facility with means to trace materials that have been used in a particular process and also provide information for ongoing supplier evaluation.

LB.7 The laboratory has reagents and solutions management system.

LB.7.1 The laboratory implements policies and procedures to ensure that prepared/reconstituted reagents and solutions are labeled, as applicable, with:

LB.7.1.1 Content.

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.

Standard Intent:

The labeling requirements may be recorded in a log or on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date or storage requirement.

The laboratories should develop an inventory management system to ensure maintenance of adequate supplies on-hand to minimize emergency requisitions and shortages of supplies, adequate accessibility to all critical supplies necessary for operations, storage under monitored conditions as specified by the manufacturer, and maintain sufficient records on:

1. Date received
2. Lot number and expiration date
3. Whether or not acceptance criteria were met and if any follow-up
4. Date placed in service or disposition, if not used.

Grades of water defined in the current edition of CLSI Guideline C3-A4 as:

1. Clinical Laboratory Reagent Water (CLRW) suitable for most laboratory procedures.
2. Special Reagent Water (SRW), defined by a laboratory for procedures that need different specifications.
3. Instrument Feed Water, specified by the manufacturers as suitable for use with their instruments.

The CLSI Guidelines provide testing information for microbial content, and resistivity, as well as total organic carbon. It also addresses the use of purchased water, the effects of storing water, and the monitoring of stored water.
The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and documented at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be documented if water does not meet acceptability criteria.
For commercial instrument-reagent systems, the laboratory must use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed to work with laboratory reagent grade water, higher-quality water systems exist and may be required for specific methods or if analytical imprecision or inaccuracy has been traced to the quality of in-lab water.

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.

Standard Intent:

Critical equipment must operate within defined specifications to ensure the quality of blood components, test results and services. Critical equipment may include instruments, measuring devices, and computer systems (hardware and software). Maintaining a list of all critical equipment helps in the control function of scheduling and performing functional and safety checks, calibrations, preventive maintenance, and repair.