



**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.

APPLICATION FOR ACCREDITATION OF MEDICAL TESTING LABORATORIES

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

First Accreditation

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)

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 ad 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
 (if yes, please specify the subcontracted work) Yes No

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

SI no	Materials examined/tested	Specific tests/examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	MU (\pm)

Note 1. When referring to publications of ICSH, ISH, IFCC, IUMS, WHO etc. please mention reference details (chapter/page) and year of publication as appropriate.

Note 2. Laboratories performing site testing shall clearly identify the specific tests/examination performed at site.

Note 3. Uncertainty of Measurement (MU) 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 issue of test certificates and reports (please refer relevant specific criteria)

Sl no	Name & Designation of Signatory	Qualification with Specialization	Relevant Training	Authorized for which specific area of testing

Note. If opinions or Interpretations are given on test reports, please indicate such information as well with relevant qualification

3.1.6 Information regarding any individual or organization who has provided consultancy in preparation for SLAB accreditation.

3.2 *Organization Chart*

3.2.1. Indicate in an organization chart the operating departments of the 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 Total number in testing laboratory for the specific field(s) applied _____

3.3.2 Total number in testing laboratory for which accreditation is being sought _____

3.3.3 Details of staff (please clearly indicate staff responsible for site testing, if applicable)

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

* Please clearly indicate the field of specialization

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

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

4. Willingness to undergo Assessment

We declare that

- 4.1 We are familiar with and will abide by the terms and conditions of maintaining SLAB accreditation included in the agreement to be signed by both parties, which is enclosed.
- 4.2 We agree to comply fully with ISO 15189: 2007 for the accreditation of medical testing laboratory.
- 4.3 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.
- 4.4 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.

Signature of Chief Executive or his authorized representative _____

Name & Designation _____

Date & Place _____

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