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.

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.

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.

LB.15 The laboratory has comprehensive work instructions and procedures manuals.

LB.15.1 The laboratory develops work instructions and procedures manuals that fulfill the following:

LB.15.1.1 Conform to the hospital document control/management system.

LB.15.1.2 Readily available at the work areas.