 **SRI LANKA ACCREDITATION BOARD**

**for CONFORMITY ASSESSMENT**

**APPLICATION FORM**

***for* accreditation *of***

**MEDICAL LABORATORIES**

***Instructions to the Applicant:***

1. Please submit the duly filled application along with all annexures and documents & records referred in the application and Self- Assessment Checklist.
2. Please read Rules and Procedures for accreditation (AC-RG(P)-26), Terms and Conditions for accreditation (AC-RG(P)-08), and the Specific criteria documents for medical testing before filling the application.
3. Please submit hard copies of application with all annexures and soft copies of annexure 01, 02 and 07.





Director /CEO

Sri Lanka Accreditation Board for Conformity Assessment

No.44, Dedicated Economic Center

Kirimandala Mawatha, Narahenpita

**APPLICATION FOR ACCREDITATION of MEDICAL Laboratories**

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| We apply for SLAB accreditation of our **medical laboratory** as per details given below: | | | | | | | |
|  | |  | |  |  |  | |
| First Accreditation |  | |  | 1. Scope Extensionin the existing accredited field of testing | | |  |
|  |  | |  |  | | |  |
| Renewal of Accreditation |  | |  | 1. Scope extension in new field of testing | | |  |

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| 1. **1. Laboratory Information** | | | | | | | |
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| **1.1** | **Name of the Medical Laboratory** | | |  | | | |
| Address | |  | | | | | |
| Telephone | |  | | | | Fax No |  |
| e-mail | |  | | | |  |  |
|  | | |  | | |  |  |
| **1.2** | **Name of Parent Organization (if part of an organization)** | | | |  | | |
| Address | |  | | | | | |
| Telephone | |  | | | | Fax No |  |
| e-mail | |  | | | |  |  |
|  | | |  | | |  |  |
| **1.3** | **Legal status and date of establishment**(Please provide copy of registration / Relevant section of act or regulation) | | | |  | | |

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| **1.4** | | **Category of medical testing facility applied under the scope of accreditation**  (please clearly indicate in the scope of accreditation (Annexure 01-ML-FM(P)-18, the test conducted) | | | | | |
|  |  | |  | |  |  |  |
|  | | 1. Permanent Facility |  | Yes | |  | No |
|  | |  |  |  | |  |  |
|  | | 1. POCT (Point Of Care Testing) |  | Yes | |  | No |
|  | |  |  |  | |  |  |
|  | | 1. Mobile Laboratory |  | Yes | |  | No |

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| **1.5** | **Does the laboratory obtain any laboratory services from external providers (eg: referral laboratories) pertaining to the scope applied?** | | | | | | | | | | | | | | | | | | | | | | |
|  |  | |  | | |  | | | |  |  | |  | | | | | | | |  | | |
|  | Yes | |  | | |  | | | | No |  | |  | | | | | | | |  | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | |
|  | If yes, please specify the testing activities obtained from external providers | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | |
| **1.6** | **Details of primary sample collection facilities**  (Please tick in as appropriate and provide list of all facilities with complete contact details)  at Permanent facility at Site Other Locations | | | | | | | | | | | | | | | | | | | | | | |
| **1.7** | **Size of the Laboratory**  Small laboratory Medium laboratory Large laboratory  (< 50 Test Requests (51- 400 Test Requests (> 400 Test Requests  per day) per day) per day) | | | | | | | | | | | | | | | | | | | | | | |
| **1.8**  **1.9** | **Indicate exactly how the name of the laboratory should appear on the certificate of Accreditation**  …………………………………………………………………………………………..  **Indicate if separate schedule of accreditation is required for each field of testing**  ………………………………………………………………………………………….. | | | | | | | | | | | | | | | | | | | | | | |
| **2.** **Accreditation Details** | | | | | | | | | | | | | | | | | | | | | | | |
| **2.1** | **Field of Testing for which accreditation is sought** (Please tick the appropriate box)   |  |  | | --- | --- | | Clinical Pathology |  | | Chemical Pathology / Clinical Biochemistry |  | | Immunology |  | | Haematology and Immunohaematology |  | | Molecular Testing |  | | Cytogenetics |  | | Microbiology and Infectious Disease Serology |  | | Nuclear medicine (in-vitro tests only) |  | | Histopathology/ Cytopathology |  | | Flow Cytometry |  | | | | | | | | | | | | | | | | | | | | | | | |
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| **2.2.** | **If the Laboratory is already accredited, attach the Scope & Tests for which accreditation granted**(Please indicate the Accreditation Body, Accredited Scope, Date of Accreditation and Validity period) -   |  |  |  |  | | --- | --- | --- | --- | | **Name of the Accreditation Body** | **Accredited Scope** | **Date of Accreditation** | **Period of validity of accreditation**  **(attach documents for proof)** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | | | | | | | | | | | | | | | | | |
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| **2.3.** | **Scope of Accreditation** (Please indicate the Scope which accreditation is sought) ***–*** *Please attach Annexure 01 and submit a copy of all the test methods mentioned in the scope of accreditation along with the application documents to SLAB. - Attachment* | | | | | | | | | | | | | | | | | | | | | |
| **2.4.** | **Does the laboratory perform in-house verification of laboratory equipment other than Analyzers?** | | | | | | | | | | | Yes | | | | |  | No | |  | |  |
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|  | If yes, please provide details | | | | | | | | | | | | | | | | | | | | | |

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| **3. Organization** | | | | |
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| **3.1.** | **Senior Management** (Name, Designation) | | | |

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| --- | --- | --- | --- |
| 3.1.1 Chief Executive of the Organization | |  | |
| 3.1.2 Person responsible for the laboratory management : | |  | |
| 3.1.3 Person/s responsible for technical operations | |  | |
| 3.1.4 Person/s responsible for POCT, if applicable | |  | |
| 3.1.5 Person/s responsible for training and competency assessment of personnel performing POCT, if applicable | |  | |
| 3.1.6. Authorized Representative for SLAB : | | **:** | |
| Telephone |  | Mobile |  |
| Email |  |  |  |
| 3.1.7 Authorized signatories for issue of test reports | | (attach Annexure 02 - Authorized signatories for issue of test reports) | |
| 3.1.8 Information regarding any individual or organization that has provided consultancy or following assistance to towards SLAB accreditation | | | |
| Development of Management System : | |  | |
| Training : | |  | |
| Conducting Internal Audits : | |  | |
| Other : | |  | |
| 3.1.9 Any affiliation or relationships to SLAB : | |  | |

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| **3.2.** | **Organization and Management Structure** | |
|  | 3.2.1. | Please annex an organization chart the operating departments of the medical laboratory for which accreditation is being sought |
|  | 3.2.2. | Indicate how the medical laboratory is related to external organizations or to its own parent organization (where applicable) |
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| **3.3.** | **Employees** |

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| 3.3.1 Total number of employees in the medical laboratory for the specific field/s applied: |  |
| 3.3.2 Details of staff : | *(Attach Annexure 03: Details of Staff)* |
| * + 1. If Trainees or Contracted persons are employed, please provide details | |
| 3.3.4 If services of consultants are obtained. Please provide details | |

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| **4. Equipment and Reference Materials** | | | | |
|  | 4.1. | Equipment List – Please attach Annexure 04 |  |  |
|  | 4.2. | List of reference materials – Please attach Annexure 05 |  |  |
|  |  |  |  |  |
| **5. Internal and External Quality Assurance Programmes** | | | | |
|  | Please attach Annexure 06 and Summary of recently participated Internal and External Quality Assurance Programmes for all test methods applied for accreditation. | | | |
| **6. Self-Assessment Checklist** – Please attach Annexure 07 | | | | |
|  |  | | | |
| **7. Please attach soft copies of the following documents / records** | | | | |
|  | 7.1  7.2  7.3  7.4  7.5  7.6  7.7  7.8  7.9  7.10  7.11  7.12  7.13  7.14  7.15  7.16  7.17  7.18  7.19  7.20  7.21 | Annexure 01- Scope of accreditation  Annexure 02 - Authorized signatories for issue of test reports  Annexure 03 - Details of staff  Annexure 04 - Equipment List  Annexure 05 - List of reference materials  Annexure 06 - Internal and External Quality Assurance Programmes  Annexure 07 - Self-Assessment Checklist- ISO 15189: 2022  Annexure 08- Details of Primary Sample Collection Facilities  Legal identity (Registration details of the Laboratory)  Management System Documentation (e.g. Quality Manual, Procedures Manual, Primary Sample Collection Manual, etc.)  Test methods mentioned in the Scope of accreditation  Procedure and Records for evaluation of Measurement Uncertainty  Organization and management structure  Summary of recently participated Internal and External Quality Assurance Programmes  A Sketch of the Laboratory Layout  Report of the last internal audit together with corrective action records  Minutes of the last management review  Test report formats  Calibration certificates of key instruments  If already accredited, the Scope & Tests for which accreditation granted  Two signed copies of Terms and Conditions for maintaining accreditation (AC-RG(P)-08) | | |

**8. Declaration**

We declare that

* 1. We are aware of and will abide by the Terms and Conditions for maintaining accreditation (AC-RG(P)-08) to be signed by both parties, which is enclosed.
  2. We agree to comply fully and continually fulfill the requirements of ISO 15189: 2022 and SLAB Rules and Procedures for accreditation (AC-RG(P)-26)
  3. Self-declaration to confirm that laboratory’s collection centre(s)/ facility(ies) are complying with relevant clauses of ISO 15189: 2022 on the basis of the internal audit conducted by laboratory.
  4. We agree to comply with accreditation procedures and pay all costs for activities related to accreditation process as per Terms and Conditions for maintaining accreditation (AC-RG(P)-08) & Fee Structure (ML-RG(P)-01) available at SLAB website: [www.slab.lk](http://www.slab.lk).
  5. 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/site that are part of the scope of accreditation.
  6. We declare that all the information provided is true and accurate to the best of our knowledge. I’m aware that giving any fraudulent information will lead to termination of the accreditation process

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| --- | --- |
| Signature of Chief Executive |  |
| Name & Designation |  |
| Date & Place |  |

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***For office use only***

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| A. | | Check whether the following have been submitted | | To be checked by the Management Assistant | | To be checked by the Technical Manager |
|  |  | | |
|  | Annexure 01 -Scope of Accreditation | | |  | |  |
|  | Annexure 02 - Authorized signatories for issue of test reports | | |  | |  |
|  | Annexure 03 - Details of staff | | |  | |  |
|  | Annexure 04 - Equipment List | | |  | |  |
|  | Annexure 05 - List of reference materials | | |  | |  |
|  | Annexure 06 - Internal and External Quality Assurance Programmes | | |  | |  |
|  | Annexure 07 - Self-Assessment Checklist- ISO 15189: 2022 | | |  | |  |
|  | Annexure 08 - Details of Primary Sample Collection Facilities | | |  | |  |
|  | Legal identity (Registration details of the Laboratory) | | |  | |  |
|  | Management System Documentation (e.g. Manuals, Procedures, Primary Sample Collection Manual, etc) | | |  | |  |
|  | Test methods mentioned in the Scope of accreditation | | |  | |  |
|  | Procedure and Records for evaluation of Measurement Uncertainty | | |  | |  |
|  | Organization and management structure | | |  | |  |
|  | Summary of recently participated Internal and External Quality Assurance Programmes | | |  | |  |
|  | A Sketch of the Laboratory Layout | | |  | |  |
|  | Report of the last internal audit together with corrective action records. | | |  | |  |
|  | Minutes of the last management review | | |  | |  |
|  | Test report formats | | |  | |  |
|  | Calibration certificates of key instruments | | |  | |  |
|  | If already accredited, the Scope & Tests for which accreditation granted | | |  | |  |
|  | A report on changes (re-assessments only) | | |  | |  |
|  | Two signed copies of Terms and Conditions for maintaining accreditation (AC-RG(P)-08) | | |  | |  |
|  | Application fee | | |  | |  |
|  | |  |  | |  | |
| |  |  |  | | --- | --- | --- | | ***Case file number:*** | *Assigned by* | *Verified by* |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | To be filled by the Technical Manager / Deputy Technical Manager before assigning the application to Authorized officer   |  |  |  |  | | --- | --- | --- | --- | | A. | Comments on the case file | : |  | | B. | Allocation of Case file | : |  | | C. | Document Review: | : | Required/ Not Required | | D. | Allocation for Document Review | : |  |   Date: …………………… Technical Manager/Deputy Technical Manager: ……………………. |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | To be filled by the Authorized officer | | | | | | A. | Check whether the SLAB fulfills the following; | |  | | | Is the activity area of CAB under the purview of SLAB | | Yes / No | | | Can the initial assessment be performed in a timely manner | | Yes / No | | | If yes, state the duration | | …………………………….. | | | Has the SLAB Competence on accrediting the CAB | | Yes / No | | | B. | Are all functions of CAB performed at one site  If No, indicate the specific activities | | Yes / No | | |  |  | | | | | C. | Time estimation (Number of man days) for initial assessment | | : ……………………………………………………. | | |  |  | |  |  | | D. | Remarks of Authorized Officer | : ……………………………………………………………………………...  ……………………………………………………………………………….  ……………………………………………………………………………….  ……………………………………………………………………………….  ………………………………………………………………………………. | | | |  | Date: …………………… Authorized Officer: …………………………….. | | | | | | | | | | |