9 LABORATORY SERVICES

OVERVIEW OF THE LABORATORY SERVICES

Laboratory investigations and rapid reporting systems are essential for patient assessment and the implementation of treatment plans.

The facility may have its own laboratory service, or it may have an arrangement with an outside laboratory service. In either case, the service must meet applicable standards, laws and regulations.

The selection of an outside source to receive laboratory specimens for analysis is based on an acceptable record and compliance with laws and regulations.

Laboratory services must be available at those times needed by the organisation, including emergency and after-hour services.
Standards

9.1  Management of the service

9.1.1  Laboratory services are available to meet the needs of services and patients, in compliance with local and national laws, regulations and standards.

Intent of 9.1.1
The organisation has a system for providing the laboratory services, including clinical pathology services, required by its patient population, clinical services offered, and healthcare providers' needs.
The laboratory services are organised and provided in a manner that meets applicable local and national standards, laws and regulations.
Laboratory services, including those required for emergencies, may be provided within the organisation, by agreement with another organisation, or both. Laboratory services are available after normal hours for emergencies.
Outside sources are convenient for the patients. The organisation selects outside sources based on the recommendations of the director or other individual responsible for laboratory services. Outside sources of laboratory services meet applicable laws and regulations and have acceptable records of accurate, timely services. Patients are informed when an outside source of laboratory services is owned by the referring physician.
Laboratory results are validated to ensure that they are those of the correct patient and physician.
Validations include the name of the validating officer.
Results are reported within a time frame based on patient needs, services offered, and the needs of the clinical personnel. Emergency tests and after-hours and weekend testing needs are included. Appropriate specimen containers are available in the organisation, with instructions for their correct use.

9.1.1  Criteria

9.1.1.1  Adequate, convenient and regular laboratory services are available to meet the organisation’s needs.

9.1.1.2  The laboratory services are organised and provided in a manner that meets applicable local and national standards, laws and regulations.

9.1.1.3  Emergency laboratory services are available, including after-hours services.

9.1.1.4  The organisation has established the expected report time for results.

9.1.1.5  Laboratory results are reported within a suitable time frame to meet patient needs.

9.1.1.6  Laboratory results are validated and include unique patient identity, date of testing/reporting, name and location of the requesting physician.

9.1.1.7  The validating officer is identified and recorded.

9.1.1.8  A list of referral laboratories is available for tests not performed on site.

9.1.1.9  There is a documented, implemented procedure for packaging specimens and transporting them to the referral laboratories.
9.1.10 A register is kept of the referred specimens and the results.

9.1.2 A qualified individual is responsible for managing the laboratory service.

Intent of 9.1.2
The laboratory service is under the direction of an individual who is qualified by virtue of documented training, expertise and experience, in accordance with applicable laws and regulations. This individual assumes professional responsibility for the laboratory facility and for the services provided. When this individual provides clinical consultations or medical opinions, he or she is a physician, preferably a pathologist. Speciality and subspeciality laboratory services are under the direction of appropriately qualified individuals. The responsibilities of the laboratory director include:
- developing service-related policies and procedures and ensuring that they are implemented;
- managing relevant human resource functions, e.g. job descriptions, personnel evaluation, staff training;
- developing, co-ordinating, and monitoring the required quality control and improvement systems.

9.1.2 Criteria

9.1.2.1 The laboratory is under the direction of a qualified individual.

9.1.2.2 The responsibilities of this person include maintaining quality control programmes.

9.1.2.3 The responsibilities of this person include administrative supervision.

9.1.2.4 The responsibilities of this person include monitoring and reviewing all the laboratory services.

9.1.3 Individuals with adequate training, skills, orientation and experience administer tests and interpret the results.

Intent of 9.1.3
The organisation identifies the laboratory personnel who may perform testing and who may direct or supervise testing. Supervisory and technical personnel have appropriate and adequate training, experience and skills, and are oriented to their work. Technical personnel are given work assignments consistent with their training and experience. In addition, there are enough staff members to perform tests promptly and to provide the necessary laboratory staffing during all hours of operation and for emergencies. The organisation is able to identify and contact experts in specialised diagnostic areas, such as parasitology or virology, when needed.

9.1.3 Criteria

9.1.3.1 Those individuals who may perform testing and those who may direct or supervise testing are identified.

9.1.3.2 There are enough staff members to meet service needs.

9.1.3.3 On-going in-service training is provided to all staff members.

9.1.3.4 Records of the training provided are kept for each staff member.
9.2 Facilities and equipment

9.2.1 Laboratory buildings are adequate to provide a safe and effective laboratory service.

Intent of 9.2.1
Departmental managers need to work closely with organisational managers to ensure that facilities and equipment are adequate. Departmental managers keep organisational managers informed of inadequate facilities, additional equipment requirements, and the current state of facilities and equipment. The general state of the laboratory will be checked. The walls, floor and ceiling should be in a good condition. As few items/instruments as possible should be placed on the floor.

9.2.1 Criteria

9.2.1.1 The laboratory is a separate designated area within, or in close proximity to, the health facility.

9.2.1.2 The size of the laboratory is appropriate to the services provided.

9.2.1.3 The ceiling and walls are clean and painted in a bright colour.

9.2.1.4 The floor has a smooth and continuous surface.

9.2.1.5 The ceiling is not leaking and does not show signs of moisture.

9.2.2 Laboratory fixtures and fittings are adequate to provide a safe and effective laboratory service.

Intent of 9.2.2
The laboratory benches and equipment should be of an easily cleaned material (NO WOOD). Assessors will check that:
• benches are not damaged;
• benches, walls and equipment are clean (no dust, blood or other material on walls);
• waste bins are not over-filled;
• the area around the water point is clean and organised.

9.2.2 Criteria

9.2.2.1 There are sufficient laboratory benches for the projected activities.

9.2.2.2 Laboratory benches are strong enough for the projected activities (e.g. large instruments).

9.2.2.3 There is either an uninterrupted power supply (UPS) or a battery backup system for selected items of equipment, which are tested regularly and the results are fully documented.

9.2.2.4 Each laboratory compartment has adequate ventilation, with room temperature below 25°C, and a temperature record is kept.

9.2.3 There is sufficient laboratory equipment is adequate to provide a safe and effective laboratory service.
Intent of 9.2.3
Laboratory personnel work to ensure that all equipment functions at acceptable levels and in a manner that is safe for the operator(s). A laboratory equipment management programme provides for:
- selecting, acquiring and replacing equipment;
- identifying and taking an inventory of equipment;
- assessing equipment use through inspection, testing, calibration and maintenance;
- the monitoring of and acting on equipment hazard notices, recalls, reportable incidents, problems and failures; and
- documenting the management programme.
Testing, maintenance and calibration frequency are related to the laboratory's use of equipment and its documented history of service.
The refrigerator temperature, especially the specimen fridge temperature, must be maintained between 2°C and 8°C and records of the daily temperature checks must be kept.

9.2.3 Criteria

9.2.3.1 Sufficient equipment is available to provide the required laboratory services for the projected activities.

9.2.3.2 All equipment is in good working order, operated appropriately, and functioning well.

9.2.3.3 Records are maintained to indicate that all equipment is regularly inspected, maintained and calibrated.

9.3 Reagents, chemicals and kits

9.3.1 The supplies of laboratory reagents, chemicals and kits are adequate to provide a safe and effective laboratory service.

Intent of 9.3.1
The organisation has identified those reagents and supplies needed to regularly provide laboratory services to its patients. There is an effective process for ordering or securing those essential reagents and other supplies. All reagents are stored and dispensed according to defined procedures. The periodic evaluation of all reagents ensures accuracy and precise results. Written guidelines ensure the complete and accurate labeling of reagents and solutions.

9.3.1 Criteria

9.3.1.1 The available supplies, reagents, chemicals and kits are sufficient for projected activities.

9.3.1.2 Specific laboratory reagents, chemicals and kits are available for blood, urine and stool tests.

9.3.1.3 All reagents and chemicals are stored and dispensed according to guidelines.

9.3.1.4 All reagents and solutions are completely and accurately labelled.

9.3.1.5 All reagents are periodically evaluated for accuracy and results.

9.3.1.6 All reagents are stored in a lockable storage room or cupboard.
9.3.1.7 Where required, reagents are stored in the correct environment, e.g. controlled temperature, humidity, exposure to direct sunlight.

9.3.1.8 Dangerous reagents and chemicals are separately and securely stored.

9.3.1.9 All reagents are checked for expiry dates.

9.3.1.10 There is a documented stock management system that keeps track of current stock.

9.3.1.11 Re-order levels are defined.

9.4 Management of specimens (samples) and results

9.4.1 Procedures are followed for collecting, identifying, safely transporting, tracking specimens/samples, and reporting the results.

Intent of 9.4.1

Procedures are developed and implemented for:
- ordering tests;
- collecting and identifying specimens;
- transporting, storing and preserving specimens; and
- receiving, logging in and tracking specimens.

There should be at least two log-books: only one Patient log-book and, depending on the size of the laboratory, one or more Laboratory log-books for various disciplines.

Laboratory results should ideally not be directly linked to names, either in the Patient or the Laboratory log-books.

Patient log-books should contain name, date of visit, date of birth, gender, which tests were requested, the time completed and the unique laboratory number.

Laboratory log-books should mention only the unique laboratory number and results, no names. In other words, both books are required to match results to patient names.

Ideally, monthly overviews of the number of tests performed are generated; test results of all quality control specimens performed should be well documented. Most important, it is essential that raw data is administered, documented, filed and remains in the laboratory.

These procedures are observed for specimens sent to outside laboratory sources for testing, and for specimens sent to on-site laboratories.

There are records of results given telephonically, at what time and to whom.

9.4.1 Criteria

9.4.1.1 Policies and procedures (SOPs) for handling specimens are implemented.

9.4.1.2 Request forms are available and contain relevant information.

9.4.1.3 Specimen labels include unique patient identification and adequate supporting information.

9.4.1.4 Specimens are registered (handwritten or digital) legibly and in an organised manner.

9.4.1.5 Results are registered in a log-book.

9.4.1.6 Laboratory results are stored in lockable cupboard.
9.4.1.7 Policies and procedures (SOPs) regarding reporting and reviewing results are implemented

9.4.2 Established norms and ranges are used to interpret and report clinical laboratory results.

Intent of 9.4.2
The laboratory establishes reference intervals or "normal" ranges for each test performed. The range is included in the clinical record, either as part of the report or by including a current listing of such values, approved by the laboratory director. Ranges are furnished, when an outside source performs the test. The reference ranges are appropriate to the organisation's patient population and are reviewed and updated when methods change.

9.4.2 Criteria

9.4.2.1 The laboratory has established reference ranges for relevant tests.

9.4.2.2 The range is included in the clinical record at the time test results are reported.

9.5 Quality control

9.5.1 Quality control procedures are followed and documented.

Intent of 9.5.1
The quality of the laboratory services can be monitored using internal and external quality control guidelines. Designing and implementing internal and external quality control activities is essential for the final quality assurance of the laboratory results.

Sound quality control systems are essential to providing excellent pathology and clinical laboratory services. Quality control procedures could include:
a) validation of the test methods used for accuracy, precision and reportable range;
b) daily surveillance of results by qualified laboratory staff;
c) rapid corrective action when a deficiency is identified;
d) testing of reagents; and
e) documentation of results and corrective actions.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognised by internal mechanisms. Thus, the laboratory participates in an approved proficiency testing programme when one is available. Alternatively, when approved programmes are not available, the laboratory exchanges samples with a laboratory in another organisation for peer comparison testing purposes. The laboratory maintains a cumulative record of participation in a proficiency testing process. Proficiency testing, or an alternative, is carried out for all speciality laboratory programmes, when available.

9.5.1 Criteria

9.5.1.1 There is a documented quality control system.

9.5.1.2 The laboratory participates in an external quality control programme.

9.5.1.3 There is a current register of quality control results and of the corrective and preventive actions taken.
9.6 Prevention and control of infection

9.6.1 The laboratory service implements infection prevention and control processes.

9.6.1 Criteria

9.6.1.1 The service identifies the procedures and processes associated with the risk of infection, and implements strategies to reduce risk.

9.6.1.2 Suitable processes are followed for cleaning and decontaminating laboratory surfaces and equipment.

9.6.1.3 Protective clothing is worn correctly.

9.6.1.4 Individuals who handle specimens are trained in the proper handling of dangerous specimens.

9.6.1.5 Organisational policy on post-exposure prophylaxis (PEP) is implemented.

9.6.1.6 Organisational policy on handling, storing and disposing of healthcare waste is implemented.