

SE09 - Laboratory Services

9.1 - Management and staffing

9.1.1 - The laboratory is managed by qualified care providers.

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.

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.

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.

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.

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.

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.

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.

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.

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.

9.3.5.1 - All reagents are stored and labelled according to manufacturers' instructions/directives or guiding document.

9.3.5.2 - The laboratory listed 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.

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.

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.

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.

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.