
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: