

**TENNESSEE MEDICAL LABORATORY BOARD
POLICY STATEMENT REMOTE LABORATORY WORK**

On April 28, 2023, the Tennessee Medical Laboratory Board approved this policy statement for remote laboratory work performed outside the licensed clinical or anatomic laboratory.

Objective:

What are the responsibilities of a medical laboratory director while working remotely?

Response:

There is no change in the responsibilities of the medical laboratory director regardless of if he or she is working physically in the lab or remotely. The medical laboratory director is responsible for all the duties in the regulations located at 1200-06-01-.20(5) which include, competency assessment, proficiency testing enrollment, monthly visits, etc. Director oversight must be documented.

Objective:

How to regulate remote lab work that includes many different areas including but not limited to cytogenetics, pathology, flow cytometry, FISH, and toxicology. The policy includes all laboratory specialties.

Response:

Oversight for testing performed remotely will occur at the main state-licensed laboratory. The interpretive process rendered by medical professionals which include the review of digital slides, histograms, and FISH are limited to the analysis of electronic data can be performed remotely and fall under the oversight of the main lab. Slides refer to only digital slides.

Objective:

Where is the diagnosis rendered?

Response:

The diagnosis is rendered at the main state-licensed laboratory. All other testing sites fall under that location's license. They are an extension of the main lab. This guidance is not limited to any specific lab specialty or department. All final patient reports need to reflect the address of the main state-licensed laboratory. The specific location where the digital slides are read must be traceable. The policy includes all laboratory specialties

Objective:

If testing is performed in a home, is it subject to inspection?

Response:

Home inspections for pathology do not add any value and are not necessary. All records can be reviewed at the main state-licensed lab. There is no need for individual facility licensure at a pathologist's home. The surveyors can review all remote testing documents when they are at the main lab.

Objective:

What is the impact on pathologists that read in multiple locations?

Response:

Pathologists that read digital slides and images remotely have an improved turn-around-time. The focus does not need to be on the location where the pathologist resides, but instead on the credentials of the pathologist performing the slide interpretation.

Objective:

How will remote work be regulated and how will oversight take place?

Response:

Lab surveyors will review all the remote documents at the main laboratory during an inspection. Remote pathologist's records and slides are maintained by the main histology laboratory which is licensed. The microscope maintenance records will be housed at the central laboratory and retrievable upon request. The lab director will perform his or her oversight either in person or remotely.

This policy was adopted on April 28, 2023. Revised July 19, 2023.