3. Assurance that the equipment performs as expected in the facility's processes.

After installation, there should be documentation of any problems and the follow-up actions taken.

**LB.10 The laboratory develops a process for test method validation.**

LB.10.1 The laboratory implements policies and procedures on test method validation including:

LB.10.1.1 Verification of accuracy/precision.

LB.10.1.2 Verification of sensitivity (lower detection limit).

LB.10.1.3 Verification of carryover acceptability.

LB.10.1.4 Verification of the Analytic Measurement Range (AMR).

LB.10.1.5 Approval of the method for clinical use.

**Standard Intent:**

When the laboratory wishes to implement a test system, validation/verification studies must be performed to confirm the performance specifications, which were established by the manufacturer before approving the method for clinical use.

Validation defined as provision of objective evidence through a defined process that a test performs as intended. While verification defined as an abbreviated validation process to demonstrate that a test performs in substantial compliance to previously established claims.

At a minimum, the laboratory must demonstrate that it can obtain performance specifications comparable to the manufacturer for accuracy, precision, reportable range, and reference intervals (normal values). Although no single format for a validation plan is required, most plans include the following common elements:

1. System description.
2. Purpose or objectives.
3. Risk assessment.
4. Responsibilities.
5. Validation procedures.
6. Acceptance criteria.
7. Approval signatures.
8. Supporting documentation.

When a validation process does not produce the expected outcome, its data and corrective actions must be documented.