
LB.11 The laboratory develops a process for establishing or verifying and evaluating reference ranges/intervals and cut off values for each analyte and specimen source.

LB.11.1 The laboratory implements policies and procedures that define:

LB.11.1.1 Circumstances and method for establishing reference ranges.

LB.11.1.2 Circumstances and method for verifying published reference ranges.

LB.11.1.3 Circumstances and method for the re-evaluation of reference ranges.

LB.12 The laboratory has a system for standardizing critical laboratory instruments.

LB.12.1 The laboratory implements policies and procedures defining the calibration, adjustment and/or standardization of critical laboratory instruments. This includes:

LB.12.1.1 Calibrations and adjustment are performed before use, after activities that may alter the calibration and at predefined intervals.

LB.12.1.2 All thermometers used in the laboratory are checked against certified standardized thermometric device before being placed in use and annually thereafter.

LB.12.1.3 All stopwatches and instrument timers are checked against standardized stopwatch before the initial use and every six months thereafter.

LB.12.1.4 All pipettes (fixed volume and/or adjustable) are checked for accuracy and reproducibility before being placed in use and semi-annually thereafter.

LB.12.1.5 Balances are placed on vibration resistance surface and checked against standardized weights before being placed in use and every six months thereafter.

LB.12.1.6 Actions are taken in the event of unsatisfactory results.

LB.12.2 Calibration, adjustment and/or standardization procedures conform to the manufacturer's instructions and best practices.

Standard Intent:

Calibration and adjustment must be performed initially, at regular intervals, after repairs or after activities that may alter the calibration. The frequency of such checks should be based on the manufacturer recommendations, regulatory requirements and historical stability of the device.

LB.13 The laboratory has a system for instruments/methods correlation.

LB.13.1 When the laboratory uses more than one method and/or instruments to test for a given analyte, the laboratory develops and implements policies and procedures on correlation to ensure the following:

LB.13.1.1 The correlation studies are conducted every six months.

LB.13.1.2 There is clear description of the correlation study.

LB.13.1.3 There are clearly defined acceptance criteria.

LB.13.1.4 There is a process for review and approval of the correlation results.

Standard Intent:

This standard applies to tests performed on the same or different instrument makes/models or by different methods. The purpose of correlation studies is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number. Otherwise, the use of human samples, rather than stabilized commercial controls, is preferred to avoid potential effects.

LB.14 The laboratory has a system for controlling the quality of test methods.

LB.14.1 The laboratory implements policies and procedures on quality control of test methods to satisfy the following:

LB.14.1.1 Assignment of performance and review responsibility (control specimens are handled and tested in the same manner and by the same laboratory personnel testing patient samples).

LB.14.1.2 Number and frequency of running controls.

LB.14.1.3 Tolerance limits of controls results.

LB.14.1.4 Corrective action to be taken in the event of unacceptable results.

LB.14.2 The laboratory quality control system conforms to the manufacturer's instructions.

Standard Intent:

Quality control (QC) testing is performed to ensure the proper functioning of materials, equipment, and methods during operations. QC performance expectations and acceptable ranges should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. The frequency for QC testing is determined by the facility in accordance with the applicable regulatory requirements, accreditation standards and manufacturer instructions. QC results should be documented concurrently with performance and unacceptable QC results must be investigated and corrective action must be taken, if indicated before continuing the operational process. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.
