



**SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT**

TERMS & CONDITIONS
for **MAINTAINING ACCREDITATION**
of **MEDICAL/CLINICAL TESTING**
LABORATORY



ACCREDITATION SCHEME FOR MEDICAL/CLINICAL LABORATORIES

Terms & Conditions for maintaining accreditation of medical/clinical laboratory accreditation

We the undersigned, on behalf the medical / clinical testing laboratory (*herein after referred to as Laboratory*)

(Name of Laboratory)

understand the Rules & Procedures and Requirements of the Accreditation Scheme for medical/clinical laboratories agree to fulfill and abide by the following terms and conditions adopted and implemented by the Sri Lanka Accreditation Board for Conformity Assessment (SLAB) for maintaining accreditation for medical/ clinical testing Laboratories as given below.

(This document shall be signed by the Chief Executive or his Authorized Representative and submitted to SLAB in duplicate along with the application form. SLAB will return a copy after grant of accreditation by endorsing it. In case of changes, SLAB will make sure that the current document is signed by the laboratory, always.)

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Agreement

1. The laboratory shall carry out its testing activities in such a way as to continuously meet the requirements of ISO 15189: 2012 which is applicable, relevant criteria for accreditation of medical / clinical Laboratories and Rules & Procedures for medical/clinical laboratories (ML-RG(P)-02).
2. The accreditation shall be initially granted after a successful initial assessment, valid for a period of three years unless otherwise decided by SLAB and thereafter shall be subject to on-site annual surveillance activities. These surveillance activities shall be conducted before the completion of each year for two years counting from the date of grant of accreditation.
3. Before expiry of the validity period, the accreditation granted shall be renewed by a re-assessment, for which the laboratory shall apply four months before the expiry of accreditation. Thereafter SLAB shall conduct re-assessment in every three years and annual surveillances.
4. In addition to planned surveillances, depending on the behavior of the laboratory or in response to complaints with regard to violation of Rules and Procedures of SLAB for accreditation, unannounced or other surveillances activities may be arranged. The laboratory shall assist in the investigation and resolution of any accreditation related complaints about the laboratory referred to it by the SLAB.
5. The laboratory shall offer SLAB and its peers , access to all relevant information including documents and records pertaining to accreditation that provide insight into the level of independence and impartiality of the laboratory from its related bodies, locations including Sample Collection Centers, all relevant personnel, Equipment, and to all testing and calibration areas to undertake any check to verify testing capability of the laboratory, and to witness the testing being performed relevant to accreditation.
6. When requested, the laboratory shall afford accommodation and co-operation to enable the SLAB to verify fulfillment of requirements for accreditation. These facilities shall be available at all premises where the conformity assessment is supposed to take place.
7. Legally enforceable arrangements with Sample Collection Centers/locations that commit to provide, on request, access to accreditation body assessment teams including observers, witnessing assessors and APAC/ILAC Peer Evaluators and any expert appoint on behalf of SLAB to assess the relevant conformity assessment activities.
8. The laboratory shall provide on request of SLAB, access to SLAB's assessment teams including observers, witnessing assessors and APAC/ILAC Peer Evaluators or any expert appoint on behalf of SLAB to assess the laboratory's performance or Performance of SLAB's assessment team. The laboratory shall provide Personnel Protective Equipment (PPE) for assessment team, when required.
9. The laboratory shall appoint competent personnel to perform and evaluate tests and authorized signatories who are responsible for authenticity and issue of test certificates / reports.
10. On grant of accreditation, the laboratory shall claim accreditation in only those premises, fields/ facility, disciplines, tests for which it has been accredited and as stated in the Certificate and schedule of Accreditation. Only those Sample Collection Centers (SCCs) which are declared to the SLAB shall be claimed as to be covered by the Schedule of accreditation. Neither the laboratory nor the SCCs shall claim that any of the SCCs are accredited.

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11. The laboratory shall abide by the Policy governing the use of SLAB Accreditation Symbols (AC-RG(P)-01). The mark shall be used for the purpose of identifying correctly and unambiguously its testing services accredited by SLAB.

12. The laboratory shall not use test reports or any part thereof in a misleading manner and not use SLAB accreditation or its accreditation symbol to imply a product, process, system or person is approved by the SLAB or/ and not state SLAB accreditation in a manner as to be considered misleading or unauthorized and bring disrepute to SLAB.

13. The laboratory shall ensure that no part of its test report is used by its clients, or be authorized by its clients for use, for promotional or publicity purposes in any way that SLAB may consider to be misleading.

14. The laboratory shall pay fees for processing of application, fees for assessments, fees for extending scope of accreditation, expenses towards travel, board & lodging for assessments, and annual accreditation fees as determined from time to time by SLAB. In the event of withdrawal of accreditation, the laboratory shall settle the due payments, if any.

15. The laboratory shall inform SLAB within 01 month of significant changes which affect the activities operations of laboratory relevant to accreditation such as in legal, commercial, ownership or organizational status, any suspension or cancellation of registration status by regulatory bodies, organizational structure, top management and key personnel, main policies, resources , premises, scope of accreditation and other such matters that may affect the ability of the laboratory to fulfill requirements of ISO 15189 as applicable.

16. The accredited laboratory shall normally perform test which is covered under scope of accreditation by itself. Where a laboratory obtains services of referral laboratories, those shall be obtained only from accredited laboratories. If there are no such laboratories, laboratory may obtain services from non-accredited laboratory having demonstrated competency through evaluation done by the laboratory as per ISO 15189. The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractor and maintain a register of all subcontracted work. The laboratory shall advise its clients at the time of contract review about the intended sub-contracting.

17. The applicant/accredited laboratory shall regularly and satisfactorily participate in External Quality Assurance Programmes covering its scope of accreditation as per SLAB policy for participation in External Quality Assurance activities (AC-RG(P)-02).

18. The accredited laboratory shall respond promptly to the changes initiated by SLAB in its accreditation criteria, policies and procedures and for necessary changes the laboratory will be given sufficient notice and time on the opinion of SLAB, as is found to be reasonable, to carry out adjustments in its system.

19. SLAB may at subsequent stage decide to suspend/reduce the scope of accreditation, granted initially, if significant deficiency/ies is/are observed during surveillance activity or re-assessment in the laboratory management system or technical competence, which is likely to adversely influence the test results or the laboratory is unable to complete corrective actions within agreed/ stipulated time of the surveillance activity or re-assessment.

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20. SLAB may suspend or withdraw accreditation of an accredited laboratory, on one or more of the following grounds:

- a. After undergoing a surveillance or re-assessment, laboratory has not taken any corrective actions after getting sufficient time and notice from SLAB
- b. Non-payment of accreditation related expenses
- c. Non-cooperation with SLAB.
- d. Refusal to allow examination of documents and records by SLAB & its assessors.
- e. Denial of access to SLAB, its assessment team or peer evaluators to its testing areas.
- f. Wrong representation of scope of accreditation.
- g. Misuse of SLAB accreditation symbol/ ILAC MRA Mark or its use during suspension or after expiry of accreditation
- h. Activity bringing disrepute to SLAB.
- i. Result of complaint analysis or any other information which indicates that the laboratory no longer complies with requirements of SLAB.
- j. In the event of compromising impartiality of laboratory's operations or violation of Rules and Procedures of SLAB
- k. Evidence of fraudulent behavior, or intentionally provides false or conceals information and misleading reporting of facts.
- l. Non adherence to significant changes as mentioned in Sec. 15 of this document

21. The accredited laboratory upon suspension, reduction or withdrawal of its accreditation (however determined), or expiry of validity of accreditation shall forthwith discontinue its use of all advertising matter that contain any reference to the accreditation status and return the certificate and schedule of accreditation to SLAB.

22. Laboratory is required to inform the SLAB, if any of the proposed assessor(s) happens to be their Consultant or associated with the laboratory in any other capacity, and SLAB shall not appoint these Consultants as assessors.

23. SLAB absolves itself of any legal or financial liability arising out of any item tested in any of its accredited laboratory involving any accidental or consequential damages to personnel or equipment at any time. Laboratory shall have arrangements (eg. Insurance, reserves or other means) sufficient to cover liabilities arising from the activities and areas in which it operates.

24. The Laboratory has the right to complaint on any dissatisfaction with SLAB accreditation process and all personnel involved in the accreditation activities as per Procedure handling Complaints (GN-PR(P)-08) or appeal on any adverse decision taken by the SLAB on accreditation and associated activities as per Procedure for dealing with appeals (GN-PR(P)09).

25. All disputes, if any, arising out of SLAB decisions that remain unresolved through mechanism provided by SLAB are subject to the exclusive jurisdiction of the Courts in Sri Lanka and none other.

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26. The SLAB publishes the details of scope of accreditation & accreditation status of the accredited laboratories along with their contact addresses and status of accreditation such as withdrawal of accreditation, suspension of accreditation and termination of accreditation status in SLAB web site.

27. The SLAB protects the confidential nature of the assessment findings unless legally obligated to do so otherwise indicated in the contractual arrangements between SLAB and the laboratory. If the laboratory provides third parties with access to the assessment report, it shall provide access only to the complete assessment report. Assessors and all other persons who, work for the benefit of the accreditation by the SLAB, shall have access to the laboratory's files/information only after they sign and handover confidentiality statement to the particular laboratory.

By signing this document, it is implied that the laboratory as an applicant and after accreditation agrees to comply at all times with all Terms and Conditions for Maintaining SLAB accreditation.

Signature of Chief Executive or his/her Authorized Representative:

Name, Designation & Laboratory:

Date & Place:

Seal of the Laboratory, if any

Signature of Director/CEO, SLAB:

Name:

Date & Place:

Date of Receipt of Accredited Certificate:

Seal of SLAB

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