

SLAB POLICY ON TRANSITION TO ISO 15189: 2022

SLAB accredited and applicant medical testing laboratories are required to comply with the requirements of this policy commencing 1st January 2023. The new ISO 15189 (Requirements for quality and competence) standard was published on the 6th December 2022 and will replace ISO 15189: 2012. The agreed transition period is 3 years from the date of publication (ILAC Resolution GA 26.08).

This means that all SLAB accredited medical testing will need to have successfully transferred to the new standard within 3 years from the publication date (2025-12-06).

It is important that laboratories **purchase a copy of the new edition**, and understand the changes that have been made, at the earliest opportunity.

As per the SLAB policy on transition, accreditation granted as per ISO 15189: 2012 would not be valid after 6th December 2025.

The requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189, ISO 22870:2016 in conjunction with ISO15189:2012 will still be recognized as a Level 4 standard for POCT for the duration of the transition period.

At the end of the transition period, accreditation of a medical laboratory to ISO 15189:2012 and accreditation of POCT to ISO 22870:2016 in conjunction with ISO15189:2012 will not be recognised under the ILAC Arrangement

In addition, the following are also applicable for this transition.

1. SLAB is ready to accept applications as per new standard ISO 15189: 2022 from 1st March 2023
2. SLAB is ready to carry out assessments as per new standard ISO 15189: 2022 from 1st April 2023.
3. SLAB does not accept new applications as per ISO 15189: 2012 after 1st June 2023.
4. Medical testing laboratories whose applications were accepted as per ISO 15189: 2012 and pending as of 1st June 2023 will be granted accreditation as per ISO 15189: 2012 up to 1st June 2024.
5. SLAB will conduct **all** assessments after 1st June 2024 as per the new standard ISO 15189: 2022
6. Medical testing laboratories granted accreditation as per ISO 15189: 2012 before 1st June 2024 shall undergo re-assessment to demonstrate their compliance to the new standard ISO 15189: 2022 and complete the process of re-assessment on or before 6th November 2025.

SLAB accredited medical testing laboratories shall demonstrate full implementation of ISO 15189: 2022 by 6th December 2025

The accreditation of any medical testing laboratory which fails to demonstrate compliance to ISO 15189: 2022 by 6th June 2025 shall be placed under temporally suspension for a maximum of 03 months. Failure to comply with ISO 15189: 2022 by 6th December 2025 would result in withdrawal of accreditation.

| SRI LANKA ACCREDITATION BOARD FOR CONFORMITY ASSESSMENT | | | | |
|---|----------------|------------|----------------------|-------------------|
| Title: Transition Policy- ISO 15189: 2022 | | | Doc No : AC-RG(P)-23 | |
| Issue No: 01 | Date of Issue: | Rev No: 00 | Date of Rev: | Page: Page 1 of 1 |