SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

APPLICATION FORM *for* ACCREDITATION *of* MEDICAL / CLINICAL LABORATORIES

Instructions to the Applicant:

Please submit this application along with the questionnaire, duly filled, the Laboratory Quality Manual and associated documents referred in the application and questionnaire.

Director /CEO,
Sri Lanka Accreditation Board for Conformity Assessment,
No. 104/A,
Kitulwatte Road,
Borella

APPLICATION FOR ACCREDITATION OF MEDICAL TESTING LABORATORIES

We apply for SLAB accreditation of our **Medical testing laboratory** as per details given below:

☐ First Accreditation ☐ Scope Extension ☐ Renewal of Accreditation

1. Laboratory Details

1.1 ***Name of the Medical testing Laboratory*** _____

Address _____

_____

Telephone _____ Facsimile _____

Fax No _____ e-mail _____

NOTE If the Laboratory operates in different locations with same legal identity, separate applications are to be submitted.

1.2 ***Name of Parent Organization*** _____
(if part of an organization)

Address _____

_____

Telephone No. _____ Fax No. _____ e-mail _____

1.3 ***Legal status and date of establishment*** _____
(please give Registration No. and name of the authority who granted the registration. Copy of the certificate shall be enclosed)

_____

1.4 ***Clients of Testing Services***
(please tick in as appropriate)

Individual Clients ☐ On contract for Corporate Clients ☐ an in-house activity ☐

percentage ☐ percentage ☐ percentage ☐

1.5 Details of primary sample collection facilities

(Please tick in as appropriate and provide list of all facilities with complete contact details)

at Permanent facility (Laboratory Premises) ☐ at Site (Visit Patient) ☐ Other Locations (Collection Centres) ☐

1.6 Do you conduct Testing in the following Category

(if yes, please clearly indicate in the scope of accreditation, para 2.3, the test conducted)

a. At Site (Undertaking testing at site of the client) ☐ Yes ☐ No

b. Temporary Facility (when a facility is created temporarily for testing) ☐ Yes ☐ No

c. Mobile Laboratory ☐ Yes ☐ No

1.7 *Is testing Subcontracted* ☐ Yes ☐ No

(if yes, please specify the subcontracted work)

1.8 Size of Laboratory

Small laboratory (< 50 Test Requests per day) ☐ Medium laboratory (51- 400 Test Requests per day) ☐ Large laboratory (> 400 Test Requests per day) ☐

1.9 Other accreditations _____

2. Accreditation Details

2.1 Field of Testing for which accreditation is sought

(please tick as appropriate)

- Clinical Pathology ☐
- Chemical Pathology / Clinical Biochemistry ☐
- Molecular Biology ☐
- Microbiology and Serology ☐
- Histopathology / Cytopathology ☐
- Immunology ☐
- Haematology and Immunohaematology ☐
- Pharmacology ☐
- Nuclear medicine (in-vitro tests only) ☐

2.2 If the Laboratory is already accredited, indicate the Scope & Tests for which accreditation granted

2.3 *Scope of Accreditation*

Sl no	Type of Samples examined/tested	Specific tests/ examination performed	standard (method), Principle/Methodology or technique used	Range of testing/ Limit of detection	MU (±)

Note 1. Laboratories performing site testing shall clearly identify the specific tests/examination performed at site.

Note 2. Laboratories are encouraged to provide estimates of Uncertainty (MU). MU should be calculate at a confidence probability of 95%.

3. Organization

3.1 *Senior Management* (Name, Designation, telephone, Fax, e-mail)

3.1.1 Chief Executive of the laboratory _____

3.1.2 Laboratory Director, if different from 3.1.1 _____

3.1.3 Person responsible for the laboratory management system _____

3.1.4 Person responsible for technical operations _____

3.1.5 Authorized Representative for SLAB _____

3.1.6 Authorized signatories for approval of reports

Sl no	Laboratory/ Department/ Section	Name & Designation of Signatory	Qualification with Specialization	Experience in years related to present work	Relevant Training	Part time/Full time (timings if part time)	Authorized for which specific area of testing	Specimen Signature

3.1.7 Information regarding any individual or organization that has provided consultancy for being prepared towards SLAB accreditation;

a. Development of Quality Management System: _____

b. Development of Technical Operations: _____

c. Specific Training: _____

d. Conducting Internal Audits: _____

e. Other: _____

3.2 *Organization Chart*

3.2.1. Indicate in an organization chart the operating departments of the Medical testing laboratory for which accreditation is being sought (please append)

3.2.2 Indicate how the testing laboratory is related to external organizations or to its own parent organization (where applicable)

3.3. *Employees*

3.3.1 Details of staff

Sl no	Name	Designation	Academic and Professional Qualifications*	Experience related to present work (in years)

* Please clearly indicate the field of specialization

Note: Laboratory operating in shifts shall clearly identify the staff working in shifts

3.3.2 If services of consultants are obtained. Please provide details.

3.3.3 If Trainees or Contracted persons are employed, Please indicate details.

4. Equipment and Reference Materials

4.1 Equipment List

Sl no	Name of equipment	Model/ type/ year of make	Receipt date & date placed in service	Range and accuracy	Date of last calibration	Calibration due on	Calibrated by*	Traceability

- Please mention the name of calibration agency. In case the equipment is calibrated in-house, same needs to be clearly indicated under this column

4.2 List of reference materials

please list down all reference materials used for verification or validation of test method or technique applied for Accreditation

Sl. no.	Name of reference material/ strain/ culture	Source	Date of expiry/ validity	Traceability

5. EQA and PT Programmes

Please list down the details of APLAC/ EQA/ any other PT programmes currently participated by the Laboratory

Sl. no.	Materials examined/ tested	Details of Test(s)/ examination	Test method or group of methods applied for Accreditation	Organizing body	Performance in terms of z score or any other criteria

6. Willingness to undergo Assessment

We declare that

6.1 We are familiar with and will abide by the terms and conditions of maintaining SLAB accreditation (ML-RG(P)-03) included in the agreement to be signed by both parties, which is enclosed.

6.2 We agree to comply fully with ISO 15189: 2012 for the accreditation of medical testing laboratory.

6.3 We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result.

6.4 We agree to co-operate with the assessment team appointed by SLAB for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of accreditation.

6.5 All information provided in this application is true.

Signature of Head of Laboratory/Laboratory Director _____

Name & Designation _____

Date & Place _____