



Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

June 2025

Dear Limited Service Laboratory registrants:

This correspondence provides additional direction to facilities holding approval for Provider-Performed Microscopy (PPM) procedures under a valid Limited Service Laboratory (LSL) registration. The New York State Clinical Laboratory Evaluation Program (CLEP) administers the LSL registration process.

On December 28, 2023, the federal Centers for Medicare and Medicaid Services (CMS) issued a Final Rule regarding Fees, Histocompatibility, Personnel and Alternative Sanctions. **This Final Rule imposes new requirements on sites where provider-performed microscopy (PPM) procedures are performed.** The federal Final Rule for Personnel took effect on December 28, 2024.

New York Public Health Law states that an LSL registrant must comply with all applicable laws, rules and regulations, including federal regulations that govern sites performing provider-performed microscopy procedures.

The federal Final Rule for Personnel requires:

1. Laboratory directors of sites performing PPM procedures must ensure that individuals performing these procedures are qualified healthcare professionals acting within the scope of practice of their licensed profession as determined by the New York Education Department. This may include physicians, nurse practitioners, physician assistants, specialist assistants, clinical nurse specialists, nurse midwives or dentists.
2. Furthermore, laboratory directors of sites performing PPM procedures must evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform PPM procedures and report results promptly, accurately and proficiently. This evaluation must be performed and documented at least semiannually during the first year the staff performs PPM procedures and annually thereafter.
3. The evaluation of competency must include, but not limited to, the following elements:
 - a. direct observation of routine performance of PPM procedures including specimen handling, processing and testing;
 - b. monitoring and reporting of test results;
 - c. review of test results or worksheets;
 - d. assessment of test performance through internal blind samples or external proficiency testing samples; and
 - e. assessment of problem-solving skills.

Please direct any questions to clepltd@health.ny.gov.