

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