



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.
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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.