

JAMES V. McDONALD, M.D., M.P.H. Acting Commissioner

**MEGAN E. BALDWIN**Acting Executive Deputy Commissioner

May 12, 2023

Governor

In accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance issued May 11, 2023, the New York State (NYS) Clinical Laboratory Evaluation Program (CLEP) will likewise allow pathologists and other laboratory personnel to review digital results and digital images remotely, under the conditions described below. The examination of physical slides requiring the use of a microscope or any examination that requires laboratory equipment other than a computer and VPN connection may not be performed at a location that does not hold a New York State clinical laboratory permit with the appropriate permit category.

## Remote examination, review, and results reporting policy conditions:

- The primary laboratory location must hold New York State (NYS) clinical laboratory permit (permit) to include the permit category(ies) relevant to the testing being offered.
- The laboratory director of the primary laboratory location is responsible for all testing performed, including tasks performed remotely.
- The primary laboratory location must maintain all documentation for testing performed, including remote work.
- Persons performing remote tasks must be bona fide employees of the primary laboratory location holding the NYS permit.
- Remote tasks are performed in accordance with policies and procedures approved by the laboratory director.
- The test report must include the location where the testing (i.e., examination or analysis) was performed. Remote sites operating under the primary laboratory location's permit may be indicated using a coding system rather than the remote site address.
- The primary laboratory location must maintain a list of all personnel performing remote work, to include name, tasks qualified to perform, and the address of the remote location including any code being used to identify the location on test reports. This list must be made available to the Department upon request.
- The personnel performing remote work must be included on the Department's facility personnel form (fpf).
- Transmission of patient data is maintained over a secure VPN or equivalent level of security.
- Confidentiality of data is maintained at all times and the primary laboratory location and all remote sites comply with applicable federal laws, including HIPAA.

Any questions related to this policy can be directed to clepcomp@health.ny.gov.

## **Beverly Rauch**

Director, Clinical Laboratory Evaluation Program

Wadsworth Center, NYS Department of Health