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 required 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.

Standard Intent
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, after-hours and weekend testing needs are included. Appropriate specimen containers are available in the organisation, with instructions for their correct use.

Criteria 9.1.1

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.
9.1.1.10  A register is kept of the referred specimens and the results.

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

Standard Intent
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 has professional responsibility for the laboratory facility and for the services provided. 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 and reviewed regularly.
- managing relevant human resource functions, e.g. job descriptions, personnel evaluation, personnel training;
- developing, co-ordinating, and monitoring the required quality control and improvement systems.

Criteria 9.1.2

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 perform tests and interpret the results.

Standard Intent
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 personnel members to perform laboratory tests promptly and to provide the required laboratory services 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.

Criteria 9.1.3

9.1.3.1  Qualified individuals are assigned to perform and supervise the provided laboratory services.

9.1.3.2  There are enough personnel members to meet service needs.

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

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

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

Standard Intent
Departmental managers need to work closely with organisational managers to ensure that facilities and equipment are adequate. Departmental managers keep organisational managers informed about inadequate facilities, the need for 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.

Criteria 9.2.1

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.

Standard Intent
The laboratory has to be constructed in such a way that it can provide the projected laboratory services. The laboratory has to have sufficient and proper laboratory benches, washing and staining facilities, sufficient power and water requirements and preferably a controlled temperature. Specific details that should be monitored are:

- Laboratory benches and equipment should be of a material that can support the laboratory instruments (strong) and should be of a material that cannot affect the surface of the table. Preferably the laboratory tables are constructed of concrete that is tiled. No wooden tables are allowed.
- At least one washing unit is available for standard cleaning and washing activities. When staining is performed 2 units are preferred.
- The number and quality of the available sockets should be sufficient for the projected activities.
- The water supply should be guaranteed to provide washing and staining activities.

Criteria 9.2.2

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), battery backup system and/or an automated voltage stabilizer (AVS) present for critical 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 that is adequate to provide a safe and effective laboratory service.

Standard Intent
In order to provide effective laboratory services, it is essential that specific equipment is available. Laboratory management and personnel are responsible for the selection and availability of the critical instruments, their operation according to manufacturer’s instructions and their appropriate maintenance. The following must be considered:

- Processes for the selection and procurement of new instruments.
- The availability of an equipment inventory management system.
- The maintenance of the available equipment through inspection, testing and calibration.
- Monitoring of and acting on equipment hazard notices, recalls, reportable incidents, problems and failures.
- The availability of a system where activities are documented.

Testing, maintenance and calibration frequencies are related to the laboratory’s use of equipment and its documented history of service.

Criteria 9.2.3

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 consumables, reagents, chemicals and kits are adequate to provide a safe and effective laboratory service.

Standard Intent
The organisation has identified those reagents and supplies needed to regularly guarantee the laboratory services provided to its patients. There is an effective process for ordering and ensuring that essential reagents and other supplies are available at all times. All reagents are stored and dispensed according to defined procedures. The periodic evaluation of all reagents, such as monitoring expiry dates, ensures accuracy and precise results. Written guidelines ensure the complete and accurate labelling of reagents and solutions.

Criteria 9.3.1

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

9.3.1.2 Specific laboratory reagents, chemicals and kits are used appropriately.
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 and tracking specimens/samples, and reporting the results.

Standard Intent
Procedures are developed and implemented for:
- Requesting laboratory tests (laboratory request form);
- Specimen collection and identification;
- Specimen storage, preservation and transport;
- Reviewing and authorising the laboratory results.

There should be at least two log books: only one patient log book and at least one log book for laboratory results. Dependent upon the size of the provider and the national requirements of the MOH, different log books for various disciplines are required or mandatory. Log books for laboratory results should not be directly linked to names. Patient log books should contain name, date of visit, date of birth, gender, which services are requested, what material should be collected and the unique laboratory identification number. In the laboratory log books only the unique laboratory number and results are registered. In other words, both log books are required to match results to patient names.

Ideally, monthly overviews of the number of tests performed are generated.

Procedures should be available for administration, collection and reporting activities of specimens tested on site or sent to outside referral laboratories.

Criteria 9.4.1

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.

Standard Intent
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.

Criteria 9.4.2

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.

Standard Intent
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 personnel;
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.
Criteria 9.5.1

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.

Criteria 9.6.1

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.