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Quality Management: Why a Medical Laboratory Requires Accreditation and Certification

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Abstract

A successful Laboratory Quality Management System is a harmonious blend of several critical elements. It all begins with a strong management commitment, where leadership demonstrates responsibility and accountability by setting clear quality policies and objectives. Effective communication is key, as clear, strong messages must be delivered to all staff levels to ensure compliance and buy-in from all the stakeholders. The system is fundamentally built upon meticulously implemented quality procedures and practices, which are supported by a comprehensive and regularly evaluated quality control program. This program must be continuously reviewed and revised to ensure ongoing improvements are made. The competency and positive work attitude of the technical staff are also paramount to the system's success. Furthermore, a laboratory's credibility is significantly enhanced by accreditation and certification from a reputable third-party organization. This thorough assessment confirms that the lab meets all defined quality standards, which adds immense value to both its quality control program and its global image. Ultimately, the quality of services not only boosts the lab's performance on a global scale but also increases the pride and morale of its dedicated workers.

Keywords: quality management; service quality determinants; internal & external quality control; laboratory errors; accreditation & certification

1. Introduction

A medical laboratory report was taken to be reliable in the past perhaps many decades ago, if the laboratory director was a natural scientist or clinical pathologist. At present, expectations of laboratory service are extremely high; and clients or customers expect more and more, and they want proof that medical laboratory service is of appropriate quality. Laboratory leaders and management are becoming increasingly aware of various needs for the provision of quality services. They put extra efforts to focus on the state-of-the-art facilities and resources, competent manpower, efficient operating system, quality control programme, etc. An ultimate purpose is likely to produce useful and reliable information having tested patient's clinical samples. For continuing service quality improvement, a programme to assess performance and to control the quality of work is widely established. Specifically speaking, quality is more than quality control. This compilation uses a comprehensive approach to highlight quality requirements, service quality determinants, internal and external quality control programmes, laboratory errors and remedies, third-party laboratory accreditation and certification requirements, so and so forth. It is simply expected that readers should get some fundamental concepts on medical laboratory service quality.

2. The Laboratory in Medical Practice

Now more than ever before, the analysis of body fluids (clinical samples) for the purpose of diagnosis, therapy and prevention of diseases has become an integral part pf medical practice. Clinicians or Physicians or Practicing doctors are relying more and more on the results of laboratory test before resorting to critical therapeutic interventions for their patients. Test results reveal the

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intricacy of physiological and biomedical mechanisms of the body. Without such knowledge, it would be impossible for physicians to arrive at an accurate diagnosis and meaningful therapy for their patients. Thus, the responsibility of the laboratory has escalated to great heights; laboratory professional must stand hands in hands with the practicing doctor in making critical decisions. Wrong judgments can cost lives. Laboratory professionals – Clinical Pathologist, Microbiologist, Medical Technologist and Medical Laboratory Technician should be prepared to accept this kind of responsibility with courage and grace. Such preparation includes a professional mindset to take the academic, technical and ethical challenges encountered in the production of laboratory results of superlative quality.

3. Quality Is More Than Quality Control

Since 1987, the International Organization for Standardization (ISO) has issued a set of standards called the ISO 9000 family dealing with Quality Management (QM) and Quality Assurance (QA). The medical laboratory is considered as a service organization. It delivers a product such as a laboratory report to the customer who may be clinician or practicing doctor or patient. The ISO definition is that quality is "**the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs**". The entity may be a process, product, organization or person; the needs depend on the stakeholder. Thus, the customer demands product quality, for example, that the clinical measurement result is relevant, reliable, timely and diagnostically effective.

In the past, perhaps many decades ago, a medical laboratory report was taken to be reliable if the laboratory director was a natural scientist or clinical pathologist. At present, various laboratory customers demand proof that medical laboratory service is of appropriate quality. Laboratory personnel are becoming increasingly aware of the need to concentrate their resources on specimens that are most likely to produce useful clinical information. The continuing improvement to assess and control the quality of work carried out by pathology laboratories is well recognized and therefore installation of QM and QA in the laboratory control system has been widely established.

Laboratory professional should not have a restricted or limited view that their task is essentially just to produce reliable, accurate, precise and timely results. The quality of a laboratory service involves more than the control of the technical quality of results. The laboratory reports provided may be of excellent technical quality, but it could have yet to meet the expectations of customer.

Professional and technical excellence, though essential, may be not enough on their own to provide a good service to customers. In modern concept of service quality, there are two basic aspects:

- the first **technical quality** or what is received by the customer and
- the other **functional quality** or how the service is delivered. This seems to be more critical aspect; it is based on the customer's perception and is therefore extremely subjective.

In conclusion, the quality of a laboratory service involves more than just the control of the technical quality of results. It must always be remembered that medical laboratory is a "service" and that to be of a high quality, it must, by definition, meet customer's requirements.

Quality of a service organization depends on quality commitment, the management's drive and employee's contributions. Therefore, the management needs to stimulate the motivation of staff by creating agreeable and happy work environment, communicating quality policies and objectives, work strategies and procedures, providing choices and suitable selection, recognition and reward, education and career planning.

4. Laboratory Tests Are Requested and Validity of Results

From various points of view there are many considerations depending on various needs and aspects. Some common questions are encountered.

"Clinician needs reliable and accurate testing for all her/his patients".

"Laboratory Manager wants automated and highly-consistent Assays with results she/he can trust".

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"Patient expects Quality Results and Effective Treatment with Cost at minimum".

Why does clinician request laboratory tests?

Some results are needed to monitor and guide treatment of critically ill patients. Other results help to provide early detection of certain diseases. Fear of legal liability especially in developed countries has an important role in stimulating requests for laboratory analyses that, otherwise, clinicians might not consider essentially for patient care. Still other tests appear to be done primarily because they are available.

There have been many studies regarding proper use of laboratory service and raised questions:

- What factors motivate clinicians to request laboratory services?
- Are laboratory tests requested really needed for the patient?
- Does the clinician fail to request laboratory tests truly needed for the patient?
- Will an abnormal result ever lead to any changes in diagnosis, prognosis or therapy?
- Are requests occasionally based on a desire to do a complete work-up for benefit of the chart, rather than the patient?

Clinician, who is the potential user of clinical laboratory is in a much better position than the laboratory personnel to stand firm on his judgments because he has patient's history and is familiar with all the clinical manifestation of the disease. Studies were carried out in the United States to find out customer's intentions and use of the laboratory results. It was stated in some studies that clinicians do not always pay appropriate attention to laboratory reports. In fact, abnormal results indicate the need of change in diagnosis and in treatment regime or treatment strategy. Unfortunately, many abnormal results, even positive were totally ignored.

5. Materials and Methods

5.1. Service Quality Determinants

Service quality evaluations by customers involve a comparison of their expectation of what an ideal laboratory service should offer with actual performance of the laboratory. Five key determinants are usually considered for such evaluations.

1. ***Reliability****:* correct, dependable, consistent and timely performance of procedures, tests and record-keeping
2. ***Responsiveness:*** swift response to customer requests, inclination of employees to be of assistance
3. ***Assurance:*** professionalism and competitiveness of laboratory personnel
4. ***Empathy:*** individual attention, attitude and dedication
5. ***Tangible:*** attention to physical attributes such as facilities and equipment, procedures and practices

Clinicians usually do not know exactly how their requests will be constructed by laboratory personnel. A customer who does not know how to use a service properly may be responsible for reducing the quality of service to himself and, possible to other customers. Often the perceptions of quality have been found to improve when users learn how a service works. A cooperative approach between clinicians and laboratory workers will lead to conservation of resources while simultaneously improving the quality of information produced for patient care.

6. Quality Concerns

Implementation of a quality control (QC) programme is always a top priority among laboratory functions. However, test result is subject to vary even though the laboratory implements the QC programme. Technically, two different laboratories could produce two different results. Results depend on many factors – methods, instruments, technical skills, quality of sample, transport, storage, etc. Medical Technologist and Medical Laboratory Technician who actually perform the tests must have sound technical knowledge. Laboratory Leader-Managers should have professional voice and mutual relationship with laboratory users or doctors. Everything needs to be in order.

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Quality concerns in laboratory service drive the laboratory management to escalate more and more improvements. Many laboratories are reaching out for certification and accreditation programme. Accreditation provides a laboratory the proof of compliance with best practice and technical competency to perform specified analysis or measurements by validated methods. The programme:

- provides independent assurance of quality and safety to deliver a world-class healthcare and value for patients:
- provides a mechanism for measuring quality improvement:
- supports consistency in quality of care; and
- encourages innovations.

7. Quality Management (QM)

Quality Management (QM) is defined by the ISO as "**all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system**". The aim of QM is to coordinate the network of processes and activities in an organization in order to maintain and improve a defined quality of product.

To achieve QM it is necessary to install a quality system, which comprises the organizational structure, procedures, processes and resources needed to implement quality management. The key to the philosophy of QM is that in any quality system the customer is the focal point, meaning that the needs of the customer should be fulfilled as far as the characteristics of the organization allow.

An important goal of the quality system is quality improvement, the "**actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organization and its customers**".

A quality system requires harmonious interaction of management responsibility, personnel and material resources, and quality system structure, procedures and processes both with each other and with customer. The modern concepts of quality management system show that service content and delivery system should be designed to meet the requirements of the organization's customers, as well as the value of the staff.

QM must include various aspects of proper laboratory operation. Principle ingredients of a total quality control programme are summarized as follow.

1. Proper preanalytical postanalytical processing of samples and test results.
2. Acquisition and preparation of laboratory supplies of good quality.
3. Maintenance of good accuracy and precision in all analysis.
4. Method for error correction, normal and abnormal control sera every day.
5. Action to be taken when analysis appear to go out of control.
6. Participation in external survey programme.
7. Preventive maintenance of instruments and equipment.
8. Training and continuing education for the laboratory personnel.
9. Documentation of the execution and the results of the quality control programme.
10. Coordination of the various individual functions of the quality control programme.

These points can be applied to all medical / clinical laboratories, irrespective of their size. The only difference between laboratories in carrying out the plan would be in the nature of the execution of the individual function.

A successful QM system is the result of harmonious mix of the management's commitment in quality service, quality policies and objectives and responsibilities, communication with clear and strong messages to all level of staff, leadership quality, procedures and practices implemented, compliances, attitude and competency of laboratory personnel.

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8. Quality Policies and Objectives

Quality policies and objectives of the QM system in the laboratory should be defined in a quality policy statement and documented in a quality manual. This policy will be readily available to appropriate personnel; will be concise and will include the following:

- The scope of service the laboratory intends to provide:
- The management's statement of the laboratory's standard of service:
- The objectives of quality management system:
- Requirement of familiarization with the quality documentation and implement the policies and procedures:
- The laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system:
- The management's commitment to compliance with the international standard.

9. Laboratory Quality Manual

Quality manual prescribes the quality management system and the structure of documentation used in the system. It includes references to the supporting procedures and technical procedures. The roles and responsibilities of technical management and quality manager including their responsibility for ensuring compliance with the international standard, will be defined in the quality manual.

All personnel must be well communicated with the quality manual implemented, all referenced documents and requirements in their operations. The quality manual will be kept up to date under an individual appointed to be responsible for quality of the laboratory.

Contents of a quality manual outlined by the ISO is stated bellow.

- Introduction
- Description of the laboratory, its legal identity, resources and duties
- Quality policy
- Staff education and training
- Quality assurance
- Document control
- Maintenance and records
- Instrument, reagents and consumable management
- Validation of examination procedures
- Workplace safety
- Waste management, transportation and environmental safety
- R & D if applicable
- SOPs and practices
- Protocols for test requests, collection and handling of samples
- Validation of results
- Quality control programme (internal, external)
- Laboratory information system
- Reporting of results
- Feedback and complaint handling
- Communications and interactions with patients, health professionals, referral laboratories and suppliers
- Audits and corrective actions

10. Theoretical Approaches

There are several theoretical methods for quality improvement, all of which initially demand the development of a clear idea of the goals to be achieved along with a strategy for achieving them.

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Various approaches to this have been published, but the best known are Total Quality Management (TQM) and Continuous Quality Improvement (CQI).

11. TQM and CQI

TQM works on the philosophy that quality is something which should be built into a product or service at every stage of its production, rather than being assessed purely by looking for errors afterwards. It should result, therefore, in increased productivity, together with increased efficiency due to a reduction in work rejected and decrease in costs due to the reduced need for product inspection and re-testing.

CQI is a term which may be applied to most types of performance improvement programme. It states that the overall improvement of a service or product should be achieved by the accumulation of many small changes and that, for this reason, improvement is a continuous process. In practice, it is a combination of these increasingly well-known processes that will prove most likely to suit each individual laboratory organization.

12. Quality Control (QC) Programme

Reliable test results cannot be achieved with ease. However, with hard work of dedicated professional, each laboratory can produce reliable test results. The method adopted to assure reliable test results is referred to as a quality control programme.

Three process stages are included in the QC programme. First, **Preanalytical quality control** focuses on sample quality for analysis. It includes patient preparation, sample collection, sample processing and sample preparation for analysis. Second, **Analytical quality control** is mainly concerned with performing of laboratory experiment. Third, **Postanalytical quality control** focuses on production of the laboratory report.

13. Quality Control Schemes

Traditionally, the concern of laboratory professional has been technical quality of results, and several methods of quality control are in operation. Quality control is now considered as essential component of the analytical process, and procedures used usually include both internal and external quality control schemes. **Internal quality control** involves the repeated analysis of in-house pooled control material or commercial pooled control material in either pre-assayed form (ie target values for each analyte are supplied) or un-assayed form (for which laboratory must produce its own values). In **external quality control** scheme, control material is distributed by an external source; the results of the laboratory are compared with those of other laboratories using the same or similar methods; statistical evaluations are made, and each laboratory is then informed of its performance.

Most efforts of laboratory staff to improve the service have historically been directed internal and concerned with technical quality improvement such as improved accuracy of analysis results. However, it is possible that even a service which offers excellent technical quality may fail to meet the needs and expectations of its customer. Professional and technical excellence, though essential, may not be enough on their own to provide a good service to customers. In modern concept of service quality, there are two basic aspects; the first technical quality or what is received by the customer and the other functional quality or how the service is provided. The latter is seen to be the more critical aspect, it is based on the customer's perception and is therefore extremely subjective.

By use of internal and external quality measures, the technical quality only can be assessed and regulated. Customers have an important part to play in the evaluation of the service and such evaluation should extend beyond the technical quality.

14. Processes in the QC Programme

Quality control process is established as the quality control checkpoint on every step in the procedure so that it is possible to monitor the quality. What are the variables in the procedure which

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can influence the quality of the final result? Errors can occur before analysis, during analysis and after analysis. The influential factors need to be identified and controlled.

15. Preanalytical QC

Preanalytical stage describes various steps taken before analysis which can affect the quality of the final result. Following points are important to check, but not limited to.

Patient preparation: Make sure that patient is prepared properly for the analysis. And patient should not have taken any interfering substances.

Specimen collection: Right specimen is taken from right patient at right time using right anticoagulant and preserved properly.

Specimen processing: Cells and blood collected on time, serum separated properly and stored appropriately.

Sample preparation for analysis: Make sure sample is fresh and not contaminated or haemolysed. And it must be properly labelled and correctly identified.

16. Analytical QC

This step is for the quality control of the analysis itself. In an automatic operation, sample loading and unloading should be done very carefully. Analytical steps are usually carried out in a close system by the automated machine. A typical manual procedure involves pipetting the patient sample, adding buffers and reagents and measuring absorbance. Calibrators for machine, standards and reagents used must be perfect. Here, methods are devised to control the quality of each step involved. For example, the incubation step should be done at the temperature and time recommended. For measuring absorbance step, make sure that spectrophotometer is functioning well; cuvettes used are clean; the reading is noise free; and the reading is made within the optimum range; etc.

17. Postanalytical QC

The postanalytical quality control involves checking calculations, verifying calibration, checking standard values and reporting results without any error.

Make sure calculations are error free. If calculations are done by hand, rechecking by another person may be helpful. Calibration curve shows normal and points of values fit fairly on the curve. Ensure that values for controls or standards are within the limits. Is there any shift in values, positive or negative, observed in the control chart? Any abnormal observation should be identified and rectified immediately. Report should be attractively formatted, clean and free from dirt. All information written are clear, complete and free of transcription errors. The laboratory should possibly review of results against patient's clinical history and diagnosis; do interpretation of the results; and offer valuable advice wherever necessary. This practice would add values to quality service of the laboratory.

18. Internal Quality Control

Internal QC or intra laboratory QC is the primary ingredients of a QC programme. Though good equipment, quality reagent, good methodology and good techniques are in use, good accuracy and precision on all analyses still cannot be guaranteed. Laboratory applies internal QC programme as a precautionary measure to assure the validity of analytical results and to detect problem in routine analyses.

The internal QC scheme involves analysis of normal and abnormal control sera, along with the patient samples. The control sera give the expected values when the test is performed properly. If the results for the analysis of control sera are acceptable, then the results for the analysis of patient samples are considered acceptable. In case of results for control sera were out, then there is a need to check the testing system thoroughly and to repeat the test again. Clinical laboratories use three types

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of control sera, (1) homemade pooled sera, (2) commercial control sera (unassayed) and (3) commercial control sera (assayed) for internal QC purpose.

19. External Quality Control

The external quality control or inter laboratory quality control scheme is a system of objectively checking laboratory results by means of an external agency. It enables a laboratory to see the effectiveness of its internal QC system. Control sera are distributed by an organizing source to laboratories that voluntarily join in the programme. A group of participating laboratories receives lyophilized control sera manufactured by the commercial sources. The group is composed of laboratories which are keen to know their quality status of performance and to establish an interlaboratory comparability. Upon receiving control samples, the participants perform the prescribed tests in a routine manner and return their results. The organizer conducts statistical analysis and evaluations on data received to determine the achievements and performance status of each participating laboratory.

The organizer could be a central laboratory with the certain level of authorisation or a professional association such as association of pathologists, medical technologists or clinical chemistry. Such arrangements are also organized by the manufacturers of lyophilised sera on a regional, national or even on an international basis. The External QC is supplement to the internal quality control system of individual laboratory and does help also in establishing its interlaboratory comparability.

20. Results

20.1. What Is Needed?

20.1.1. Is the Laboratory in Error?

In many cases, the usefulness of the positive result will vary with the SENSITIVITY and SPECIFICITY of the test and with the PREVALENCE OF THE DISEASE in the population tested. And PREDICTIVE VALUE, which defines the percentage of positive results that are true positive, will vary with sensitivity, specificity and prevalence. Such evidence could be observed if statistical analysis were carried out. It is easy to understand how sensitivity and specificity affect the predictive value. However, the important role of prevalence often is not fully appreciated.

Thus, a test with same sensitivity and specificity will have a higher predictive value in subjects with a clinical history of disease than without such history. Those clinical data or information (limited for the laboratory personnel) are used to increase the likelihood of the disease and thus to increase the likelihood that a positive test result is a true positive. This effect should be well understood by most clinicians. In practice, the prevalence of disease is very little counted. Therefore, they usually expect the laboratory result to agree with their clinical diagnosis or findings and if it does not, they often assume that the laboratory is in error. But the problem often is not the “laboratory error”, rather, it is the complex interaction of sensitivity, specificity and prevalence.

20.1.2. Errors in the Clinical Laboratory

Errors naturally take place in every process or operation. There is a degree of uncertainty in every laboratory testing. It is not possible to obtain the exact value in the measurements all the time. A good laboratory, keen on maintaining quality service, cannot afford a single mistake. No patient will tolerate a mistake on his test, even if it is the first mistake the laboratory has ever made.

Errors highlighted below are only a part of real world; there could be many more. Perhaps, errors in clinical laboratories can be simply divided into three main groups – clerical errors, sampling errors and analytical errors. Clerical errors originate from a mix-up in entry or patients but are nothing to do with the sample or actual analysis. Sampling errors originate during the processing of samples for

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tests. Analytical errors are encountered in the actual performance of the test. However, with a quality control programme, the degree of uncertainty could be reduced considerably.

(A) CLERICAL ERRORS

A series of operations beside the actual testing and sampling that the laboratory carries out may be considered as clerical operations. When hundreds of samples and patients are handled in the laboratory, there are possibilities of some mix-up between samples or between patients. The nature of clerical errors may vary from laboratory to laboratory, depending on method of communication between the clinician, the healthcare staff or nursing staff and the laboratory. It is hard to classify the exact source of errors. However, common sources of errors may be grouped into (1) wrong patient, (2) wrong specimen and (3) wrong entry. Highlighted examples bellow stand as a part of reality.

Clerical errors must be taken seriously because they are avoidable. As soon as an error is noticed, the root cause must be investigated thoroughly and identified. Corrective actions must be taken. Preventive measures should be adopted immediately because many of those errors go unnoticed. A good study of the problem itself and identifying the root cause will be the most important step in solving these problems.

Wrong Patient:

Clerical errors may be involved in various scenarios. After having busy rounds with the clinician, nurse makes a laboratory request with wrong name of patient. Consequently, the laboratory technician collects the specimen from the wrong patient. There could be patients with the same name and laboratory sends out the test results of the first patient to the second one. A laboratory test is ordered on the patient in room 111. By the time the laboratory technician goes to collect specimen, the right patient is in the operation theatre. Finding another patient in room 111 and thinking the right patient, the technician takes blood without bothering to check the patient identification.

Using the wrong name plate for ordering the test is, in fact, an error of the nursing department. However, the laboratory should become involved in solving this type of error. A solution to this type of problem is never to leave the patient's name plate anywhere but always to attach it to the patient's file itself. In case of patients with the same name, the best way is to label laboratory requisitions and specimens with complete information such as patient's name, age, room number, name of physician, etc. so that it is easy to trace and differentiate. It is very important for a laboratory technician to check the ID of the patient before taking the specimens. If a patient doesn't have an ID, the technician should ask the nursing staff to identify the patient. One should never rely completely on the patient for anything, especially he is semiconscious, half-awake or taking psychiatric treatment.

Wrong Specimen:

Errors still can occur even after the right specimens have been taken from the right patient. For example, when carrying many samples in a tray, two labels have fallen off two tubes and have been matched to the wrong tube in the process of relabelling. The technician responsible takes sample number 15 and separates serum into tube number 18. Sometimes, having done the test the technician finds out that two specimens were labelled with the same number.

The problem of label falling off can be solved by using good quality labels, waterproof or at least humidity proof. The technician should have mindfulness or full concentration in what he is doing. It is the best way to avoid his careless mistake of separating serum into wrong tube. Responsible technician respects his work and shall adopt a habit of checking every step carefully.

Wrong Entry:

If wrong entry were made, results still can be wrong even though the right sample has been collected and the right test performed. Have a look at different scenarios. The laboratory tests sample number 25 and enters the results under the number 26. A serum sample is tested for calcium and sodium. Having done the test, the calcium result is entered under sodium and the sodium result under calcium. Specimen number 200 has a glucose value of 108 mg/dl. The laboratory enters a value of 200 for the glucose value of number 108.

The root causes of these errors may be considered as a "mix-up in numbers". Even most careful person, when caught in fatigue, can make these types of mistake. When a person sees or works with

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numbers for several hours, he will become blurred and fed up by the process. The best solution may be that every number entered at the laboratory must be checked by a second person. It is difficult for a person to find his own mistakes.

(B) SAMPLING ERRORS

Quality of the sample is vital to produce quality results. Even the best technologists cannot produce good results with poor quality sample. Sampling errors indicate the improper methods of sample collection, processing, storage and preservation. Before performing the actual analysis, one should be sure of the quality of the specimen. In general, the analytical methodology and instrumentation do not make any adjustment or compensation for interfering factors. It is the responsibility of the analyst to see that the samples are free from interference, contamination or deterioration. Blood sample can be considered as a major biological fluid on which quantitative analyses are performed. Consequently, specimen requirements are most rigid for blood samples.

Appropriate samples should be the right specimen from the right patient and properly labelled. Perfect sample is fresh, clear and free from haemolysis or contamonation. Plasma is not turbid due to contamination or interference; the right anticoagulant is used in it. Ensure that there is adequate patient preparation; correct use of anticoagulant and specimen is well preserved.

Patient preparation:

If patient preparation is inadequate, the results could be either diagnostically useless or even misleading. Patient preparation is important in many tests. The laboratory provides instructions to the nursing staff and patient regarding all details of preparation for specific test. Test may be carried out on random sample or postprandial sample; for which test the fasting sample is needed or preferable; how long the patient needs to fast for the fasting sample; adequate carbohydrate diet for oral glucose tolerance test; and so forth.

Anticoagulants:

Interference of anticoagulants on the test is a serious matter. Various type and quantity of anticoagulants makes a lot of confusion to use for certain laboratory test. Life is much easier when Vacutainers are available for blood collection. These tubes are supplied with the right amount of the right anticoagulant for the type of use. Tubes are colour coded too. The laboratory only needs to list the type of Vacutainer to be used for each test.

- No sodium test should be done on plasma where a sodium salt is used as anticoagulant.
- Calcium measurement should not be done on plasma containing EDTA, fluorides or oxalates combined with calcium.
- Fluorides and oxalates should not be used for enzyme analysis.

Preservation:

With time many chemical constituents deteriorate to varying degrees. No preservation may be required if test can be done fast or immediately after collection. If the specimens are saved for certain length of time or if they are to be sent out to other laboratories, some preservative measures are used. Preservation may be required for one or more reasons:

- Microbial growth
- Deterioration of the analyte
- Interfering substances generated on standing.

Haemolysis:

Haemolysis is one of the most frequent influences found in laboratory test. Slight haemolysis usually may affect the results negligibly, but grossly haemolysed sera should not be used for any analysis. The concentrations of blood constituents differ in erythrocytes and in plasma. Some analyte such as calcium and some enzymes such as acid phosphatase and aspartic aminotransferase are present in large amount in the red cells. Consequently, haemolyzed plasma gives higher values for these tests. Haemolysis usually results from mechanical errors during blood collection, processing and separating serum or plasma.

(C) ANALYTICAL ERRORS

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There are two types of analytical errors. One is the indeterminate or random error and the other is the determinate or systematic error.

Indeterminate Errors

Errors whose causes cannot be determined are called indeterminate or random errors. Fluctuations in the temperature and the voltage, small variations in volumetric apparatus, minute differences in wavelength of colourimetry measurements, etc could take place during the experiment. These factors are hard to control. Their origins are not easily traceable. Random errors may affect results high or low. Statistical techniques and methods are applied in the quality control programme and such random errors could be described or controlled significantly. In statistical evaluation, test result can be expressed in a value with an acceptable range or the confidence limits. Result with a minute error due to indeterminate factors will fall in the 95% confidence limits.

Determinate Errors

Determinate errors originate from incorrect operations or malfunction in instrumentation or poor quality of materials used for the experiment. They are systematic errors. Having put in appropriate efforts, these errors could be minimised or eliminated.

Instrumentation and materials:

Lower or higher results are usually caused by some determinate errors. For example, a spectrophotometer that records a higher optical density or a decomposed standard used in the test can give higher results. A lower temperature of analysis or a shorter incubation period may give lower results. However, these systematic errors are traceable and controllable.

All instruments and miscellaneous equipment, such as centrifuge, refrigerators, balances, thermometers, heating baths, incubators which aid in analyses must be functioning well. It is very important to keep them well maintained, tested and calibrated. Regular preventive actions at every stage of testing process should be taken, rather than being assessed purely by looking for errors afterwards. It should result, therefore, in increased productivity, together with increased efficiency due to a reduction in the number of tests rejected and in need for re-testing.

Quality of materials used in analysis determines the quality of results as well. Even the glassware which is commonly used in the laboratory have different types with physical and chemical properties. A significant error can be introduced by improper use and inadequate cleaning of laboratory glassware. Reagents, standards, calibrators and even purified water used in analysis must be of great quality because they have certain influences on the quality of results.

The Analyst:

Systematic or determinate errors could originate from the analyst's errors too. Errors caused by the analyst are rather difficult to detect and rectify. They could be a result of poor working conditions or lack of effective training.

The workload in a laboratory influences the technician's ability to perform a good analysis. Heavy workloads and shortage in the technical workforce shall result a degradation in the quality of the performance of the laboratory. The technician cannot pay enough attention to little details of the test. On the other hand, it also affects the quality of result if the technicians have very little work to do and if they are so free. A correct balance between workforce and workload will be productive and able to maintain the quality performance.

Training and skills development programme for laboratory workforce must be in place. Technicians should be aware of the importance of the quality control, principles of the tests, sources of errors in analyses, and clinical significance of the test results. If technicians do not know what is right, they cannot detect what goes wrong and might overlook an error. Degrees certificates or whatever stand for the preliminary qualifications only. It is very hard to say that a degree holder (Medical Technologist) is always a better analyst than a certificate holder (Medical Laboratory Technician). Both need to develop their skills, knowledge and experience. Their attitude is important as well. Before they are asked to perform the certain test, they should be thoroughly trained depending on their background, to make them familiar with all theoretical and practical aspects of the test.

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21. Discussions & Conclusions

21.1. Laboratory Certification and Accreditation

Certification and Accreditation play as a tool to demonstrate quality and competency of the laboratory ensuring delivery of timely, accurate and reliable results. And the medical laboratory ought to be internationally recognized with standards and requirements necessary for a diagnostic laboratory. Practices are voluntary unless the legal requirement is stated. Both are granted by an external Certification and Accreditation organization.

Laboratory engages a third-party organisation such as the International Organization for Standardizations (ISO), College of American Pathologists (CAP), Joint Commission International (JCI), etc. for certification and/or accreditation. Having gone through the certification process and met its requirements, the laboratory will be certified and/or accredited. This practice, though not mandatory, is highly preferred as it provides assurance, impression, reputation, whilst creating a confident, professionally proud and happy working environment.

The International Organization for Standardizations, ISO is a worldwide federation of National Standards Bodies from more than 140 countries. It is a non-governmental organization established in 1947 and its mission is to promote the development of standardization to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity.

Medical laboratory service is essential in the diagnosis and assessment of the health of patients. ISO 15189 covers the essential elements for medical laboratories to demonstrate quality and competency of their services, as well as to ensure a consistent delivery of timely, accurate and reliable results. It is the medical laboratory version of both ISO 9001 (Quality management systems – Requirements) and ISO/IEC 17025 (General requirements in competency of testing and calibration laboratories). ISO 15189 addresses the independent assessments for the qualifications and on-going competency of Medical Laboratory Personnel, the laboratory accommodation, equipment, reagents, supplies, pre-analytical and analytical factors, quality assurance considerations and post-analytical factors.

Specialist scientific and clinical assessors or experts conduct a thorough evaluation of all factors in the laboratory that could affect the test results, including:

- technical competence of staff
- validity of test methods and procedures, including pre and post analytical elements
- sample quality, patient identification, handling, transport, storage
- review of results and any known clinical diagnoses
- procedures relating to the use of referral labs
- traceability of measurements and calibrations to relevant standards
- suitability, calibration and maintenance of equipment
- testing environment
- quality assurance of testing data
- acceptable turnaround time
- application of ethical values
- etc.

Whilst medical laboratories may be ISO 9001 certified, it would be prudent to know that such certification does not reflect the technical competency of a laboratory. ISO 15189 provides recognition of the medical laboratory's competency including both management system and technical practice. Through a system of international agreements, accredited laboratories receive a form of international recognition which allows their results to be more readily accepted in participating countries. There are over 70 accreditation bodies in practice and are currently over 2200 laboratories worldwide accredited to ISO 15189.

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21.2. ISO 9001 Certification vs ISO 15189 Accreditation

The ISO 9001 standard is widely used for many industries and services to evaluate their system for managing quality of product or service. This certification confirms the compliance of the quality management system.

ISO 15189 accreditation provides recognition of the medical laboratory's competence of both the quality management system and technical practice. The standard has been developed for the use of medical laboratories in practicing their management systems and maintaining competence to deliver reliable services.

21.3. Accreditation Bodies

To get the medical laboratory accredited, it engages an Accreditation Body that will inspect and evaluate whether or not the laboratory meets the specified standards. Accreditation Bodies are non-governmental groups, but they have signed as members of mutual arrangements with the International Laboratory Accreditation Cooperation (ILAC) and/or the International Accreditation Forum (IAF).

ILAC is the international authority which promotes the increase use and acceptance, by industries as well as government, of the results from the accredited laboratories. IAF is a global Association of Accreditation Bodies which promotes worldwide acceptance of certificates of conformity issued by certification bodies and adds value for all stakeholders through its programme.

Laboratories are keen to improve their own quality and standard. To achieve this, laboratories alternatively engage third-party organizations. This practice is of great help for raising standard of individual laboratory. Developed countries organize a strong technical group like the "National Standardisation and Accreditation Council" (NSAC) which includes personnel from government departments as well as experts from various technical and professional associations. The NSAC well appreciates the efforts laboratories have put in and the services of those third-party organizations in keeping the standard and quality of laboratory service. At the same time, it is responsible for setting up the national standards required and for providing full support and cooperation.

21.4. Rewards of a Good QC Programme

The rewards of a good QC programme are many. The clinicians, the patients, the laboratory personnel, and whole medical profession benefit from a good QC programme. It can produce more reliable test results. Clinicians can make faster and more accurate diagnosis, in turn, patients get faster and better medical care. Quality in laboratory service and test results can create a good reputation for the laboratory among clinical staff. Laboratory performance is well recognized and it goes global. Moreover, the pride and morale of laboratory workers increase with the quality of their services. The laboratory may also be beneficial when it is dealing with the law and the government. The QC programme is an absolute necessity for laboratory accreditation and licensing if legally required.

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