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.