Standard Intent:

Point-of-Care Testing (POCT) is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Other standards for quality management, results reporting, and safety are applied. The POCT program should be centrally coordinated in the laboratory, with designated qualified personnel who review testing and quality control procedures, conduct/oversee training and competency assessment of testing personnel. The surveyor will review all centrally maintained records and visit at least three testing sites in order to evaluate compliance.

LB.29 Laboratory records are retained for defined periods.

LB.29.1 The laboratory implements a general laboratory records retention system that ensures the following:

LB.29.1.1 Laboratory test request forms, specimen accessioning logs, instrument printouts, reported results, records of quality control, proficiency testing records, and quality management reports (quality indicators, audits, process improvement projects) are retained for three years.

LB.29.1.2 Method/instrument validation records are retained for the entire period of using the method/instrument and three years after discontinued.

LB.29.1.3 Maintenance records are retained for the life time of the instrument and three years after retirement.

LB.29.1.4 Employee identification records (signature, initials, identification code, and inclusive dates of hiring) are retained for the entire period of hiring and three years after departure.

LB.29.2 The implemented blood bank and transfusion services records retention system ensures the following:

LB.29.2.1 Inspection records (blood, blood components and critical supplies), proficiency testing records, and quality management reports (quality indicators, audits, process improvement projects) are retained for five years.

LB.29.2.2 Whole blood collection, apheresis collection, therapeutic phlebotomy, therapeutic apheresis, component preparation, component modification, quality control, and normal pre-transfusion testing records are retained for ten years.

LB.29.2.3 Donation history, donor testing, donor notification, deferred donors, final disposition of blood/blood components, and look back records are retained permanently.

LB.29.2.4 Abnormal patients testing records (records of patients with antibodies, transfusion reactions or special requirements), patient's transfusion

history, transfusion reaction, and transfusion transmitted diseases investigation records are retained permanently.

LB.29.3 The implemented anatomical pathology records retention system ensures the following:

LB.29.3.1 Surgical pathology reports, outside consultations report and images of studies are retained for ten years.

LB.29.4 Discontinued (retired) blood bank and transfusion controlled documents are retained for five years after the retirement date.

LB.29.5 Discontinued (retired) general laboratory controlled documents are retained for three years after the retirement date.

Standard Intent:

Documentation provides a framework for understanding and communication throughout the organization. Documents describe how processes are intended to work, how they interact, where they must be controlled, what their requirements are, and how to implement them. On the other hand, records provide evidence that the process was performed as intended and provide information needed to assess the quality of products and services. Together, documents and records are used by quality oversight personnel to evaluate the effectiveness of a facility's policies, processes, and procedures.

The laboratory should maintain a log listing all current policies, processes, procedures, forms and labels with the locations of copies. The log contains other information as appropriate, such as dates when documents were placed in service, schedule of review, identity of reviewer(s), and dates when documents were discontinued/superseded.

When forms are used for capturing or recording data, steps, or test results, the forms become records. Data should be recorded in a format that is clear and consistent. Records provide evidence that critical steps in a procedure have been performed appropriately and that products and services conform to specified requirements. Review of records is an important tool to help evaluate the effectiveness of the quality management system. Records should be created concurrently with the performance of each significant step and should clearly indicate the identity of the individuals who performed each step and when it occurred. The process for managing records should address the following items:

1. Creation and identification.
2. Protection from accidental or unauthorized modification or destruction.
3. Verification of completeness, accuracy, and legibility.
4. Storage and retrieval.
5. Retention periods.
6. Confidentiality.