA
3.	EDTA Whole Blood or Bone Marrow	BCR-ABL quantitative	Real-time PCR/ddPCR	<0.001	NA
4.	EDTA Whole Blood or Bone Marrow	AML1-ETO t (8:21) quantitative	Real-time PCR/ddPCR	10^{-4}-10^{-5}	NA
5.	EDTA Whole Blood	Haemophilia – A (Intron 22)	Polymerase chain reaction (PCR)	1-5%	NA
6.	EDTA Whole Blood	Beta Thalassemia Mutation	Sanger Sequencing/ASO PCR/RFLP	20-25%	NA
7.	EDTA Whole Blood	Alpha Thalassemia Deletion/ Duplication	MLPA	NA	NA
8.	EDTA Whole Blood or Bone Marrow	BRAFV600E	ASO-PCR/Sanger sequencing/Realtime PCR/Pyrosequencing,	1-5%	NA
9.	EDTA Whole Blood	Calreticulin (CALR)	Fragment analysis/Sanger Sequencing	20-25%	NA
10.	EDTA Whole Blood	Factor V (Leiden Mutation)	Sanger sequencing/Real time PCR/RFLP	20-25%	NA
11.	EDTA Whole Blood or Bone Marrow	FLT3-ITD mutation	Fragment analysis/Sanger Sequencing	5-10%	NA
12.	EDTA Whole Blood or Bone Marrow	JAK2 V617	Sanger sequencing, Realtime PCR/AS-PCR	<2%	NA

13.	EDTA Whole Blood	Chimerism	Fragment analysis/Sanger Sequencing	5%	NA
14.	EDTA Whole Blood or Bone Marrow or FFPE	T-cell Gene Rearrangement	Fragment analysis/Sanger sequencing/ NGS	5-10%	NA
15.	EDTA Whole Blood or Bone Marrow	Myeloid DNA multigene Panel	Next Generation Sequencing	5-10%	NA
16.	EDTA Whole Blood	Charcot Marie Tooth disease X-linked - GJB1 MLPA	MLPA	NA	NA
17.	Paraffin Block (FFPE)	Cancer: Gliomas (IDH1/IDH2 and MGMT- MLPA)	MLPA	NA	NA
18.	EDTA Whole Blood	Albinism – (OCA1A) TYR gene common Indian mutation	PCR/Gene Sequencing	NA	NA
19.	DNA from peripheral blood / CVS or Amniotic or CB	Thalassemia – beta mutation study (family)	PCR – ARMS/ targeted gene sequencing	NA	NA
20.	DNA from peripheral blood / CVS or Amniotic or CB	Hemophilia (prenatal diagnosis)	MLPA / Gene sequencing/ Inv1 &22	NA	NA
21.	DNA from peripheral blood / CVS or Amniotic or CB	Huntington’s disease	PCR	NA	NA
22.	DNA from peripheral blood / CVS or Amniotic or CB	Spinal muscular atrophy- Prenatal diagnosis	PCR + RFLP / MLPA	NA	NA
23.	DNA from peripheral blood / CVS or Amniotic or CB	Factor V Leiden	Real time PCR / Gene sequencing	NA	NA
24.	DNA from peripheral blood / CVS or Amniotic or CB	Fragile X screen	PCR	NA	NA

25.	DNA from peripheral blood / CVS or Amniotic or CB	Hemophilia (carrier test)	MLPA / Gene sequencing/Inv1 &22	NA	NA
26.	Peripheral blood, stored DNA from the same	Chromosomal microarray for post-natal constitutional indications on peripheral blood	Platform to be specified eg. Affymetrix 750K snp	NA	NA
27.	Chorionic villus sample, stored DNA from the same	Chromosomal microarray for prenatal constitutional indications on CVS	Platform to be specified	NA	NA
28.	Bone marrow, stored DNA from the same	Chromosomal microarray for haematological malignancies	Platform to be specified	NA	NA
29.	Peripheral blood, amniotic fluid, CVS, cord blood, stored cell pellets, stored DNA	Quantitative Fluorescence PCR (QF PCR)	Specify chromosomes targeted eg. Chromosomes 13,18,21	NA	NA
30.	Urine	Glycosaminoglycans (GAGs) Quantification	Spectrophotometry	NA	NA
31.	Urine	Glycosaminoglycans (GAGs) Qualitative	Electrophoresis	NA	NA
32.	Whole blood leukocytes/ Dried Blood Spot/ Chorionic villi	α- Mannosidase (Mannosidosis A)	Fluorometry	NA	NA
33.	Urine	Porphyria – Total porphyrin in urine (Quantitative)	Spectrophotometry	NA	NA

34.	Heparin/ EDTA blood (5-6 ml) / Whole blood Leukocytes/ Chorionic villus sample (30 mg)	Acetyl- CoA: α-glucosaminide Nacetyl transferase Sanfillipo IIIC (MPS-3C)	Fluorometry	NA	NA

h) Flow Cytometry

Sl.	Materials or Products tested	Component, Parameter or Characteristic tested/ Specific Test Performed/ Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	Range of testing/ Limit of Detection	%CV/ (±MU)
1.	EDTA/Heparin Whole Blood	HLA B27 Assay	Flow Cytometry	Positive / Negative	NA
2.	EDTA/Heparin Whole Blood	CD3	Flow Cytometry	0-100%	NA
3.	EDTA/Heparin Whole Blood	CD4	Flow Cytometry	0-100%	NA
4.	EDTA/Heparin Whole Blood	PNH assay for RBC and Granulocyte (Routine)	Flow Cytometry	01 %	NA
5.	EDTA/Heparin Whole Blood	PNH assay for RBC and Granulocyte (High sensitivity)	Flow Cytometry	RBC ≥ 0.01% WBC ≥ 0.05	NA
6.	Whole Blood/ Bone Marrow/ Body Fluids (Specify type of body fluids tested)/ Lymph Node Aspirate	Acute Leukemia Panel	Flow Cytometry	NA	NA

7.	Whole Blood/ Bone Marrow/ Body Fluids (Specify type of body fluids tested)/ Lymph Node Aspirate	Chronic lymphoproliferative disorder panel	Flow Cytometry	NA	NA
8.	EDTA Bone Marrow	B ALL MRD assay	Flow Cytometry	0.01%	NA
9.	EDTA Bone Marrow	T ALL MRD assay	Flow Cytometry	0.01%	NA
10.	EDTA Bone Marrow	AML MRD assay	Flow Cytometry	0.1%	NA
11.	EDTA Bone Marrow	MM MRD assay	Flow Cytometry	0.001%	NA
12.	EDTA/Heparin Whole Blood	Leucocyte Adhesion Deficiency (LAD-1)	Flow Cytometry	Positive/ Negative	NA
13.	Pre/Post Harvest sample	Stem cell (CD34+) enumeration	Flow Cytometry	0-10,000 cells/ µl	NA
14.	Whole Blood/ Bone Marrow/ Body Fluids (Specify type of body fluids tested)/ Lymph Node Aspirate	CD45	Flow Cytometry	Positive / Negative	NA
15.	Whole Blood/ Bone Marrow/ Body Fluids (Specify type of body fluids tested)/ Lymph Node Aspirate	CD19	Flow Cytometry	Positive / Negative	NA
16.	Whole Blood/ Bone Marrow/ Body Fluids (Specify type of body fluids tested)/ Lymph Node Aspirate	CD34	Flow Cytometry	Positive / Negative	NA

17.	Whole Blood/ Bone Marrow/ Body Fluids (Specify type of body fluids tested)/ Lymph Node Aspirate	CD117	Flow Cytometry	Positive / Negative	NA

i) <u>Histocompatibility & Immunogenetics</u>

Sl.	**Materials or Products tested**	**Component, Parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed**	**Test Method Specification against which tests are performed and/or the techniques/ equipment used**	**Range of testing/Limit of detection**	**% CV /MU (±)**
1.	Citrated Blood from Donor and Clotted Blood /Serum from Recipient	HLA T and B Cell Crossmatch	HLA Serology – Complement Dependent Cytotoxicity	Semiquantitative	NA
2.	Citrated Blood from Donor and Clotted Blood/Serum from Recipient	HLA T and B Cell Crossmatch	Flow Cytometry	Semiquantitative	NA
3.	Clotted Blood /Serum	Panel Reactive antibody (PRA) screen	Luminex X map technology	NA	NA
4.	Clotted Blood /Serum	HLA Single Antigen \Assay – Class I and II	Luminex X map technology	NA	NA
5.	EDTA Whole Blood/ DNA	HLA Typing A, B, C, DR, DQ, DP	PCR- SSP (Sequence Specific primers)	NA	NA
6.	EDTA Whole Blood/ DNA	HLA Typing A, B, C, DR, DQ, DP	PCR – SSOP (Sequence Specific Oligonucleotide Probes) - Luminex	NA	NA

7.	EDTA Whole Blood/ DNA	HLA B27	PCR – SSP /SSOP	Qualitative	NA
8.	EDTA Whole Blood/ DNA	HLA B27	Flow Cytometry	Qualitative	NA
9.	EDTA Whole Blood/ DNA	DR/DQ typing for disease association	SSOP/SSP	Qualitative	NA
10.	EDTA Whole Blood/ DNA	HLA Typing at High resolution A, B, C, DR, DQ, DP	SBT (Sequence based Typing)	NA	NA
11.	EDTA Whole Blood/ DNA	HLA Typing at High resolution A, B, C, DR, DQ, DP	NGS (Next Generation Sequencing)	NA	NA

j) Cytogenetics

Sl.	**Materials or Products tested**	**Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed**	**Test Method Specification against which tests are performed and / or the techniques / equipment used**	**Range of testing/ Limit of Detection**	**%CV/MU**
1.	Whole Blood/Bone Marrow Aspirate	BCR/ABL1 t(9;22)	FISH (Type of Probe)	NA	NA
2.	Whole Blood/Bone Marrow Aspirate/FFPE	BCL2 (18q21)	FISH (Type of Probe)	NA	NA
3.	Whole Blood/Bone Marrow Aspirate	PML/RARA t(15;17)	FISH (Type of Probe)	NA	NA
4.	Whole Blood/Bone Marrow Aspirate	RUNX1/RUNX1T1 (ETO/AML1) t(8;21))	FISH (Type of Probe)	NA	NA

5.	Whole Blood/Bone Marrow Aspirate /FFPE	17p- Deletion TP53 17p13.1	FISH (Type of Probe)	NA	NA
6.	Whole Blood/Bone Marrow Aspirate	BCR/ABL1 t(9;22)	FISH (Type of Probe)	NA	NA
7.	Conventional karyotype for post- natal constitutional indications on peripheral blood	Peripheral blood collected in sodium heparin	Short term phytohemagglutinin stimulated tube culture, GTL banding	NA	NA
8.	Conventional karyotype for haematological malignancies	Bone marrow aspirate collected in sodium heparin	Short term tube/flask culture, GTL banding	NA	NA
9.	Conventional karyotype for prenatal indications on amniotic fluid	Amniotic fluid	Long term flask/ in situ culture, GTL banding	NA	NA
10.	Conventional karyotype for prenatal indications on CVS	Chorionic villus sample	Long term flask/ in situ culture, GTL banding	NA	NA
11.	Conventional karyotype for prenatal indications on cord blood	Cord blood collected in sodium heparin	Short term phytohemagglutinin stimulated tube culture, GTL banding	NA	NA

12.	Conventional karyotype on products of conception/foetal tissue	Products of conception/foetal tissue (unfixed)	Long term flask culture, GTL banding	NA	NA
13.	Conventional karyotype on skin fibroblasts	Skin (unfixed)	Long term flask culture, GTL banding	NA	NA
14.	Conventional karyotype on solid tumours	Tumour tissue (unfixed)	Long term flask culture, GTL banding	NA	NA
15.	Fluorescence in situ Hybridization (FISH) for constitutional disorders.	Peripheral blood, skin (unfixed), buccal smears; harvested cell pellets from cultures of peripheral blood, skin, amniotic fluid, chorionic villus samples, cord blood	Probes and application to be specified eg. XY centromere enumeration probe for rapid detection of aneuploidy, XY centromere enumeration probe for detection of mosaicism, etc.	NA	NA
16.	Fluorescence in situ Hybridization (FISH) for non-solid haematological malignancies	Peripheral blood, bone marrow aspirate; enriched bone marrow preparation, harvested cell pellets of cultured peripheral blood or bone marrow	Probe and application to be specified eg. BCR/ABL dual color- dual fusion probe for determining bcr/abl status; BCR/ABL dual color- dual fusion probe for CML follow-up, etc.	NA	NA

17.	Fluorescence in situ Hybridization (FISH) for Oncology on formalin fixed paraffin embedded tissue	Formalin fixed paraffin embedded tissue from tumour	Probe and application to be specified. Eg. HER2 LSI for determining HER2/neu status in breast carcinoma	NA	NA
18.	Fluorescence in situ Hybridization (FISH) for Oncology on cultured tumour	Tumour tissue (unfixed), harvested cell pellets from cultured tumour tissue	Probe and application to be specified	NA	NA

4. Guidelines for lot verification

a. Quality Controls

i. **Clinical Biochemistry:** New lot of controls should ideally be run in parallel with old lot of controls

ii. **CBC and Coagulation controls:** The new QC lots may be verified against the old lot by running them parallel.

Acceptance criteria – Review the data to ensure that there are no trends. Outlier should be eliminated before calculating the laboratory mean and ranges. The ranges are acceptable when it is within manufacturer's recommendations (available in the instrument or method documentation). Calculate the new mean and standard deviation for each analyte (as applicable)

b. Reagents

i. **Chemistry assays:**

- A minimum of 2 patient samples or QC should be run on the old and new lot number.
- Acceptability limits should be within analyte's Measurement uncertainty.

ii. CBC analyzer reagents

- Material of known value may include patient samples or controls – minimum of 2 patient samples.
- Background checks must be performed on inert materials such as diluent to ensure that new lots do not interfere with patient results.

c. Coagulation reagents:

i. PT reagent

- Parallel testing of new lots of PT reagents also includes verifying the reference range, geometric mean and programming the correct ISI (International Sensitivity Index) into coagulation analyzer.
- To verify the reference range and geometric mean it is necessary to collect specimens from 20 “normal” subjects and to run a PT with the new lot of thromboplastin reagent. 90% of the samples must fall within the current range in order to verify the range and geometric mean. If they do not, a new reference range study must be conducted to determine them. Microsoft Excel or other appropriate clinical reference range software must be used to calculate the new range and geometric mean.
- Perform comparison studies between the old and new lot number to verify the consistency of patient results and controls. The R value for the correlation study should be ≥ 0.97.
- Validate the PT reference range with 20 specimens. If the reference range does not validate perform a new reference range study using at least 60 specimens.
- Finally, perform a manual check of the INR and compare with the instrument generated INR result.

ii. PTT (APTT) reagents:

- Parallel testing of PTT reagents should be conducted well in advance of the expiration of the old reagent.
- Perform comparison studies between the old and new lot number using patient samples and controls. The R value for the correlation study should be R ≥ 0.97.
- Please note that if patient on heparin therapy are being monitored, the laboratory should perform a new heparin curve with each change of reagent lot.

d. Semi quantitative tests urine analyser strips:

- A minimum of 2 patient samples are run in parallel on both the old and the new lots (The samples should demonstrate varying results across the range for different strip analytes).
- The QC and patient results should be reproducible between the two lots. Generally negative results should remain negative, positive results should give the same results or be one level up or down from the original result).

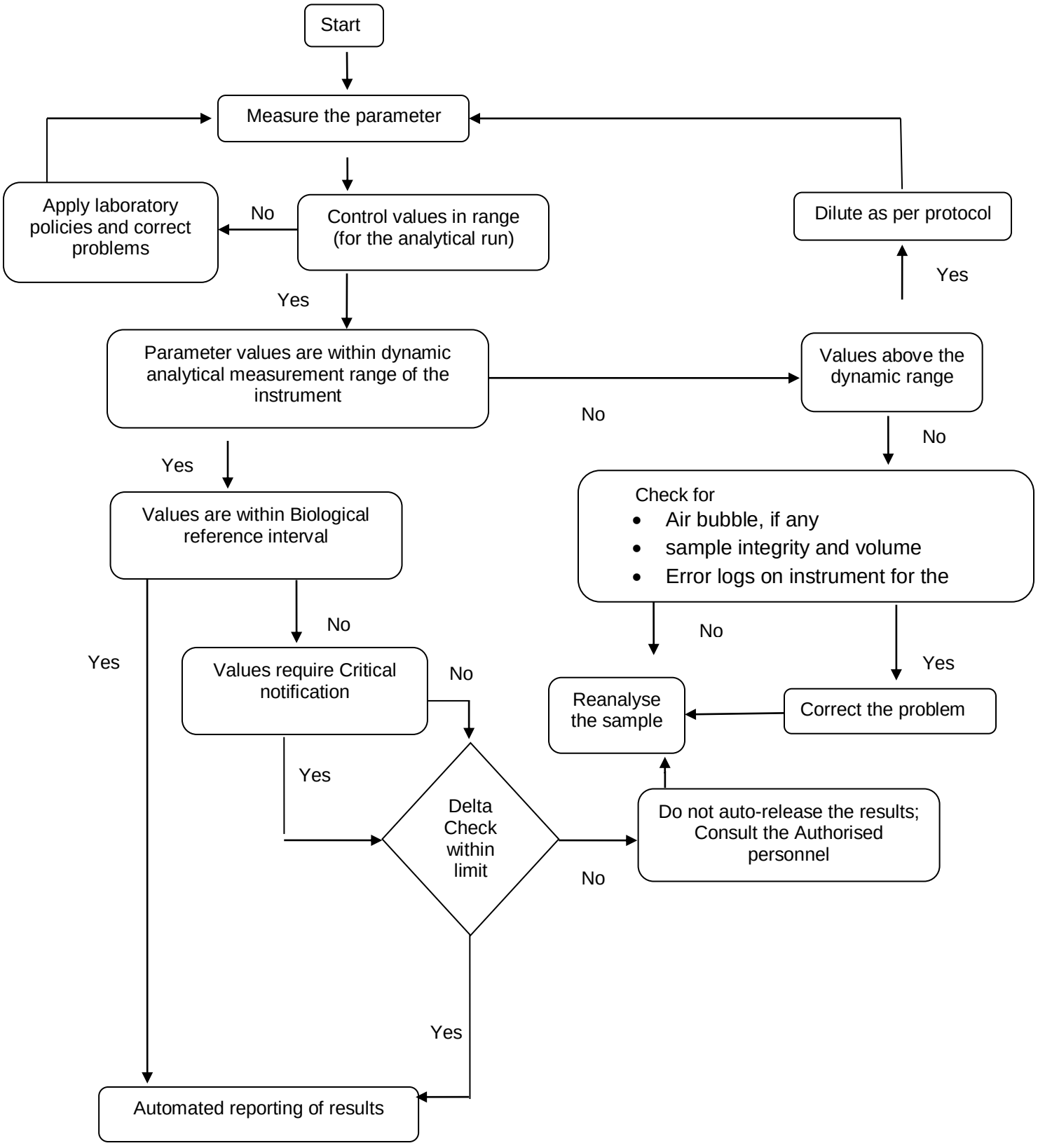
Automated Urine analyser: Parallel testing of reagents should be conducted at the time of reagent lot change with a minimum of 2 patient samples.

e. Acceptance testing for reagents and kits in microbiology and infectious serology and infectious tests of molecular diagnostics:

Sl.	Parameter	Methodology	Acceptability Criteria
1.	Stains	Appropriate standard strain of microorganism (e.g., ATCC).	Satisfactory staining on microscopic examination.
2.	Culture media & Biochemicals	Appropriate standard strain of microorganism (e.g., ATCC).	The growth of the organism should be supported.
3.	Antimicrobial susceptibility testing	Appropriate standard strain of microorganism (e.g., ATCC).	The zone sizes should be within acceptable limits.
4.	Serological assays- Qualitative result relying on test which produces qualitative output data (e.g., Immunochromatography, Immunoconcentration etc.,)	At least two prior tested patient samples/ EQAS samples /third party controls, one negative and one positive (preferably low positive).	The results should be reproducible i.e., negative sample should give negative result and positive sample should give positive result.
5.	Serological assays- Semi-quantitative results (e.g., VDRL test, Widal test)	At least two prior tested patient samples, one negative and one positive (preferably low positive).	The results should be reproducible i.e., negative sample should give negative result and positive sample should give positive result within one dilution.
6.	Serological assays-	At least two prior tested patient	The results should be

	Qualitative result relying on test which produces quantitative output data (e.g., ELISA, CLIA)	samples, one negative and one positive (preferably low positive).	reproducible, i.e., negative sample should give negative result and the difference between the quantitative output data (S/Co) for positive sample should be within 10% or within the uncertainty value established by the lab, whichever is higher.
7.	Molecular assays - Qualitative (e.g., SARS-CoV-2 qPCR)	At least two prior tested patient samples, one negative and one positive (preferably low positive, i.e., C_T value>25).	The results should be reproducible, i.e., negative sample should give negative result and the difference in C_T values for the positive sample should be within ±2.
8.	Molecular assays- Quantitative (e.g., HIV-1-qPCR, HBV-qPCR)	At least two prior tested patient samples, one negative and one positive (preferably low positive i.e., 3-4 Log10 copies or IU/ml).	The results should be reproducible, i.e., negative sample should give negative result and the difference in Log_{10} transformed values for the positive sample should be within ±0.5.
9.	Absolute CD4+T-Lymphocyte count & percentage by immunophenotyping	At least two prior tested patient samples, one low (200-400 cells/µl) and one high count (>500 cells/µl).	The results should be reproducible, i.e., the difference should not be more than 20% (for both absolute count and percentage) for each of the two samples.

5. Guidance on algorithm for automated selection and reporting of results



6. Competence assessment form

Name:	Qualifications:	Experience in Laboratory	Date of Joining
Designation:			Full time /Part time /Locum:
Date of Assessment:		Assessor(s) Name	

S. No	Disciplines of work		Primary	Secondary	Not Applicable
A.	Clinical Biochemistry				
B	Hematology & Immunohematology				
C	Clinical Pathology				
D	Micro &Infectious Disease Serology:				
E	Histopathology				
F	Cytopathology				
G	Flow Cytometry				
H	Molecular Diagnostics	Infectious (Inf) Molecular Non-Infectious (Non Inf)			
		Others:			
I	Histocompatibility & Immunogenetics				
J	Cytogenetics				
S. No. 2.	Job Description & Responsibilities				Mention as given (A-J; Primary, Secondary)
	a. Appropriate involvement in ensuring validity of examination results: • Internal Quality Control • External Quality assessment				

	b. Trouble shoot, accurately interpret the results generated	
	c. Providing Advisory services	
	d. Appropriate involvement in ensuring compliance to regulatory requirements	
	e. Meets the organizational requirements in the discipline/s of work	

S.no	Performance Evaluation on Competence: a) Evidence of involvement in day to day to work b) Demonstration of competency of reporting & trouble shooting c) Evidence of training	Competent	Not Competent
3.			

Name & Signature with Date:	
a. Person proposed to Sign test reports with Disciplines as given A-J above	
b. Assessed by and/or Laboratory Director	

7. Examples of common biochemistry parameters with type of sample and their stability from the time of sample collection

Sl.	Analytes	Sample type	Stability		
			Room temperature (18º to 24ºC)	Refrigerated (2º to 8ºC)	Frozen (< -20ºC)
1.	Glucose	P	6 hr	72 hr	1 wk
2.	Urea	S	2 hr	1 wk	4 wk
3.	Creatinine	S	6 hr	1wk	2 wk
4.	Total protein	S	2 hr	1 wk	4 wk
5.	SGPT/SGOT	S	2 hr	3 D	1 wk
6.	ALP	S	2 hr	3 D	1 wk
7.	T BIL/D BIL/I BIL	S	2 hr	3 D	2 wk
8.	Amylase	S	8 hr	4 wk	4 wk
9.	ALP	S	4 hr	3 D	4 wk
10.	Lipase	S	6 hr	1 wk	4 wk
11.	Cholesterol	S	8 hr	1 wk	2 wk
12.	HDL	S	2 hr	1 wk	2 wk
13.	Uric acid	S	2 hr	1 wk	4 wk
14.	Iron	S	8 hr	3 wk	4 wk
15.	Ferritin	S	8 hr	2 D	4 wk
16.	LDH	S	6 hr	4 D	Do not Freeze
17.	Cortisol	S	8 hr	2 D	2 wk
18.	ACTH	P (EDTA), Pre-Chilled, Separate, transfer Plasma and freeze	NA	NA	4 wk (No Thaw, Only in House Collection)
19.	VIT D (CLIA)	S	8 hr	3 D	3 wk
20.	VIT D (LCMS)	S	8 hr	3 D	3 wk
21.	Bismuth (ICP-MS)	U	6 hr	5 D	14 D
22.	Lead (ICP-MS)	WB (K2EDTA)	6 hr	3 D	Do not Freeze
23.	Cadmium (ICP-	WB	6 hr	2 D	Do not Freeze

	MS)	(K2EDTA)			
24.	Lead (ICP-MS)	U	6 hr	3 D	1 wk
25.	Mercury (ICP-MS)	U	24 hr	2 D	1 wk
26.	Metal screen (ICP-MS)	U	6 hr	2 D	1 wk
27.	Diazepam (LCMS)	S (Red top; NO SST)	NA	5 D	14 D
28.	Thyroid profiles	S	2 hr	1 wk	4 wk
29.	Tumor markers	S	8 hr	1wk	2 wk
30.	Prolactin	S	8 hr	2 D	4 wk
31.	LH	S	8 hr	2 D	4 wk
32.	FSH	S	8 hr	2 D	4 wk
33.	Bicarbonate	S	8 hr	3 D	4 wk
34.	Ammonia	P (EDTA)	NA	3 hr	24 hr
35.	Growth hormone	S	NA	NA	2 months
36.	iPTH	S	8 hr	8 hr	1 month
37.	B HCG	S	6 hr	1 wk	4 wk
38.	PSA	S	2 hr	24 hr	4 wk
39.	Insulin	S	2 hr	24 hr	4 wk
40.	IGF-1	S	NA	NA	4 wk
41.	Calcium	S /WB	1 hr	1 wk	Do not Freeze
42.	Testosterone	S	6 hr	1wk	1 month
43.	Catecholamines	U	8 hr with HCl	3 D	1 month
		P (EDTA)	NA	NA	3 months
44.	Ascorbic acid, VIT C	S, separate within 2 hr	NA	NA	1 month
45.	VIT A (HPLC)	S (Red Top)	NA	12 hr	3 wk
46.	VIT E (HPLC)	S (Red Top)	NA	12 hr	3 wk
47.	VIT K (chromatography)	P (EDTA)	NA	NA	3 months
48.	Cyanocobalamin, VIT B12	S	8 hr	2 D	8 months
49.	Folate	S	8 hr	2 D	8 months
50.	Copper/ zinc/	S / U	6 hr	1wk	2 wk

	lead/ Mn/ Se/ As (ICP-MS)				
51.	Procalcitonin	S	NA	24 hr	3 months
52.	Valproate	S (Red Top)	8 hr	2 D	2 wk
53.	Protein Electrophoresis (IEF)	CSF	NA	1 wk	NA
54.	Protein/Lactate/ Glucose/ Albumin (Nephelometry)	CSF	Albumin: 2 hr Protein: NA Lactate: NA	3 D Protein: 2 D Lactate: 24 hr	6 months Protein: NA Lactate: 4 wk
55.	5- HIAA	U	8 hr	1 wk	30 D
56.	Electrolyte	S / U	8 hr	1 wk	2 wk
57.	5 ALA/ Porphobilinogen (Column)	U	NA	1wk	4 wk
58.	ADA	S / P	6 hr	1 wk	6 months

NA: Not applicable; S-Serum; U-Urine; P-Plasma; WB-Whole Blood; hr-hour(s); wk-week(s); D-Day(s).

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Plot No. 45, Sector 44,

Gurugram - 122003, Haryana

Tel. no.: 91-124-4679700 (30 lines)

Fax: 91-124-4679799

Website: www.nabl-india.org