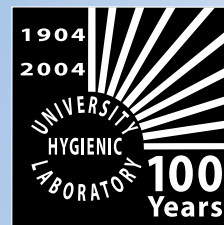


# CLIA Corner

Hygienic Laboratory at the University of Iowa

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## In This Issue...

### The CLIA requirements for laboratories performing PPM procedures.

A certificate of Provider-Performed Microscopy Procedures (PPM) allows the laboratory to perform one or more of the following microscopic procedures, as well as any waived testing. Laboratories that hold a PPM certificate are not subject to routine on-site inspections. However, the regulations do allow for inspections to be conducted either periodically or when a complaint is filed.

PPM procedures are limited to:

- Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites or cellular elements;
- Potassium hydroxide (KOH) preparations;
- Pinworm examinations;
- Fern tests;
- Post-coital direct, qualitative examinations of vaginal or cervical mucus;
- Urine sediment examinations;
- Fecal leukocyte examinations;
- Qualitative semen analyses (limited to presence or absence of sperm and detection of motility);
- Nasal smears for eosinophils.

A printable list of PPM procedures and CPT codes can be found on the CLIA website: [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia), under the Categorization of Tests link.

*Reminder: Provider-performed microscopy procedures are categorized as moderate-complexity. Laboratories with certificates of compliance or accreditation must also comply with the following requirements even when providers are the only personnel performing the PPM procedures (see Personnel Requirements).*

The PPM testing must be performed during the patient's visit on a specimen obtained from the practitioner's own patient or group practice. Due to the type of testing being performed, the primary instrument for performing the PPM procedures is a microscope, limited to bright-field or phase-contrast microscopy. The laboratory must meet all the applicable regulations for non-waived testing, which includes, but is not limited to:

- **General Laboratory System:** proficiency testing, personnel competency, confidentiality, communication and specimen integrity;
- **Pre Analytic System:** test requests and specimen collection, processing and handling (including written policies and procedures);
- **Analytic System:** procedures, performance verification, equipment maintenance and function checks, reagent and supply management, and test records;
- **Post Analytic System:** test reports and reporting systems;
- **Quality Assessment:** monitors, reviews and assesses the all four quality systems; and
- **Personnel Requirements:** qualifications for director and testing personnel.

#### General Laboratory System

The PPM procedures are considered unregulated analytes; therefore the laboratory is not required to enroll in proficiency testing. However, the laboratory must verify the accuracy of testing at least twice annually. This may be accomplished by enrolling in proficiency testing (most proficiency testing companies offer a limited PPM testing challenge or module), split sampling with another facility, or an in-house testing program (e.g. blind testing between two testing personnel).

Initial training, a six month review, and then annual competency assessments must be documented for all testing personnel. (Successful proficiency testing may be one way to document competency.)

#### **Pre Analytic System**

A written request is required for all patient tests. The written request must include: name and address of the testing facility, patient's name or unique patient identifier, sex and age or date of birth of the patient, test to be performed, source of specimen (when appropriate), date and time of collection, and any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results.

The laboratory must establish and follow written policies and procedures for the following: patient preparation; specimen collection; specimen labeling (including patient name or unique patient identifier); specimen storage and preservation; conditions for specimen transportation; specimen processing; specimen acceptability and rejection; and specimen referral.

#### **Analytic System**

The laboratory must establish and follow written policies and procedures for: requirements for patient preparation (see pre-analytic requirements); microscopic examinations; step-by-step performance of the procedure (including interpretation of results); preparation of materials used in testing ( e.g. slides, stains, controls, etc.); calibration and calibration verification procedures (if applicable); reportable range for the test results; control procedures; corrective action to take if controls or calibrators fail; limitations in testing; reference intervals (normal values); panic values; pertinent literature references; system for entering results in the patient's record; and description of the course of action to take if the test system becomes inoperable.

The laboratory must follow the manufacturer's requirements for maintenance and function checks of equipment used for PPM procedures (i.e. microscope and centrifuge). If the manufacturer does not have specific guidelines, then the laboratory must establish and follow written procedures for the performance and frequency of maintenance and/or function checks. The laboratory is responsible for documenting all maintenance and function checks performed.

For non-waived tests, a minimum of two levels of external quality controls are required each day of patient testing. However, for urine microscopic examinations and those microscopy tests where quality controls are not available, the laboratory may meet the control requirement by having the appropriate reference material (e.g. photomicrographs or charts of the different microscopic components) available to review and compare with patient specimens.

The laboratory must have a system in place to check for expired reagents. The laboratory may only perform the tests a few times throughout the year, and it is important to have fresh reagents in use and available.

The laboratory must also have an information or record system that monitors the positive identification of the specimen, date and time of specimen receipt into the laboratory, and records of all specimen testing (including the identity of the testing personnel.) One way this requirement can be met, is by the use of a patient log or worksheet.

#### **Post Analytic System**

For each test being performed, the laboratory must document the result on the patient's test report. The test report must contain two patient identifiers (i.e. patient's name and identification number, or unique patient identifier and identification number). The report must also contain the name and address of the testing facility, test report date, test performed, specimen source (when appropriate), and test result. The patient's chart may be used as the test reporting system.

#### **Quality Assessment**

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems in each of the four areas of quality systems (see above). The quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and a discussion of the findings with the appropriate staff.

#### **Personnel Requirements**

The director and testing personnel must possess a current license in the state in which the laboratory is located (if licensing is required) and meet one of the following requirements:

- Physician (MD or DO) or podiatrist (DPM); or
- Mid-level practitioner, under the supervision of a physician or in independent practice authorized by the State; or
- Dentist

Medical technologists and medical laboratory technicians are not qualified to perform microscopy testing under a PPM certificate. In order for other testing personnel (medical technologists, medical laboratory technicians, nurses, etc.) to perform the microscopy testing, the laboratory would need to apply for either a Certificate of Compliance or Accreditation. *There are no personnel requirements for performing waived testing.*

**For more information regarding the CLIA requirements pertaining to PPM certificate, refer to the State Operation Manual, Appendix C-Interpretative Guidelines, §493.1253, Subparts C, H, J, K, M and Q available on the CMS website at [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia), under the Interpretive Guidelines for Laboratories link.**

**Contact Information:**  
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