LB.7.1.2 Concentration/titer.

LB.7.1.3 Preparation/reconstitution date.

LB.7.1.4 Expiration Date.

LB.7.1.5 Storage requirements.

LB.7.2 Laboratory supplies and reagents are stored under appropriate conditions.

LB.7.2.1 Critical laboratory supplies and reagents are stored according to the manufacturer's recommendations under controlled conditions or in an appropriate storage device.

LB.7.2.2 Critical supplies and reagents storage conditions are continuously monitored using appropriate temperature monitoring/recording system.

LB.7.2.3 In the event of monitoring systems failure, the storage temperature is monitored and recorded every eight hours using a standardized thermometric device.

LB.7.3 The laboratory defines and specifies water types.

LB.7.3.1 There is definition of the specific type of water required for each of its testing procedures.

LB.7.3.2 Water quality is tested at least annually.

LB.8 The laboratory has a process describing its role in equipment management.

LB.8.1 The laboratory has a role in the selection of critical laboratory equipment (equipment that must be operated at defined specifications to ensure the quality of the product or service).

LB.8.2 The laboratory has a role in the receipt, installation and identification of critical laboratory equipment.

LB.9 The laboratory has a system for equipment validation.

LB.9.1 The laboratory implements policies and procedures describing the validation of critical laboratory equipment for its intended use, including:

LB.9.1.1 Installation Qualification.

LB.9.1.2 Operational Qualification.

LB.9.1.3 Detailed functional validation study with predefined acceptance criteria.

LB.9.1.4 Critical laboratory equipment are not used before completing the validation studies.

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.

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.

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