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QUALITY MONTH



Cerba Lancet
Kenya

NEWSLETTER

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Why focus on quality assurance is a safeguard to healthcare excellence.

In medical diagnostic, the cornerstone of precision and reliability lies in quality assurance. Its practice is not merely a formality but a fundamental necessity that underpins the integrity and accuracy of the results. The highest standards of quality assurance are therefore paramount to safeguarding patient care and upholding the credibility of healthcare institutions.

In layman's language, **Quality Assurance (QA)** is a planned, and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled by medical laboratories to improve the quality and clinical usefulness of medical laboratory test results. It includes training of personnel, purchase, and maintenance of equipment and reagents, the analytical process itself, and reporting and interpretation of results.



In a typical diagnostic setup, quality assurance entails three phases: pre-analytical, analytical & post-analytical phases.



Pre-analytical Phase

This represents one of the most vulnerable areas in the specimen journey. It includes identifying the patient, the type of sample to be collected, how the specimen is collected and transported, how unsuitable specimens are handled and rejected, and the forms to be filled out or verified. Here, patient details and samples are collected to review the activities against a checklist that guides the receiver on mandatory requirements before accepting the samples. Some of these include verifying the name, signing the requisition forms by the patient, requesting a clinician, test selection, storage and transportation of samples, and the sufficiency of samples.

This takes place inside the laboratory and involves the preparation of the specimen for analysis on the microscope or any of the equipment that the laboratory may have chosen to use in its process. Internal Quality Control (IQC) done in the analytical phase is used to verify the attainment of the intended quality of results and safeguard consumers from harm and mimics patient samples containing multiple parameters for testing.



Analytical Phase



Post-analytical Phase

At this stage, the results are reviewed by a technician and or a pathologist, after which the results are released. It entails a review of results, management of abnormal/critical and urgent results, review of interface and manual results verification, storage retention, and disposal of clinical samples within the organization. Only authorized technical staff and pathologists have the authority to release test results after reviewing and evaluating them against internal quality controls, reference ranges, available clinical information, and previous test results.

The above guidelines point to the fact that Internal Quality Control is not an option but a mandatory undertaking as one of the ways to safeguard the integrity of the tests. This is because failure to do that would jeopardize the entire testing process and might lead to repeating the entire exercise. Diagnostic laboratories are therefore urged to embrace peer-to-peer review to provide the latest insights on laboratory management and performance.

Finally, regular Internal and External Quality Audits as well as Accreditation to the ISO 15189 standard are an excellent way to ensure that the company and its staff are committed to patient safety, understanding that every test result carries significant implications for an individual's health journey.



* Reference/ Sources:

ISO 15189 Standard, WHO , UK NEQAS, NIH, Cerba Lancet Africa Manuals

<https://www.iso.org>

<https://www.who.int>

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<https://www.cerbalancetafrica.com>

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