

**Medical Laboratory Board
Task Force Meeting
July 27, 2021**

Participants: Tonia Church-Associate Quality Director-Integrated Oncology
Carla Davis, MD-Board Member
Danielle Gibson, MD-Board Member
Michael Johnson-Board Member
Jordan Mayo-Manager Quality-Aegis Sciences Corporation
Kristie Shafer-AVP Quality-HCA Healthcare
Derek Welch, MD-CMO-PathGroup

Staff: Sandra Bogard-Director Med Lab Board
Nina Smith-Board Consultant

Meeting was called to order at 9:10am CDT

Goal of Task Force: Discussion regarding digital imaging and remote work as it pertains to all areas of the laboratory.

Recommendations of the Task Force:

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

Response: 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. There is no change in the responsibilities of the medical laboratory director regardless if he or she is working physically in the lab or remotely.

Objective: How to regulate remote lab work that includes many different areas including but not limited to cytogenetics, pathology, flow cytometry, FISH, and toxicology.

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 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.

Objective: Identify any issues with pathologists using digital imaging to read clinical slides.

Response: The reading of digital images can occur at multiple locations. HIPAA policies are in effect at the main lab along with training requirements for staff.

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.

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 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. The lab director will perform his or her oversight either in person or remotely.

Adjournment: Meeting ended at 10:30am.

Minutes were approved at the October 28, 2021 meeting of the Medical Laboratory Board.