SQHN STANDARDS REVIEW

DIAGNOSTIC SERVICES

Overview

Diagnostic Services facilitates the provision of timely, cost-effective, and high quality diagnostic care in safe and secure environments. It includes the clinical services of Pathology and Laboratory Medicine, Radiology, and Nuclear Medicine. Diagnostic tests make it possible to identify the causes of a disease and prescribe the most appropriate type of treatment at the right time; thereby improving patient care, reduces safety issues that can arise from trial-and- error, over prescriptions or prolonged hospital stay and in turn helps to limit healthcare spending.

LAB.7. LABORATORY

Overview

Laboratory services are an essential component of quality healthcare service delivery.

The purpose of these standards is to provide guidance on development and implementation of quality systems for laboratory services to ensure accuracy of test results, increase patients' confidence and healthcare professionals in the value of laboratory testing and to inform patient management.

These standards would help health organisations meet regulatory requirements either at local, state or national levels, thereby ensuring laboratory safety and consistency of performance. It is important that quality laboratory results are achieved to support clinical diagnosis, rationalize and monitor treatment. Prompt and quality results can also be useful in epidemiological purposes, surveillance and control of disease of public health importance and provide early warning of disease outbreaks.

LAB.7.1. Laboratory Services are available

Intent

The organisation has a structure for providing laboratory services for categories of patients seen to enable healthcare givers make an informed decision about patients' care. The laboratory services provided by the organisation must be carried out in a manner that it

meets the legal and regulatory requirements of **Medical Laboratory Science Council of Nigeria** and/or the local, State or National laws.

Outside laboratory sources should be identified based on the recommendation of the individual who heads the laboratory services. Outside laboratories must meet the required State and National laws and regulations.

Requirements

LAB.7.1.1. The organisation has defined and documented the laboratory services available in the organisation.(D)

LAB.7.1.2. The laboratory services comply with laws and regulations.

LAB.7.1.3. Laboratory services are available to meet the needs related of the patient population and to enable the hospital meets its mission including after regular hours.

LAB.7.1.4. Referral laboratories are selected based on an acceptable record and compliance with laws, regulations and recognized professional standards.

LAB.7.2. Management and Responsibilities

Clinical laboratory staff have clearly defined roles and responsibilities and the required education, qualifications, and experience to administer and perform the tests and interpret the results.

Intent

Leadership of clinical laboratory services are under assigned to an individual who has the appropriate documented qualifications, training, expertise, and experience, consistent with applicable laws and regulations. S/he has responsibility for the laboratory facility and the services provided in the laboratory as well as tests performed outside the laboratory, such as those performed at the point of care or by contracted laboratories.

Responsibilities of the laboratory leader include:

i. developing, implementing, and maintaining policies and procedures

ii. administering, monitoring, and reviewing all laboratory services.

iii. a quality control and safety program

iv. recommending outside sources of laboratory services and monitoring their performance

The hospital identifies the education, training, qualifications, and experience of 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.

Requirements

LAB 7.2.1. The clinical laboratory, and other laboratory services throughout the hospital, are under the direction and oversight of one or more qualified individuals with defined roles and responsibilities.

LAB 7.2.2. All laboratory staff have the education, training, and qualifications necessary to administer, perform, and interpret tests.

LAB 7.2.3. Supervisory staff are identified and have the proper qualifications and experience.

LAB 7.2.4. Experts in specialized diagnostic areas are contacted when needed.

LAB 7.2.5. A staffing plan to ensure tests are performed promptly and to provide staffing coverage during all hours of operation and during emergencies is implemented.

LAB.7.3. Point-of-Care Testing

Intent

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

Oversight and supervision for testing performed in all areas are provided by the individual responsible for managing the laboratory services or a designee. The hospital must have a clearly defined and well-structured approach to POCT to ensure that it is performed safely and correctly and that the results generated are accurate and reliable.

A POCT program includes planning for tests to be performed and identifying the areas of the hospital where they will be performed, identification of staff who will be performing the test(s), and a protocol for reporting abnormal test results, including critical results. All staff performing POCT require training for each test being performed, along with a competency evaluation to ensure that results are accurate.

Quality control (QC) should be performed for each test as recommended by the manufacturers e.g., daily or weekly checks, as well as between new batches of test kits.

QC testing documentation, and evaluation should be performed within defined specifications recommended by the manufacturer.

A POCT program should be monitored and evaluated to ensure that it is meeting its' objectives by developing and monitoring quality improvement measures, reviews of utilization reports and reviews of quality control and proficiency testing results.

Requirements

LAB 7.3.1. The individual responsible for managing the laboratory services, or a designee, also has oversight and supervisory responsibilities for the POCT program.

LAB 7.3.2. There are policies and procedures guiding POCT.

LAB 7.3.3. Reference intervals for POCT results are available and readily accessible to staff performing POCT testing.

LAB 7.3.4. The POCT program includes a defined process for reporting abnormal test results, including reporting critical results.

LAB 7.3.5. POCT testing results are documented in the patient's medical record and include date and time of the testing, the test result(s), the name of the person performing the testing, the ordering physician (as appropriate) and any action taken to notify the most responsible physician of the result(s).

LAB 7.3.6. Infection control measures are established and implemented to ensure safe use of devices.

LAB 7.3.7. The POCT program includes quality control performance, documentation, and evaluation.

LAB 7.3.8. The POCT program is monitored and evaluated and included in quality improvement activities.

LAB 7.3.9. All healthcare professional performing POCT must have the required qualifications, must be trained and successfully demonstrate competency for each device or manual procedure.

LAB 7.3.10. Competency assessment should be done annually for all healthcare professional for every Point of Care (POC) device or test they use.

LAB.7.4. Facilities

Intent

Laboratory facilities are adequate to provide a safe and effective laboratory service. Service managers need to work closely with facility managers to ensure that facilities are available for the provision of the required services. Service managers must keep facility managers informed about inadequate facilities and the current state of facilities.

The laboratory should have sufficient space and appropriate work surfaces, power, water and ventilation preferably temperature controlled. Appropriate washing and staining facilities should be provided. Separate handwashing facilities are required

Requirement

LAB 7.4.1. The laboratory is a separate designated area with limited access to non-authorized personnel.

LAB 7.4.2. The size of the laboratory is appropriate to the services provided.

LAB 7.4.3. The walls, ceilings and floors are easy to clean, impermeable to liquids and resistant to chemicals.

LAB 7.4.4. There is sufficient and appropriate work surfaces to perform activities.

LAB 7.4.5. Each laboratory compartment is adequately ventilated, and the room temperature is recorded and maintained.

LAB 7.4.6. Handwashing facilities with running water, soap and paper towels are provided in each laboratory room.

LAB 7.4.7. Separate facilities are provided for personnel to store personal items.

LAB 7.4.8. Separate rest area where personnel can eat, and drink are provided.

LAB 7.5. Laboratory Equipment

Intent

It is essential that the required equipment is available to provide effective laboratory services. Laboratory staff work to ensure that all equipment, including, function at acceptable levels and in a manner that is safe to the operator(s). The laboratory develops and implements a program to provide and manage equipment including medical devices used for point-of-care testing

The laboratory equipment management program is documented and includes:

i. laboratory equipment and medical equipment selection and acquisition

ii. identification and taking inventory of laboratory equipment and medical equipment.

iii. assessment of laboratory equipment-use through inspection, testing, calibration, and maintenance according to manufacturers' instructions.

iv. monitoring and acting on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failure.

Requirement

LAB 7.5.1. The laboratory develops and implements, a documented equipment management program to manage laboratory equipment, including i) to iv) in the intent.

LAB 7.5.2. There is a documented inventory of all laboratory equipment.

LAB 7.5.3. Laboratory equipment is inspected and tested on acquisition and according to the manufacturers' recommendations and the inspections are documented.

LAB 7.5.4. The laboratory develops and implements a calibration and planned preventive maintenance schedule according to manufacturers' recommendations, and the calibration and maintenance are documented.

LAB 7.5.5. The hospital has a system in place for monitoring and acting on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failures.

LAB 7.6. Reagents, Test Kits, and Supplies

Intent

The hospital has identified those essential reagents, test kits, and supplies required to provide laboratory services to its patients and ensures they are available. There is a process to order or secure those essential reagents and supplies. Processes address situations when equipment malfunction or when reagents are not available

All reagents are stored and dispensed according to manufacturers' directives. All equipment and reagents are labelled, stored, and evaluated according to written guidelines to ensure accuracy and precision of results.

Requirement

LAB 7.6.1. Essential reagents, test kits and supplies are identified and available, and there is a process to address when essential reagents are not available.

LAB 7.6.2. All reagents test kits and supplies are stored and dispensed according to manufacturers' instructions.

LAB 7.6.3. The laboratory establishes and follows written guidelines for the evaluation of all reagents and test kits to ensure accuracy and precision of results.

LAB 7.6.4. All reagents, test kits and solutions are completely and accurately labeled.

LAB 7.7. Handling of Specimen

Intent

The quality of the specimen at the time of testing directly impacts the results of the tests. It is therefore necessary to ensure specimen are collected, transported, and stored in the correct manner. Documented procedures for collecting, identifying, handling, safely transporting, and disposing of specimens should be established and implemented.

Processes for correct identification of specimen should be established and followed to avoid mix-up of specimen leading to wrong results being given to the wrong patient.

Requirements

LAB 7.7.1. Procedures are established and implemented for the ordering of tests.

LAB 7.7.2. Test request forms and specimen labels include unique patient identifiers and adequate supporting information according to established procedures.

LAB 7.7.3. Specimens are collected and identified according to established procedures.

LAB 7.7.4. Specimens are transported, stored and preserved according to established procedures.

LAB 7.7.5. Specimens are received and tracked according to established procedures.

LAB 7.7.6. Specimen are disposed of according to established procedures.

LAB 7.7.7. Procedures are established and followed for requesting tests and handling of specimen for outside laboratories.

LAB 7.8. Clinical laboratory Results and Reporting.

Intent

The laboratory must establish reference intervals or "normal" ranges for each test performed. The range is included in the medical record, either as part of the report or by including a current listing of such values approved by the laboratory leader. Ranges are provided when a reference/contract laboratory service performs the test. The reference ranges should be appropriate to the hospital's community and should be reviewed and updated when methods change.

Requirements

LAB 7.8.1. The laboratory has established reference ranges for each test performed including population specific values.

LAB 7.8.2. Results are reported according to established procedures.

LAB 7.8.3. The range is included in the test results which are included in the patient's medical record.

LAB 7.8.4. Ranges are provided when tests are performed by reference/contract laboratory services.

LAB 7.8.5. Norms and ranges and reviewed and updated as needed.

LAB 7.9. Time Frames for Reporting Test Results

Intent

The hospital establishes time frames for reporting laboratory test results including for emergencies, after regular hours and weekends. Results from urgent tests, such as those from the emergency department, operating theatres, and intensive care units, are given special attention in the laboratory and hospital's quality management program.

Time frames for services provided by outside laboratories are stipulated in hospital policy or in the contract with the organisation. These are also monitored as part of the quality management program.

Requirements

LAB 7.9.1. The hospital establishes the expected turn-around time for test results.

LAB 7.9.2. Laboratory results are reported within a time frame to meet patient needs.

LAB 7.9.3. The hospital measures the timeliness of reporting of urgent/emergency tests.

LAB 7.9.4. The hospital acts on the findings of the measurements

LAB.7.10. Laboratory Safety

Intent

Laboratory is a potentially dangerous place to work in due to chemical, electrical, physical, mechanical or biological hazards. Those at risk include laboratory staff, patients and visitors entering the laboratory; it is therefore important that laboratory staff can recognise and minimise the potential dangers. The level of risk is dependent on the activities that are carried out in the laboratory.

The laboratory or any area in the organisation where tests are carried out must be safe for the staff, patients and visitors. The organisation must promote safety awareness and encourage safe working practices in the laboratory through the development of a safety programme.

Requirements:

LAB.7.10.1. The Laboratory has a safety programme that has been incorporated into the safety programme of the organisation.

LAB.7.10.2. The safety program addresses potential safety risks in the laboratory and other areas outside the laboratory where laboratory services are provided.

LAB.7.10.3. There is a documented process that the staff of the laboratory have been trained on the safe handling, use and maintenance of laboratory equipment.

LAB.7.10.4. An individual has been identified to be the laboratory safety officer and shall be responsible for monitoring compliance to the safety programme

LAB 7.10.5. The laboratory safety program is part of the hospital's infection prevention and control program and reports to the infection prevention and control program regularly as determined by the hospital and when any infection control events occur.

LAB 7.10.6. Identified safety risks are addressed by specific processes and/or devices to reduce the safety risks.

LAB 7.10.7. Laboratory staff are oriented to safety procedures and practices and receive ongoing education and training for new practices and procedures.

LAB 7.10.8. Infections acquired in the laboratory are reported, as defined in the policy, and in compliance with applicable laws and regulations.

LAB 7.10.9. When problems with practice are identified, or accidents occur, corrective actions are taken, documented, and reviewed.

LAB 7.11. Quality Control and Quality Assurance

Intent

Well-designed internal and external quality control and quality assurance systems are essential to providing excellent pathology and clinical laboratory services.

Quality control procedures include

- validation of the test methods used for accuracy, precision, and reportable range,
- daily surveillance of results by qualified laboratory staff,
- testing of reagents,
- rapid corrective action when a deficiency is identified; and
- documentation of results and corrective actions.

The laboratory participates in an approved proficiency-testing program with a recognized organization or by conducts proficiency testing by exchanging samples with a laboratory in another organization for purposes of peer comparison testing. The laboratory maintains a cumulative record of participation in a proficiency-testing process.

Requirements

LAB 7.11.1. The hospital establishes and implements a quality control program for the clinical laboratory.

LAB 7.11.2. The program includes the validation of test methods.

LAB 7.11.3. The program includes daily surveillance and documentation of test results.

LAB 7.11.4. The program includes testing of reagents.

LAB 7.11.5. The program includes rapid correction and documentation of deficiencies.

LAB 7.11.6. The laboratory participates in a proficiency-testing program, or a peer comparison testing program.

LAB 7.11.7. The laboratory's proficiency testing results meet satisfactory performance criteria for each specialty, subspecialty, analyte, or test, in accordance with laws and regulations.

LAB 7.11.8. The laboratory maintains records of its participation in a proficiency-testing program.

LAB 7.11.9. The facility regularly reviews quality control and proficiency testing results from all outside sources of laboratory services.

LAB 7.12. Blood Banking and Transfusion Services

Blood banking and transfusion services meet Lagos state, national laws and regulations and recognized standards of practice and enable the hospital deliver safe and efficient services.

Intent

The hospital develops and implements documented processes for the delivery of safe and efficient blood banking services to meet the needs of the healthcare professionals and the community served. This should include processes to provide blood in emergencies or when massive transfusion is required.

The processes include

i. blood donor selection.

ii. blood collection.

iii. blood storage.

iv. compatibility testing; and

v. blood distribution.

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

Requirements

LAB 7.12.1. The blood bank and transfusion services comply with applicable Lagos State laws and regulations and recognized standards of practice.

LAB 7.12.2. The blood bank has established, implemented documented processes for i) through v) of the intent.

LAB 7.12.3. Documented quality control measures are established, implemented, and recorded.

Thank you for reading through the Laboratory Accreditation standards, the next step will be to review the standards by filling the questionnaire in the link below to assess the standards using the RUMBA principle (Relevant, Understandable, Measurable, Beneficial, Achievable).

https://forms.gle/biKdArX83Mxh4Ehh7