

| Document Code:      | DPOTMH-E-60-P06               |  |
|---------------------|-------------------------------|--|
| Effective Date:     | 08-30-2022                    |  |
| Document Type:      | Policy                        |  |
| Page Number:        | 1 of 4                        |  |
| Department/Section: | Molecular Laboratory          |  |
| Document Title:     | DOCUMENTS AND RECORDS CONTROL |  |

### **PURPOSE:**

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

#### LEVEL:

Molecular Laboratory Pathologist, All Molecular Laboratory Personnel

### **DEFINITION OF TERMS:**

- Document. A piece of written, printed, or electronic matter that provides evidence, information about policies, processes, and procedures that serves as an official record.
- 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 collection of
  information produced by the molecular biology laboratory in the process of
  performing and reporting RT-PCR test results.
- 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 Molecular Laboratory's document control process shall ensure that all documents are valid, current, approved, and readable.
- 2. Documents may be in paper or electronic form (or both), but document control shall be maintained in both formats.
- The Laboratory Supervisor shall be responsible for ensuring that all documents are uniquely and correctly identified by their title, code, and any other identifiers applicable to the document in question.



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- 4. All forms used in the Molecular Laboratory shall be routed through the hospital's Documentation Section for coding. The same is true for policies and standard operating procedures where code assignment is the responsibility of the relevant 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.
- Only currently authorized versions of documents shall be available for active use at relevant locations.
- 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 and archived from all active points of use.
- 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 information about patients undergoing various tests and their results shall be kept strictly confidential at all times.
- 12. Compilations of the checklists, reports, and records pertaining to the daily operations of the laboratory shall be kept on file for a maximum of 3 years.



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Disposal 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 overall responsible for the reliability of the results.

#### **DOCUMENTATION:**

**New Policy** 

## **DISSEMINATION:**

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



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