



Medical Laboratory (ISO 15189) Accreditation Procedure

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to a conformity assessments body (CAB) **providing medical/clinical laboratory testing (ISO 15189). This is a Supplemental Procedure to PJLA's Accreditation Procedure (SOP-1). Both procedures shall be followed for the entirety of this accreditation program.**



Medical Laboratory (ISO 15189) Accreditation Procedure

1.0 SCOPE/PURPOSE

- 1.1 PJLA's medical accreditation program is based on ISO 15189, *Medical Laboratories Requirements for Quality and Competence* including ISO 22870 *Point-of-care testing (POCT) — Requirements for quality and competence*. This also includes PJLA criteria for proficiency testing, traceability, measurement uncertainty and scope of accreditation for testing laboratories. Consideration has been made in the development of this program based on well-established national medical programs from various economies.
- 1.2 This procedure includes the process for which PJLA carries out its accreditations for the medical laboratory accreditation program. It is the expectancy that laboratories shall meet the requirements of ISO 15189 as well as their national regulated medical program as applicable.

2.0 REFERENCES

- 2.1 ISO 15189:2012 Medical Laboratories Requirements for Quality and Competence
- 2.2 International Standard ISO/IEC 17011:2017 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- 2.3 ISO 22870:2016 Point-of-Care Testing (POCT) – Requirements for quality and competence Second Edition 2016-11-01
- 2.4 ILAC-G26:11/2018 Guidance for the Implementation of a Medical Laboratory Accreditation System

3.0 APPLICATION FOR ACCREDITATION

- 3.1 The following information will be requested from the CAB to ensure the appropriate amount of time is designated for the assessment:

Discipline	Medical laboratory testing area
Process of Examination	Specific test or examination being performed
Property	The item that is being measured, determined or identified
Test Sample	The portion of a specimen subjected to the test procedure, e.g. product of pre-analytical processing, specimen type, specimen source.
Parameter (Range)	A numerical or other measurable factor of a system which sets the conditions of its operation
Measurement Techniques	The methodology of the test which detects, quantifies, or identifies the property, including any pre-analytical processes to present the sample to the measuring device (e.g. PCR)



Medical Laboratory (ISO 15189) Accreditation Procedure

- 3.2 CAB(s) with multiple locations as defined below will be analyzed on a case-by-case basis to ensure a full assessment of each facility can be assessed. CABs are required per the PJLA application LF-1med to inform PJLA of multiple labs such as: satellite, branch, mobile, Point of Care Testing Facilities and of in-house calibration activities.
- 1) Branch Lab: Additional laboratories owned and operated by the same organization, utilizing the same management system, and managed by a Laboratory Director.
 - 2) Satellite Lab: Laboratory is on the same campus or in the same contiguous building as the main laboratory, operates under the same management system as the main laboratory, can have prompt supervisory oversight from the main laboratory, when necessary, and has appropriate oversight from the same laboratory director that represents the main laboratory.
 - 3) Mobile Clinical Lab- Fully equipped, self-contained, transportable clinical testing laboratory capable of performing clinical tests under controlled environmental conditions. A mobile laboratory may perform testing only when the laboratory is stationary. Mobile clinical laboratories left at one location for three years are considered permanent laboratories.
 - 4) Point of Care (POCT) Testing Labs: Facilities where tests are being performed at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside of the physical facilities of the clinical laboratory.
 - 5) In-house Calibration: Calibration (for which the organization is not seeking accreditation for) performed internally that directly affect the traceability of the calibration and/or test results (See PL-2 PJLA Traceability Policy. (This section potentially applies to both calibration organizations and Testing organizations calibrating their own equipment)

4.0 ASSESSMENTS AND DOCUMENTATION

- 4.1 PJLA will perform on-site assessments to include the latest version of ISO 15189 and PJLA Policy Requirements. This includes organizations with satellite labs, branch labs and mobile labs. Each assessment will include the completion of a checklist and supplemental documents that provide sufficient evidence that all applicable elements of the standard have been assessed. Prior to each assessment PJLA will require documentation to be submitted that includes: the quality manual, master listing of SOPs, proficiency testing data, internal audit and management review at minimum. Internal audit and management review data should not be greater than 12 months from the date of the initial assessment. Proficiency Test data shall not be greater than 6 months from the date of the initial assessment.

5.0 PROFICIENCY TESTING (ACCREDITATION PROCESS)



Medical Laboratory (ISO 15189) Accreditation Procedure

- 5.1 PJLA requires all CABs applying or maintaining accreditation under this program to comply with PJLA Policy PL-1 and with the requirements of ISO 15189. Applicant or accredited CABs shall ensure that all items on their scope of accreditation undergo a proficiency test at least every 6 months. Prior to initial accreditation at least one round of PT for the CAB's entire scope shall be completed and should be no greater than 6 months from the initial assessment date. These proficiency tests shall be conducted by competent providers i.e. ISO 17043 when available. In the case, third party providers are not available then the CAB must be able to demonstrate their adherence by utilizing other sources as outlined in PJLA Policy PL-1 (i.e. inter lab comparison, intra lab comparison, repeatability studies). This must be approved by PJLA.

6.0 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

- 6.1 PJLA currently accredits CABs for a two-year accreditation cycle, supplemented with yearly surveillance assessments. Accreditation and re-accreditation assessments involve a full system assessment of the CAB.

7.0 ANALYSIS OF FINDINGS AND REPORT

- 7.1 PJLA will follow its documented procedures in the conduct of the assessments, documentation of findings (non-conformities/observations), and on-site reports. PJLA assessors are expected to leave the documentation of findings and the report with the organization at the conclusion of the closing meeting. Also, the lead assessor is expected to send this documentation to PJLA HQ within 14 days from the end of the assessment (with allowances for travel, weekends, etc.). Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of corrective action, and objective evidence or an assessable plan with objective evidence of implementation of the plan within 60 days of the closing meeting. All non-conformities must be so resolved prior to recommending accreditation.

8.0 CERTIFICATES OF ACCREDITATION

- 8.1 PJLA only issues certificates of accreditation upon the final approval of the Executive Committee. These certificates will contain the effective date, the scope of accreditation including: 1) discipline, 2) process of examination, 3) property, 4) Test sample, 5) parameter (Range) and 6) measurement technique. A flexible scope may be granted for medical testing laboratories depending on the risk of the lab and their proven ability to manage the requirements as outlined in PJLA's Scopes of Accreditation Procedure (PL-4). A listing of all accredited CABs will be published on the PJLA website to include the: CAB name, address, phone number, scope of accreditation. Upon receipt of accreditation all CABs will be provided the PJLA accreditation symbol for medical testing. CABs shall follow the requirements as outlined in PJLA's Accreditation Symbol Procedure (SOP-3).