Name of Policy: Documentation/Record-keeping/Record Review

Policy Number: 3364-107-311

Department: Pathology-Laboratory

Approving Officer: Chief Operating Officer-UTMC

Responsible Agent: Director, Clinical Pathology
Administrative Director, Lab

Scope: Pathology-Laboratory

Effective Date: 1/4/2023
Initial Effective Date: 10/6/2003

(A) Policy Statement

The Laboratory provides a uniform format for documentation relating to requisition, performance and reporting test results in the form of records, procedures, and policies and retains these records for the time specified by CLIA, FDA, CAP and standards.

(B) Purpose of Policy

To describe a system of generation, implementation, revision, and review of all records pertinent to the care of patients at UTMC.

(C) Procedure

- All pertinent documents such as forms, policies, procedures and records shall bear the “University of Toledo or University of Toledo Medical Center, Toledo, Ohio” name and location.

- Format and revisions of forms or records that will be part of the patient’s permanent medical record must be reviewed and approved by the UTMC Forms Committee. These forms must be submitted for review to the Medical Records department and bear a Medical Record form number.

- A designated Technologist or Supervisor reviews the following:
  - Follow-Up Work Lists:
    a. Criticals,
    b. Delta Checks,
    c. Abnormals,
    d. Comm Log.
  - Monthly results of reagent quality control, instrument function checks and equipment temperature monitoring.
  - POCT results and QC

- The Medical Director reviews the following:
  - Special Studies, including antibody identifications and elution studies, electrophoresis reports, coagulation studies, immunofluorescence studies. Written reports, if necessary, are signed before release.
  - Transfusion reaction investigations. Results are interpreted, reported and signed by the Medical Director.
Policies Superseded by This Policy:  Q-10