



SE09

LABORATORY SERVICES

The healthcare facility ensures all tests are performed according to standardized operational procedures (SOPs) in the laboratory, including appropriate (internal) controls for validation purposes of test results. Validated test results are timely reported back to the requester and each test result produced in the laboratory is traceable for accuracy and accountability purposes (e.g. linked to date, specimen, test, patient, controls, stock). The equipment used in the laboratory is well maintained and appropriate stock levels for consumables and test kits are kept. The laboratory complies with national regulations in terms of size and layout, including a designated handwashing station, essential for infection prevention. Laboratory staff ensures safe sample collection, appropriate hand hygiene, correct use of PPE, and strictly follow waste segregation guidelines (e.g. sharps, infectious, non-infectious).

The SafeCare standards cover the full range of clinical services and management functions for healthcare facilities in 13 Service Elements. These Service Elements contain a number of standards that relate to specific services or functions. The rationale of each standard is explained by the standard intent and gives you an idea what the standard really entails.

Each standard contains measurable elements, also called criteria. Measurable elements are related to specific processes, assets or documents (e.g. process for triage, resuscitation equipment or a job description for the lab manager). Compliance to each measurable element is assessed, and scores awarded are either Fully Compliant (FC), Partially Compliant (PC), Non-Compliant (NC) or Not Applicable (NA). The combined scores of the underlying measurable elements reflect the level of compliance to the whole standard.

9.1 MANAGEMENT AND STAFFING

9.1.1 The laboratory is managed by qualified care providers.

STANDARD INTENT:

The laboratory service is under the direction of an individual who is qualified and has 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. 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, staff evaluation, staff training;*

- *Developing, coordinating, and monitoring the required quality control and improvement systems.*

The laboratory staff is identified based upon their education, training, qualifications, and experience for laboratory staff members performing and interpreting laboratory tests, those who are approved to perform point-of-care screening tests at the bedside, and those who direct or supervise staff who perform testing. Supervisory staff and technical staff are oriented to their work. Technical staff are given work assignments consistent with their training and experience. Records of trainings are kept.

Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals.

MEASURABLE ELEMENTS:

- 9.1.1.1** A designated qualified staff member is responsible for managing the laboratory.
- 9.1.1.2** The qualifications of the laboratory staff members correspond with the scope of practice.
- 9.1.1.3** New laboratory staff members are orientated on relevant topics.
- 9.1.1.4** Records are kept of the training (CME) provided.

9.1.2 Laboratory services are managed and performed in a coordinated manner.

STANDARD INTENT:

In order to provide effective and efficient laboratory services there are requirements that have to be addressed.

The number of staff needs to be matched with the patient load and utilization. The standards sees to ensure that sufficient staff is available to provide the required laboratory services, because understaffing could have a direct effect on the quality of the laboratory results.

Next to the regular laboratory services emergency services are available in order to ensure that the projected healthcare and related laboratory services is guaranteed.

Overviews of the number of tests performed and the related results can play an important role in decision making within a healthcare facility. It could provide information on the needs for the next period and could have an effect on stock and financial forecasting. The utilization figures

in relation with the positivity rate could have implications on medical decision processes.

MEASURABLE ELEMENTS:

- 9.1.2.1** There are sufficient laboratory staff members to meet the patient needs.
- 9.1.2.2** Emergency laboratory services are available, including after-hours services.
- 9.1.2.3** Weekly and/or monthly overviews are prepared with total number of tests performed, including positivity rates (HIV, STI, TB etc.).
- 9.1.2.4** Weekly/monthly overviews are shared with appropriate staff members in the healthcare facility for review.

9.2
INFECTION
PREVENTION AND
CONTROL (IPC)

9.2.1 The infrastructure of the laboratory is adequate for preventing infections.

STANDARD INTENT:

The laboratory infrastructure has to comply to the (inter) national laws and regulations. In order to provide a safe environment to the laboratory staff and to ensure that the laboratory services are performed adequately the laboratory infrastructure has to comply with the following requirements:

- *The size of the laboratory is appropriate for the projected services and available staff;*
- *The different laboratory services and activities are separated;*
- *The laboratory is constructed with proper materials and is in a good condition;*
- *Sufficient handwashing facilities are available.*

MEASURABLE ELEMENTS:

- 9.2.1.1** The lay-out of the laboratory service is in line with the in-country regulations.
- 9.2.1.2** The size and bench space of the laboratory is appropriate for the services provided.
- 9.2.1.3** Materials used for floors, benches and sinks are in line with the in-country regulations (e.g. easy to clean, no cracks).

9.2.1.4 Dedicated handwashing facilities including water are available in the laboratory.

9.2.2 Adequate precautions are taken to prevent infections for staff and patients in the laboratory.

STANDARD INTENT:

In a laboratory biological materials are processed and analyzed. The handling of biological specimens requires specific safety precautions that allow for the protection of the laboratory staff, including other healthcare facility staff and visitors.

In order to prevent infections the laboratory has to implement specific safety measures and precautions.

Safety measures that should be in place are:

- *Ensure that the laboratory is only accessible for authorized staff;*
- *Ensure that the laboratory is well ventilated;*
- *Ensure that proper handwashing materials are available;*
- *Ensure that PPE [Personal Protective Equipment] is available (gloves, lab coats, etc.)*

MEASURABLE ELEMENTS:

9.2.2.1 Adequate PPE is available for the laboratory staff (gloves, lab coats, etc.).

9.2.2.2 Access to the laboratory is controlled.

9.2.2.3 The laboratory area is well ventilated, enabling safe laboratory practices.

9.2.2.4 Soap and single use (paper) towels are available for handwashing.

9.2.3 Staff is guided in procedures to prevent infection.

STANDARD INTENT:

In order to guide the laboratory staff on infection prevention control (IPC) measures clear guidance and instructional documentation should be available. In order to ensure that IPC is effective and standardized

it is essential that several laboratory processes are guided, and staff aware of these. The key processes for which guidance documentation should be available are:

- *Guidance on the use of PPE (Protective and Preventive Equipment);*
- *Guidance on cleaning;*
- *Guidance on (biological) waste management;*
- *Guidance on how to act when staff is exposed to infectious agents (e.g. PEP procedure when a needle stick accident has occurred).*

An assigned staff member who is responsible for the development of an infection prevention control (IPC) program, training and monitoring can ensure constant adherence.

MEASURABLE ELEMENTS:

- 9.2.3.1** There is a document guiding staff in waste segregation and disposal.
- 9.2.3.2** Staff can explain appropriate use of PPE.
- 9.2.3.3** Staff can explain the cleaning and decontaminating processes.
- 9.2.3.4** Staff can explain appropriate measures after exposure to infectious agents.

**9.3
DIAGNOSTIC
PROCESSES AND
GUIDING DOCUMENTS**

9.3.1 Staff is guided in the process of safe specimen collection.

STANDARD INTENT:

The healthcare facility needs to ensure that patient specimens can be collected at all times, can be collected and processed in a safe and organized manner and that the patient information and corresponding request forms are registered in an orderly manner. To this end, the following requirements apply:

- *The supplies and materials are adequate to provide a safe and effective specimen collection;*
- *There are guiding documents such as standard operating procedures for safe specimen collection and processing and specimen rejection and acceptance;*

- *Laboratory request forms are used on which patient specific information is available with the request for the specific assay(s);*
- *A dedicated administration should be available in which relevant patient information and requests are kept.*

MEASURABLE ELEMENTS:

- 9.3.1.1** Sufficient supplies are available in the specimen collection area to enable safe practices.
- 9.3.1.2** There are guiding documents for safe handling of specimens.
- 9.3.1.3** Specimens are appropriately processed (centrifuged and stored).
- 9.3.1.4** Laboratory request forms are available and contain relevant information.

9.3.2 Staff is guided on proper patient and specimen identification processes.

STANDARD INTENT:

It is essential that the correct results are reported for each patient in order to ensure that the diagnosis and subsequent treatment of the patient is correct. Proper identification of patients and laboratory specimens is very important in order to ensure that the correct specimens are processed and that the patient specific results are reported. There are several aspects that have a direct effect on the identification of patients, such as:

- *Are the specimens appropriately labelled?*
- *Are the specimens appropriately checked before testing?*
- *Is there a patient identification process?*
- *Are the specimens, patient information and results registered in an organized manner?*

MEASURABLE ELEMENTS:

- 9.3.2.1** There are guiding documents for the labelling of specimens throughout the specimen processing activities and these guidelines are followed.
- 9.3.2.2** Patients are identified during the specimen collection and reporting process.
- 9.3.2.3** Specimens information and results are registered in an organized manner.

9.3.2.4 Relevant patient information and results are registered in an organized manner.

9.3.3 Staff is guided to perform the laboratory tests provided.

STANDARD INTENT:

In order to ensure that the laboratory tests provide quality results several requirements have to be in place. For each assay in the service package it is required that:

- *SOPs are in place for each assay/test performed. In the SOP the specific steps are described that ensures that the test is performed consistently which results in a uniform and guaranteed quality. An SOP is also used as training documentation and should be used as a resource for the training of new staff. All available documentation is brought together in a laboratory manual;*
- *There are sufficient products, consumables and reagents available in order to provide the specific and projected number of laboratory tests provided;*
- *Quality control activities are in place (addressed in other standard).*

MEASURABLE ELEMENTS:

9.3.3.1 There is an SOP for each assay/test performed in the laboratory.

9.3.3.2 There are sufficient kits, reagents and materials to perform the laboratory assays required to meet the patient needs.

9.3.3.3 Staff can explain the procedures for the laboratory services provided.

9.3.3.4 There is an organized laboratory manual in which SOPs and related documentation are filed and kept up to date.

9.3.4 Essential laboratory equipment is available and used appropriately.

STANDARD INTENT:

The laboratory manager and laboratory staff need to ensure that all equipment and medical technology, including medical devices used for (point-of-care) testing are available and function at acceptable levels and in a manner that is safe to the operator(s). The laboratory leader is responsible

to ensure that several requirements are in place in order to guarantee that the equipment is working appropriately. The next points need to be in place:

- *The laboratory equipment and related medical technology is appropriate for the projected laboratory services in relation to the healthcare facility/patient needs;*
- *There is an inventory of laboratory equipment available;*
- *The instruments are kept in good/clean condition, maintenance is performed and controlled appropriately;*
- *Clear operating instructions are available and staff is appropriately trained.*

MEASURABLE ELEMENTS:

9.3.4.1 Sufficient laboratory equipment is available to meet the patient needs, and are clean and in good condition.

9.3.4.2 There is a document/instructions which guides the staff in appropriate usage of the equipment.

9.3.4.3 There is a document/instructions which guides the staff in appropriate cleaning and/or maintenance of the equipment.

9.3.4.4 Cleaning schedule, maintenance and control logs (where relevant) are kept current (incl. fridge).

9.3.5 A stock management system is in place that guarantees efficient and quality laboratory services.

STANDARD INTENT:

This standard sees to ensure that laboratory products are kept in stock and quality is ensured. The quality and identification of laboratory products is essential for the provision of good laboratory services. Therefore the products have to be kept according to the storage requirements, such as temperature and storage environment (e.g. dark), specified by the manufacturer's instructions, the products are not used after the projected expiry date and the laboratory products are appropriately labelled and dated. Processes have to be in place that guide the staff on these specific matters. A stock management system ensures the current assets (=inventory) for all individual laboratory tests are known at all times. An SOP should be in place that lists all laboratory items, including manufacturers and package sizes. The SOP should also define how often stock taking of

current assets should take place, which information should be captured, and how this information is issued for procurement/stock keeping purposes. The following information should be captured and kept current:

- *Product specifications (supplier, manufacturer, product name, catalog number, unit size);*
- *Cost, date of purchase and expiry date of each item;*
- *Quantity of each item in stock on a specific day (preferably specified as; non-expired, close to expired, expired).*

Expiry dates need to be checked. When there is a digital system in place these checks can be performed by the IT system because all the dates of expiry are entered in the system. When there is a manual bin card system this should preferably be performed daily or weekly. Administration records of this process should be kept accordingly.

MEASURABLE ELEMENTS:

- 9.3.5.1** All reagents are stored and labelled according to manufacturers' instructions/directives or guiding document.
- 9.3.5.2** The laboratory lists all reagents, chemicals, kits and other consumables that are required for the projected services.
- 9.3.5.3** Staff monitors and records the status of current stock in the laboratory.
- 9.3.5.4** Records of regular expiry checks are kept current, and items expiring shortly are marked.

9.3.6 Quality control/assurance activities regarding assays/test are performed.

STANDARD INTENT:

The quality of the laboratory services can be monitored using both internal and external quality control approaches. Designing and implementing internal and external quality control processes and activities is essential for assuring that the laboratory results are of good quality.

Quality control/assurance is ensured when:

- *test methods are validated for accuracy, precision and reportable range;*
- *daily surveillance of results is performed by qualified laboratory staff;*
- *there are deficiencies identified and that rapid corrective actions (CA) are performed and documented;*

- reagents used for laboratory tests are tested.

There are different quality control /assurance processes. They can be divided into internal and external control processes. For both processes clear instructions, SOPs, should be available. In the SOPs details on the range and frequency of the internal controls, frequency of proficiency testing (confirmation) when mandatory by national law and regulations, or how participation in external quality control programs is organized are defined.

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 recognized by internal mechanisms. Thus, the laboratory participates in an approved proficiency testing program when one is available. Alternatively, when approved programs are not available, the laboratory exchanges samples with a laboratory in another healthcare facility for peer comparison testing purposes. The laboratory maintains a cumulative record of participation in a proficiency testing process.

MEASURABLE ELEMENTS:

- 9.3.6.1** Internal quality controls (IQC) are performed and recorded for each assay/test to verify reagent/kit quality.
- 9.3.6.2** There is a documented quality control program in which all quality control aspects are defined.
- 9.3.6.3** The laboratory participates in an external quality control (EQC), like a proficiency-testing program or an alternative, for all (specialized) laboratory tests.
- 9.3.6.4** The laboratory keeps and maintains records of all the results of the internal quality assurance (IQA) and external quality assurance (EQA) activities and the related corrective actions (CA).

9.3.7 Reporting of reliable results is performed appropriately and timely.

STANDARD INTENT:

Laboratory test results need to be reliable and reported in a appropriate and timely manner.

Test results that are reported need to be reliable and therefore post-examination instructions have to be available. Post-examination instructions should provide information on reporting the results, including the unit

of measurement to be used, the normal (reference) range, ranges that are life-threatening (sometimes called “panic values”) and instructions for how to deal with an urgent report. They should also include references to the published sources of the procedures, including published evidence that the procedures are scientifically valid.

Test results have to be reported within a specific time frame in order to guarantee that the diagnosis can be performed as quickly as possible.

Several aspects are important to provide an appropriate and timely result. Such as:

- *The results of the laboratory assays are registered in specific logbooks in an organized and orderly manner;*
- *The turnaround times (TAT) for laboratory tests (in-house and referral) are defined;*
- *The results are reviewed and validated as described in the specific assay SOPs;*
- *Reference and critical values are defined.*

MEASURABLE ELEMENTS:

9.3.7.1 Results are registered in a logbook in an orderly manner.

9.3.7.2 Results are reviewed and validated according to assay specific SOPs.

9.3.7.3 The laboratory has established reference ranges and critical values for all relevant tests.

9.3.7.4 Turn-a-round times for in-house laboratory tests, as well as those for referral services, are established.

9.3.8 Referral services are available and appropriately arranged.

STANDARD INTENT:

A referral system needs to be in place in order to provide the laboratory services that cannot be performed within the healthcare facility or when a specific test cannot be performed in case of unexpected shortage of staff (due to illness/absence), in case there is an unforeseen stock-out of essential materials or in the case the specific instruments needed are out of order.

In order to provide a good referral process, some essential requirements have to be in place, such as:

- *A list of referral services that is up to date and contains all relevant information from the referral laboratory (contact details, list of referral services/tests, turnaround times and related prices). The selection of referral laboratories can be guided by reviewing performance of the referral laboratories or by selecting a recognized laboratory (one that is accredited or in a certification program that has been reviewed and endorsed by a laboratory professional society or governmental or private agency);*
- *Guidance on how specimens are packaged and transported to the referral laboratory;*
- *A dedicated specimen register in which details are kept of which specimens are sent for referral, when they are sent, when the result was reported back etcetera;*
- *A system is in place in which the performance of the referral laboratory is monitored. Examples of monitoring topics are response times, critical result reporting and problems with specimens such as missing identifiers or specimen rejection. The results of the monitoring process are used in order to define appropriate corrective or preventive actions.*

MEASURABLE ELEMENTS:

- 9.3.8.1** A referral register for the referred specimens is kept.
- 9.3.8.2** Referral forms are available and used.
- 9.3.8.3** There are guiding documents for packaging specimens and transporting them to the referral laboratories.
- 9.3.8.4** A list of referral laboratories and laboratory services is available.

9.3.9 Staff is guided in providing safe blood transfusion services.

STANDARD INTENT:

Blood banking and transfusion services need to be compliant with the applicable laws and regulations. Blood banking services and distribution is part of the responsibility of the local government, but the healthcare facility is responsible for the storage and internal distribution process.

If and when the laboratory is the department that is assigned to store and distribute the blood products for blood transfusion, the following requirements need to be in place:

- *A dedicated blood transfusion refrigerator for blood (product) storage with back-up, temperature control measures and current log;*
- *A dedicated blood transfusion administration in which details about the transfusion products are recorded;*
- *A process for blood access and distribution in both planned and emergency situations.*

Quality control processes for all transfusion services are established, implemented, and documented to ensure the safety of transfusion services.

MEASURABLE ELEMENTS:

- 9.3.9.1** There is a dedicated and functioning refrigerator for blood products and back-up is arranged.
- 9.3.9.2** Temperature control measures are in place and logs are kept current.
- 9.3.9.3** There is a process in place for accessing blood in planned (and emergency) situations.
- 9.3.9.4** There is a dedicated administration related to blood transfusion products.