



**SRI LANKA ACCREDITATION BOARD**  
**for CONFORMITY ASSESSMENT**

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



## ACCREDITATION SCHEME FOR MEDICAL LABORATORIES

### TERMS & CONDITIONS FOR MAINTAINING MEDICAL/CLINICAL LABORATORY ACCREDITATION

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

\_\_\_\_\_ agree to fulfill

(Name of Laboratory)

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 and relevant criteria for accreditation of Medical / Clinical Laboratories by SLAB.
2. The accreditation shall be initially granted after a successful initial assessment, valid for a period of three years and thereafter shall be subject to on-site annual surveillances. These surveillances shall be conducted before the completion of each year for two years counting from the date of initial assessment.
3. Before expiry of the three year 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, surprise or ad hoc on-site or other surveillances may be arranged.
5. The laboratory shall offer SLAB, 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, if applicable, to all relevant personnel 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. The laboratory shall appoint competent personnel to perform and evaluate tests and authorized signatories who are responsible for the review of results of examination and issue of test certificates / reports.
7. 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 Accreditation Certificate. Only those sample collection centers (SCCs) which are declared to the SLAB shall be claimed as to be covered by the scope of accreditation. Neither the laboratory nor the SCCs shall claim that any of the SCCs are accredited.
8. The laboratory shall abide by the guidelines for use of SLAB accreditation mark (AC-RG(P)-01) and may use it on its letterheads, test reports and any other relevant documents. The mark shall be used for the purpose of identifying correctly and unambiguously its testing services accredited by SLAB.
9. 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.
10. 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.

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11. The laboratory shall pay fees for processing of application, fees for assessment; expenses towards travel, boarding & lodging for assessment, surveillance and re-assessment fees and annual accreditation fees as determined from time to time by SLAB.

12. The laboratory shall inform SLAB within 01 month of significant changes which affect the activities and operations of laboratory relevant to accreditation such as in legal, commercial, ownership or organizational status, organizational structure, main policies, resources and premises, scope of accreditation and other such matters that may affect the ability of the laboratory to fulfill requirements of ISO 15189 as applicable.

13. The laboratory shall continuously keep in touch with SLAB to keep itself updated with the latest versions of SLAB documents and relevant national and international standards.

14. The accredited laboratory shall normally perform test which is covered under scope of accreditation by itself. Where a laboratory subcontracts a substantial or critical part of the test, this work shall be assigned only to another accredited laboratory. 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.

15. As per the SLAB policy for participation in Proficiency testing activities (AC-RG(P)-02), the accredited laboratory shall periodically prepare a Proficiency Testing (PT) plan by analyzing PT needs considering the tests that are most commonly handled by the laboratory in day today work in compatible with type of samples and the scope of accreditation, methodology, instrumentation and previous performance of the laboratory and satisfactorily participate in PT programmes based on the PT plan. The level and frequency of participation as in the PT plan shall be sufficient to maintain the quality of laboratory performance. When the PT plan is prepared the laboratory shall source reliable PT service providers and the PT programmes coordinated by SLAB and other possible sources are given in the SLAB website. In the event when established PT programmes are not available the laboratory should participate in inter-laboratory comparisons on the same or similar items between two or more accredited laboratories as described in Policy for participation in proficiency testing activities. The minimum stipulated participation is one parameter/ type of test per major discipline prior to gaining accreditation and all parameters/ types of tests included in the accredited scope of each discipline at least three times a year.

16. The satisfactory performance shall be determined in terms of  $|Z| \leq 3$  or  $|En| < 1$  or any other criteria depending on the programme design. The laboratory shall carry out investigation for unsatisfactory performance in proficiency testing and inform SLAB of the necessary corrective action within a month. The laboratory shall part with all available information related to proficiency testing to the assessors at the time of surveillance and re-assessment.

17. 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. The laboratory shall inform SLAB when such adjustments have been completed.

18. SLAB may at subsequent stage decide to reduce the scope of accreditation, granted initially, if major non-compliance is observed during surveillance 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

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to complete corrective actions within agreed/ stipulated time of the surveillance/ re-assessment related to specific tests or the performance in a proficiency testing programme coordinated by SLAB or equivalent organization recognized by the SLAB is unsatisfactory or is declared an outlier in terms of  $|Z| \geq 3$  or  $|En| > 1$  or any other criteria depending on the programme design and the laboratory could not take appropriate corrective actions within a month.

19. The accredited laboratory shall comply with the guidelines for use of accreditation symbol - AC-RG (P)-01.

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 action after getting sufficient time and notice from SLAB.
- b. Non-payment of accreditation expenses like assessment or surveillance or re-assessment charges and annual accreditation fees.
- c. Not applied four months before the expiry of accreditation and SLAB has not been able to take a decision for renewal of accreditation.
- d. Non-cooperation with SLAB.
- e. Refusal to allow examination of documents and records by SLAB & its assessors.
- f. Denial of access to SLAB & its assessors to its testing areas.
- g. Wrong representation of scope of accreditation.
- h. Misuse of SLAB Mark or ILAC MRA Mark or its use during and after expiry of accreditation.
- i. Misleading reporting of facts.
- j. Activity bringing disrepute to SLAB.
- k. Result of complaint analysis or any other information which indicates that the laboratory no longer complies with requirements of SLAB.

21. The accredited laboratory upon suspension 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 certificates of accreditation to SLAB.

22. The accredited laboratory can relinquish accreditation by giving three months notice in writing to SLAB.

23. 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.

24. 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.

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25. The Laboratory has the right to appeal on any adverse decision taken by the SLAB on accreditation and associated activities and all appeals shall be resolved using the Procedures adopted by the SLAB on that behalf and the decision on the approval of the Governing Council of SLAB shall be the final.

26. 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.

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 Authorized Representative \_\_\_\_\_

Name, Designation & Laboratory \_\_\_\_\_

Date & Place \_\_\_\_\_

Seal of the Laboratory, if any

Signature of Director of SLAB or Authorized Representative \_\_\_\_\_

Name & Designation \_\_\_\_\_

Date & Place \_\_\_\_\_

Date of Receipt of Accredited Certificate \_\_\_\_\_

Seal of SLAB

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