1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing,
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results,
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records,
4. Direct observation of performance of instrument maintenance and function checks,
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills.

?Analysis of competency assessment data can be very useful in identifying staff learning needs.

LB.6 The laboratory has a system for the receipt of incoming supplies and services, inventory management, and tracking of critical materials.

LB.6.1 The laboratory implements policies and procedures on documenting the receipt, inspection, and testing (as applicable) of incoming critical material or service.

LB.6.2 The laboratory implements policies and procedures on inventory management and tracking the use of critical materials, supplies, and reagents to ensure the following:

LB.6.2.1 Materials are used within their expiration dates.

LB.6.2.2 New reagents lot numbers are tested against old lots or suitable reference materials before use.

LB.6.2.3 Kit components are used within the kit lot number.

LB.6.2.4 Lot number use is traceable to patient/blood donors or inclusive dates of use.

Standard Intent:

Before acceptance and use of critical materials, reagents, supplies or services, they should be inspected and tested (if necessary) to ensure that they meet specifications for their intended use. It is essential that supplies used in the collection, processing, preservation, testing, storage, distribution, transport, and administration of blood, components meet predefined acceptance criteria. Laboratories must develop procedures to control and prevent inadvertent acceptance and use of materials, reagents and services that do not meet specifications. Corrective action may include returning the material to the vendor or destroying it. Receipt and inspection records provide the

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: