PURPOSE:

1. To ensure control over the creation, approval, distribution, usage and updates of documents and records being used in the molecular laboratory.
2. To establish document control process in the laboratory and ensure the security of information.

LEVEL:

Molecular Laboratory Pathologist, All Molecular Laboratory Personnel

DEFINITION OF TERMS:

1. ***Document.*** A piece of written, printed, or electronic matter that provides evidence, information about policies, processes, and procedures that serves as an official record.
2. ***Record.*** A thing constituting a piece of evidence about the past, especially an account kept in writing or some other permanent form. It is a collected information produced by the molecular biology laboratory in the process of performing and reporting RT-PCR test results.
3. ***Document Control.*** It is a document management profession whose purpose is to enforce controlled processes and practices for the creation, review, modification, issuance, distribution and accessibility of documents.

POLICY:

1. The document control process of the Molecular Laboratory shall ensure that all documents are valid, current, approved, and readable.
2. Documents may exist in either paper or electronic format (or both), but document control shall be maintained in both formats.
3. The Laboratory Supervisor shall ensure that all documents are uniquely and correctly identified by its title, code and other identifier applicable to the concerned document.
4. All forms being used in the Molecular Laboratory shall pass through the Documentation Section of the hospital for the assigning of codes. Same goes for the

policies, standard operating procedures where the assigning of codes shall be done by the said section.

5. All documents issued to personnel as part of the Quality Management System (QMS) are reviewed by the Total Quality Division and approved by the Management Committee (MANCOM) prior to being issued.
6. Only currently authorized versions of documents shall be available for active use at relevant locations.
7. Documents shall be periodically reviewed, revised when necessary, and approved for use by the head of the department.
8. Invalid or obsolete documents shall be promptly removed from all points of active use and archived.
9. Previous versions of documents that are retained or archived shall be appropriately identified to prevent their inadvertent use as the current version.
10. Documents of external origin:
    - 10.1 are identified and their distribution controlled
    - 10.2 are reviewed and approved for adequacy before use.
11. All logbooks containing the information of patients undergoing different testing and their results shall be kept confidential at all times.
12. Compilations of the checklists, reports, and records pertaining to the daily operations of the laboratory shall be kept in file for a maximum of 3 years. Discarding of documents shall be done according to the Data Privacy Office protocols
13. All laboratory reports shall bear the name of the pathologist who shall be the overall responsible for the reliability of the results.

DOCUMENTATION:

New Policy

DISSEMINATION:

1. Policies and Procedures Manual
2. Unit Orientation and Meeting

APPROVAL:

	Name/Title	Signature	Date
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