

Standard AOP.03.01

A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff are qualified to perform the tests and interpret the results.

Intent of AOP.03.01

Clinical laboratory services are managed by an individual who is qualified to ensure that the laboratory and its services meet patient needs, laws, and regulations. Qualified laboratory staff perform tests and interpret results to ensure that the data collected through laboratory services are accurate.

Clinical laboratory services are under the direction of an individual who is qualified through documented education, training, experience, and the requirements of laws and regulations. This individual is responsible for the laboratory facility, the services provided in the laboratory, and tests performed outside the laboratory, including point-of-care testing.

The oversight of services outside the laboratory does not include daily supervision of those activities. Daily supervision remains the responsibility of the leaders of the department or unit in which the testing is conducted. When this individual provides clinical consultation or medical opinion, they are a physician, preferably a pathologist. Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals.

Laboratory staff are oriented to their work and are given work assignments consistent with their training and experience. The laboratory implements a staffing program that allows staff to perform tests promptly and to ensure laboratory staffing during all hours of operation and for emergencies.

The hospital identifies a qualified laboratory leader to oversee laboratory services. Oversight responsibilities include those services that are provided within and outside the laboratory.

The oversight of services outside the laboratory includes ensuring consistent hospitalwide policies and practices, including the following:

- Training
- Supply management
- Inspection and maintenance of equipment
- Oversight of the point-of-care-testing program

Laboratory staffing requirements include the following:

- Education, training, qualifications, and experience of laboratory staff members performing and interpreting laboratory tests
- Identifying staff approved to perform point-of-care testing
- Identifying staff who direct or supervise other staff who perform testing

Measurable Elements of AOP.03.01

1. The clinical laboratory, and other laboratory services throughout the hospital, are under the direction and oversight of one or more qualified individuals. (See also GLD.06.00, ME 1)
2. Responsibilities of the qualified laboratory leader include the following:
 - Developing, implementing, and maintaining policies and procedures
 - Administrative oversight of laboratory services
 - Maintaining any necessary quality control programs
 - Developing and implementing a staffing program
 - Recommending outside sources of laboratory services
 - Monitoring and reviewing all laboratory services
3. All laboratory staff have the required qualifications to perform and interpret tests.
4. A laboratory staffing program is implemented so staff can perform tests promptly and provide staffing during all hours of operation and during emergencies.
5. Laboratory supervisory staff are identified and have the proper qualifications and experience for the role.

Standard AOP.03.02

The hospital has defined requirements for the oversight and supervision of the point-of-care testing program.

Intent of AOP.03.02

The hospital must have a clearly defined and well-structured approach to point-of-care testing to ensure that it is performed safely and correctly and that the results generated are accurate and reliable.

Point-of-care testing (POCT) is testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to the patient.

The individual responsible for laboratory services or other qualified designee is responsible for the oversight and supervision of POCT.

The hospital develops a program for POCT that includes the following:

- Selecting tests to be performed
- Identifying staff who perform the test(s)
- Establishing a protocol for reporting abnormal test results
- Determining a process for reporting critical results
- Defining a process to include representatives of clinical staff in developing and evaluating the POCT program

Staff performing POCT require training for each test being performed. Staff must complete a competency evaluation for each test to confirm that they know how to perform the test and to ensure that results are accurate. Staff performing POCT understand the process to report abnormal and critical results.

Quality control tests and their documentation are required to be performed according to manufacturers' guidelines. All staff performing POCT adhere to quality control procedures and know what actions to take if a quality control sample is out of the test range specified by the manufacturer. The results of the quality control testing and any corrective actions are documented.

POCT is monitored and evaluated to ensure that the program is meeting the needs of patients and health care providers.

Point-of-care tests include those performed and interpreted at or near the patient. Examples of point-of-care tests include the following:

- POCT blood glucose tests
- POCT blood gas tests