



Importance of Standard Molecular and Clinical Microbiology Laboratory: Bangladesh Perspective

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Clinical Laboratory Science which is also called Medical Laboratory Science, is the health profession that provides laboratory information and services and these are needed for the diagnosis and treatment of diseases¹. Clinical Laboratory Scientists perform a variety of laboratory tests, ensure the quality of the test results, explain the significance of laboratory tests, evaluate new methods and study the effectiveness of laboratory tests². There are several laboratory tests which have been performed by Clinical Laboratory Scientists.

Molecular Diagnostic Science is a specialized area of Clinical Laboratory Science that uses sensitive and specific techniques to detect and identify biomarkers at the most basic level³. Common applications of molecular methods include medical diagnosis, establishing prognosis, monitoring the course of disease, and selecting optimal therapies. Molecular diagnostic tests are increasingly used in many major areas of medicine including genetic disorders, infectious diseases, cancer, pharmacogenetics and identity testing. These include genetic disorders where molecular methods are used to detect common inherited diseases such as cystic fibrosis, hemochromatosis, and fragile X syndrome. Infectious diseases including hepatitis, tuberculosis, human immunodeficiency virus (HIV), human papilloma virus (HPV), Chlamydia, Neisseria gonorrhoeae, and methicillin-resistant Staphylococcus aureus (MRSA) can be identified faster and more accurately using molecular techniques as compared to traditional

culture or antibody assays⁴. Some leukemias and solid tumor cancers can be detected and identified by molecular probes which target the abnormal gene rearrangements occurring in these disorders. In pharmacogenetics, molecular testing can be used to individualize a specific dosing schedule for patients on a common blood thinner, warfarin, and thereby reduce the likelihood of overmedication and potential bleeding problems.

Clinical microbiology laboratory plays an important role in patient care by providing the cause of infection and antimicrobial susceptibility data to physicians. Rapid diagnosis of pathogens is important for initiating effective antibiotic administration and improving the outcomes of treatment. Conventional diagnosis of microorganisms uses phenotypic identification and gene sequencing, which is tedious and time-consuming. In contrast, MALDI-TOF/MS is a simple, rapid, reproducible, and low-cost technique that has been successfully applied to identify pathogens⁵. Based on characteristic peptide and protein profiles obtained from intact cells, MALDI-TOF/MS allows a highly discriminatory identification of bacteria, yeasts, and filamentous fungi even after 10 min of culture.

Microbiological investigations are important in the diagnosis, treatment, and surveillance of infectious diseases and policies regarding the selection and use of antimicrobial drugs. It is, therefore, essential that test reports are relevant, reliable, timely, and interpreted correctly. High cost of culture media and reagents, lack of rational approach to the selection and use of microbiological investigations, and a shortage of trained technical staff and clinical microbiologists are important factors in preventing the establishment of essential microbiology services in developing countries³.

Quality assurance (QA) has been defined by WHO1 as the total process whereby the quality of laboratory

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reports can be guaranteed. It has been summarized as the: right result, at the right time, on the right specimen, from the right patient, with the result interpretation based on correct reference data, and at the right price. Quality control (QC) covers that part of QA, which primarily concerns the control of errors in the performance of tests and verification of test results. QC must cover all aspects of every procedure within the department. It must be practical, achievable, and affordable. All materials, equipment and procedures must be adequately controlled. Culture media must be tested for sterility and performance².

Each laboratory must have standard operating procedures (SOPs) sometimes referred to as the local laboratory bench manual. It is required for the reasons to improve and maintain the quality of laboratory service to patients and identify problems associated with poor work performance, to provide laboratory staff with written instructions on how to perform tests consistently to an acceptable standard in the laboratory, to help avoid short-cuts being taken when performing tests, to provide written standardized techniques for use in the training of laboratory personnel, to facilitate the preparation of a list and inventory of essential reagents, chemicals and equipment, to promote safe laboratory practice⁵. Standard operating procedures must be prepared, written and implemented by a qualified experienced laboratory officer, and followed exactly by all members of staff. Each standard operating procedures must be given a title and identification number and be dated and signed by an authorized person. Standard

operating procedures are the main building blocks of a laboratory quality assurance framework and are, as such, embedded in the Quality Management System (QMS), which defines and rules the quality organization and management of a laboratory service⁴. Effective QA detects errors at an early stage before they lead to incorrect test results. Laboratory personnel need to be aware of the errors that can occur when collecting specimens (pre-analytical stage), reporting and interpreting test results (post-analytical).

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