



PRIVATE HEALTH SERVICES REGULATORY COUNCIL

PHSRC GUIDELINE 07

Revision and Finalized 19/03/2021

Guideline for Private Medical Laboratory Services

1. Labs in the private sector could be classified depending on the type of tests and number of tests perform.

- i. Small Lab –
 - Basic Tests
 - Performing 0-100 tests per day
- ii. Medium Lab –
 - Basic tests and tests which have to perform in a semi-automated lab.
 - Performing 101-500 tests per day
- iii. Large Lab -
 - Basic tests, tests which have to perform in a semi-automated lab and tests which have to perform in an automated lab.
 - Performing more than 500 tests per day.
- iv. Collecting Centers – Places which collect samples. These centers are not permitted to perform any kind of lab tests.

2. Basic Requirements

- i. Space: The space required by a laboratory shall be commensurate with the number, type and range of tests performed, the level of automation available, degree of computerization, workload and manpower. Adequate space should be provided to enable efficient maintenance of equipment and ensure safety of personnel. Each laboratory, however, must ensure adequate provision of space for the following:
 - Patient Reception

- Sample Collection
- Sample analysis
- Storage of samples, reagents, chemicals, spares, stationery and records
- Washing
- Toilets

The Laboratory should have adequate lighting, power plugs and uninterrupted power supply. All computers, peripherals, equipment and communication devices should be supported in such a way that service is not likely to be interrupted. The Laboratory shall have procedures in place to ensure the integrity of refrigerated and/or frozen stored samples/reagents/consumables in the event of an electrical failure and emergency exist. The accommodation and environmental conditions are also applicable to primary sample collection facilities as sites other rather than the permanent laboratory facility.

ii. Layout of the Laboratory

- There shall be a waiting area for the service recipients to wait till their turn comes. This waiting area shall have no access to the testing area.
- Bleeding room shall be separated from the sample room where samples are stored for retained. There should not be beds or other furniture used for bleeding purpose inside the sample room.
- The laboratory shall limit and restrict entry to authorized personnel to
- Testing areas to ensure confidentiality and safety of patients and visitors.
- Sample testing area maybe demarcated and separated by Cubicles or Particle Board or Glass partitioning depending on size of Lab and number of samples received. However all areas of testing must be clearly marked depending on the tests being carried out.

iii. Environment:

Laboratory must be well-lit and ventilated to provide a healthy environment. Toilets shall be clean and properly washed to assure sanitation of service recipients. It is preferable, if there are no water taps inside the sample taking area of toilets.

iv. Medical Waste Disposal:

Method of general and clinical waste disposal. (According to the Central Environmental Authority Requirements.)

3. Human Resources:

Supervisory, Technical and Non-technical staff should be available according to the size of the Laboratory and type of tests performed.

4. Equipment:

The Laboratory must be equipped with basic instruments listed below.

- Colorimeter
- Spectrophotometer
- Glucometer
- Hemocytometer
- Microscope
- Oven
- Incubator
- Centrifuge
- Distilled Water Plant
- Vortex Mixer
- Rotary Shaker

Depending on the test menu being offered other Semi-automated and Fully Automated Instruments can be installed. These include but are not limited to Biochemistry Analyzers, Hematology Cell Counters, Coagulation Analyzers, Immunoassay Analyzers, Coagulation Analyzers and Histopathology Processing Instruments.

5. Test Menu:

The Test Menu will depend on:

- The Location of the Lab
- Category of Lab
- Other medical facilities being offered by the Hospital such as ICU, Fertility Centre, Diabetes Centre, Heart Centre. Laboratories catering to these specialized facilities should be equipped with Point of Care Testing (POCT) tests and instruments, such as Glucometers, Blood Gas Analyzers.
- Size of the Lab, depending on number of requests per day
- Equipment
- Supervisory Personnel

The following is a List of Tests to be carried out and released under authority of a Registered MLT.

A. CLINICAL BIOCHEMISTRY AND CHEMICAL PATHOLOGY:

PROFILES:

- **CARDIAC PROFILE:** SGOT, CK(TOTAL), CK-MB
- **LIPID PROFILE:** CHOLESTEROL, TRIGLYCERIDES, HDL CHOLESTEROL, LDL CHOLESTEROL, CHOLESTEROL/HDL CHOLESTEROL RATIO
- **LIVER PROFILE:** SGPT, SGOT, ALKALINE PHOSPHATE, GGT, BILIRUBIN, TOTAL PROTEINS
- **RENAL PROFILE:** BUL, CREATININE, ELECTROLYTES, CALCIUM, PHOSPHORUS, URIC ACID

TESTS:

- ALANINE AMINOTRANSFERASE (SGPT)
- ALBUMIN
- AMYLASE
- ASPARTATE AMINOTRANSFERASE (SGOT)
- BILIRUBIN (TOTAL & DIRECT)
- CALCIUM
- CHLORIDE
- CHOLESTEROL
- CK(TOTAL)
- CK MB
- CREATININE
- CREATININE CLEARANCE
- FLUID – FULL REPORT
- FLUID – PROTEIN
- FLUID – SUGAR
- GAMMA GLUTAMYL TRANSFERASE (GGT)
- GLUCOSE
- HDL CHOLESTEROL
- LDL CHOLESTEROL
- ORAL GLUCOSE TOLERANCE
- PROTEINS(TOTAL)
- SODIUM
- TRIGLYCERIDS
- UREA
- URIC ACID
- URINARY POTASSIUM (SPOT SAMPLE)
- ALKALINE PHOSPHATE
- URINARY SODIUM (SPOT SAMPLE)
- URINE FOR BILIRUBIN
- URINE FOR GLUCOSE
- URINE FOR KETONE BODIES
- URINE FOR PROTEINS
- URINE FOR REDUCING SUBSTANCES
- URINE FOR UROBILINOGEN
- URINE FOR SDYMORPHIC RED CELL

B. HAEMATOLOGY

- FULL BLOOD COUNT

- ERYTHROCYTE SEDIMENTATION
- RATE (ESR)
- PACKED CELL VOLUME
- RETICULOCYTE COUNT
- ABSOLUTE EOSINOPHIL COUNT
- PLASMA HEMOGLOBIN
- URINE HEMOSIDERIN
- PROTHROMBIN TIME
- PARTIAL THROMBOPLASTIN TIME
- BLEEDING AND CLOTTING TIME
- BLOOD PICTURE
- PLATELET COUNT
- BLOOD GROUP
- MALARIAL/FILARIAL PARASITE

C. MICROBIOLOGY

- IDENTIFICATION OF MICROORGANISMS IN STERILE FLUIDS e.g. CSF, PUS, PLEURAL FLUID
- HANGING DROP PREPARATION FOR VIBRIO CHOLERAEE
- BACTERIOLOGY CULTURE: BLOOD, CSF, OTHER STERILE FLUIDS, URINE, SPUTUM, STOOLS, THROAT SWAB
- CSF MICROSCOPY
- STOOLS: PARASITES, OVA AND CYSTS
- SPUTUM FOR AFB
- URINE FULL REPORT
- STOOL AOC
- OCCULT BLOOD

D. SEROLOGY

- ANTI STREPTOLYSIN O TITRE (LATEX AGGLOUTINATION TEST)
- SALMONELLA AGGLOUTINATION TEST
- VDRL
- PREGNANCY TEST (RAPID IMMUNOCHROMATOGRAPHIC METHOD)
- HIV I & II (RAPID IMMUNOCHROMATOGRAPHIC METHOD)
- HbsAg (RAPID IMMUNOCHROMATOGRAPHIC METHOD)
- DENGUE ANTIBODIES (RAPID IMMUNOCHROMATOGRAPHIC METHOD)

All other specialized and highly specialized Tests must be carried out and reports released under supervision of a Laboratory Consultant/s.

Histo/cytopathology, Immunohistochemistry and Molecular Pathology **List of Special and Highly Specialized Tests**

Special tests:

- Histochemistry stains
- Frozen section examination
- Cell block examination
- Immunohistochemistry

Highly specialized tests:

- Gross examination and sampling of tissue
- Pathological autopsy
- Obtaining tissues or cells from patients for any test procedure
- Flow cytometry
- Electron microscopic examination of tissue/cells
- Immunofluorescence of tissue samples
- Molecular genetics

Chemical Pathology/ Clinical Biochemistry
List of Special and Highly Specialized Tests

Special Tests

- Acid phosphatase
- Aldolase
- Bicarbonate
- Calcium (ionized)
- CK-MB
- Creatinine clearance
- Ferritin
- Folate
- Fructosamine
- Glucose challenge test (GCT)
- Haptoglobin
- HbA_{1c}
- HDL cholesterol
- Iron
- Ketone bodies in plasma
- LDL cholesterol
- Lipase
- Lithium
- Magnesium
- Myoglobin
- Oral glucose tolerance test (OGTT)
- Serum osmolality
- Stone analysis
- Triglycerides
- Troponin 1
- Urinary albumin/creatinine ratio
- Urinary amylase
- Urinary Calcium (24 hour excretion)
- Urinary Calcium (spot urine)
- Urinary Copper (24 hour excretion)
- Urinary micro-albumin/creatinine ratio
- Urinary myoglobin
- Urinary osmolality
- Urinary phosphate (24 hour excretion)
- Urinary phosphate (spot urine)
- Urinary porphyrins
- Urinary potassium (24 hour excretion)
- Urinary protein/creatinine ratio
- Urinary sodium (24 hour excretion)
- Urinary uric acid (24 hour excretion)

- Urine for Gravindex dilution
- Vitamin B₁₂

Highly Specialised Tests

- Amino acids (serum and urinary)
- Ammonia
- Amylase (Pancreatic)
- Apolipoprotein A-1
- Apolipoprotein B
- BNP
- β_2 -microglobulin
- β carotene
- Homocysteine
- C₁ esterase inhibitor
- Cholinesterase
- Copper
- Cryoglobulin
- Lactate
- Lead
- Lipoprotein_(a)
- Protein electrophoresis (serum and urine)
- Toxicology profile – identified
- Toxicology profile – unidentified
- Zinc
- Urinary β_2 -microglobulin (24 hour excretion)
- α_1 -antitrypsin
- High sensitive CRP (hs CRP)
- Haptoglobin

Highly specialized – Endocrine tests

- 1,25(OH)₂ cholecalciferol
- 17-OH progesterone
- 25(OH) cholecalciferol
- ACTH
- Aldosterone
- Androstenedione
- Catecholamines (Epinephrine and norepinephrine in plasma and urine)
- Cortisol
- C-peptide
- Dehydroepiandrosterone sulphate (DHEAS)
- Dehydroepiandrosterone
- FSH
- GH
- Insulin
- Insulin-like growth factors (IGF-I, IGF-2)
- LH
- Metanephrines (metanephrine and normetanephrine) in serum
- Metanephrines (metanephrine and normetanephrine) in Urine
- Oestrogen
- Parathyroid hormone (PTH)
- Plasma renin activity (PRA)
- Progesterone
- Prolactin
- T₃ (Free and total)
- T₄ (Free and total)
- Testosterone
- TSH
- Urinary free cortisol (24 hour)
- Urinary HIAC
- Urinary VMA

Highly Specialized – Tumor markers

- CA 125

- CA 15-3
- Ca19.9
- Carcinoembryonic antigen (CEA)
- Prostatic Specific Antigen (PSA)
- PSA (free)
- Thyroglobulin
- α -fetoprotein (AFP)
- β -HCG

6. Quality Control

Quality Control in a Laboratory should include Internal and External Quality Assessment. Quality Assurance (QA) is a comprehensive term that refers to all aspects of operation from preparation of the patient to sample collection, sample analysis, recording of the result and its dispatch. The result of analysis must be available within a reasonable period so as to be useful for patient management. All QA procedures shall be documented. Stages of QA include pre-analytical and post analytical.

7. Minimum requirements for Registration.

- Small Lab – Availability of a qualified SLMC registered MLT.
- Medium Lab – Availability of a qualified SLMC registered MLT & one of the Medical Laboratory Consultants full time or part time.
- Large Lab – Availability of a qualified SLMC registered MLT full time and all Medical Laboratories consultants full time or part time.
- Collecting Centre –
 - ✓ Responsible MO's details or MLT's details (Sri Lanka Medical Council registration certificate with the renewal – Certified copies)
 - ✓ Details of the trained person/s available
 - ✓ Place of where the tests are being done and whether it is a PHSRC registered institution?
 - ✓ Clarification from the concerned institution.
 - ✓

8. Board of Investment (BOI) approval necessary for foreign investors.