IOWA | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa Second Quarter 2026

In This Issue…

PPM procedures are a select group of microscopy tests that healthcare providers can perform during patient office visits. Due to the requirement of training and specific skills for these tests, they may not be performed under a CLIA Certificate of Waiver. A CLIA Certificate for PPM Procedures must be obtained to allow licensed physicians, midlevel practitioners, and dentists to perform the select group of moderately complex microscopic examinations during a patient visit. All waived testing may also be performed under a Certificate for PPM Procedures.

PPM procedures must be performed using bright-field or phase-contrast microscopy and include:

1. All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
2. All potassium hydroxide (KOH) preparations

   NOTE: "All KOH preparations" include KOH that is mixed directly with a stain or the stain is added directly to the KOH preparation.
3. Pinworm examinations
4. Fern tests
5. Post-coital direct, qualitative examination of vaginal or cervical mucous
6. Urine sediment examinations
7. Nasal smears for granulocytes
8. Fecal leukocyte examinations
9. Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

The following are not within the PPM subcategory:

- Arachnid (tick) Identification
- Mohs procedure tissue slides
- Body fluid exam for crystals
- Tzanck smear
- Gram stains
- Quantitative semen analysis

Laboratories or facilities with a Certificate of PPM Procedures are not subject to routine biennial inspections. However, inspections may be conducted to assess potential risks to public health, investigate public complaints, determine whether testing is performed outside the scope of the laboratory's CLIA certificate, or collect information on the appropriateness of tests designated as waived or PPM procedures.

In addition, every laboratory or facility that performs PPM testing must meet the CLIA quality standards for moderate complexity testing. This includes establishing and maintaining written policies and procedures for a quality system covering all phases of the total testing process.

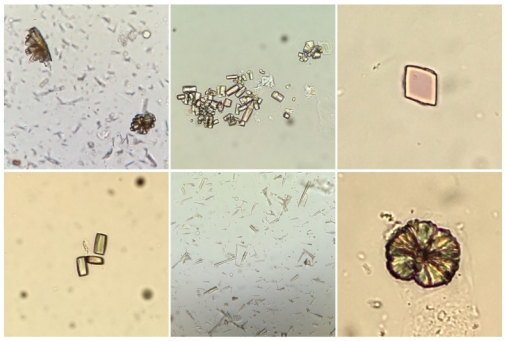
PPM Procedures Personnel Qualifications

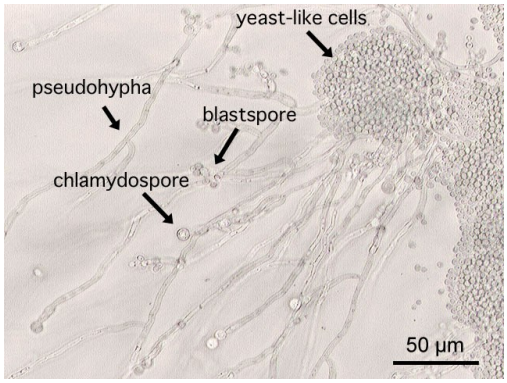
To qualify as a PPM Laboratory Director and/or Testing Personnel, individuals must meet one of the following:

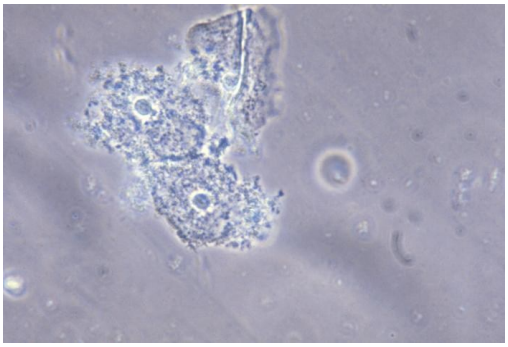
1. **Be a doctor of medicine (MD), doctor of osteopathy (DO), or doctor of podiatric medicine (DPM) licensed to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located; OR**
2. **Be a midlevel practitioner, authorized by a state to practice independently in the state in which the laboratory is located; OR**
   - **"Midlevel practitioner" means: nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician's assistant licensed by the state (if required) within which the laboratory is located.**
3. **Be a dentist.**
   - **"Dentist" includes a doctor of dental medicine or doctor of dental surgery license by a state to practice dentistry within the state in which the laboratory is located.**

PPM Procedures Personnel Responsibilities

The PPM laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. They must also do the following:







1. Direct no more than five laboratories;
2. Ensure PPM testing personnel meet regulatory qualification requirements;
3. Ensure PPM testing is performed in accordance with applicable requirements listed in subparts H (Proficiency Testing), J (Facility Administration), K (Analytic Systems), and M (Personnel for Non-waived Testing) of the CLIA Regulations and Interpretive Guidelines;
4. Evaluate and document the competency of all testing personnel at least semi-annually during the first year the individual performs patient testing and at least annually, thereafter; and
5. Ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently.

The PPM testing personnel are responsible for the following:

1. Specimen processing, test performance, and reporting test results;
2. Performing PPM procedures on specimens obtained from his or her own patient or from a patient of a group medical practice of which the provider is a member or employee; and
3. Performing PPM procedures using a microscope limited to bright-field or phase contrast microscopy.

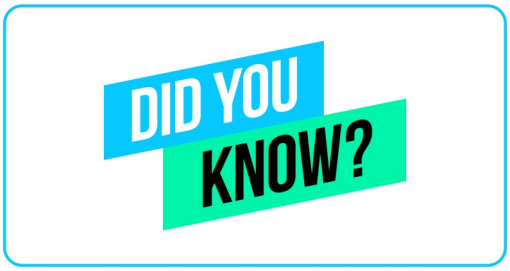
A single, qualified individual may serve in both roles as the laboratory director and testing personnel.

PPM Personnel Competency Assessment

The laboratory director is responsible for ensuring all PPM testing personnel undergo competency assessment to ensure accurate and reliable testing and reporting. All testing personnel must be assessed for each test they are authorized to perform. Competency assessments must include (but are not limited to) the following:

1. Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;
2. Monitoring the recording and reporting of test results;
3. Review of test results or worksheets;
4. Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
5. Assessment of problem-solving skills.

Competency assessment must be evaluated and documented for each testing personnel twice within the first year of testing patient specimens and annually thereafter. The laboratory director may delegate, in writing, competency assessment to others in the laboratory who meet the educational and licensure requirements for the CLIA position of laboratory director.



If a CLIA Certificate of Compliance (CoC) or Certificate of Accreditation (CoA) laboratory performs PPM procedures, then the laboratory is subject to all CLIA regulations related to moderate complexity testing. In those laboratories with a CoC or CoA, a technical consultant can perform competency assessment for moderate complexity testing, including PPM procedures. *However, in laboratories with a CLIA Certificate of PPM, the laboratory director is responsible for performing competency assessment.*

SCENARIO 1:	ANSWER:
The physicians in the OB department of a hospital perform fern testing under a Certificate of PPM. Can the Point of Care Supervisor (who qualifies as a technical consultant) perform the competency assessment for fern testing personnel?	**NO.** The CLIA technical consultant (TC) position is not a personnel position under a Certificate of PPM. The laboratory director is responsible for performing competency assessment.

SCENARIO 2:	ANSWER:
The physicians in the OB department of a hospital perform fern testing under the hospital's main laboratory Certificate of Compliance (CoC). Can the Point of Care Supervisor (who qualifies as a TC) perform the competency assessment for fern testing personnel?	**YES.** The CLIA TC position is a personnel position under a CoC, and the Point of Care Supervisor can perform competency assessments for fern testing if they meet the TC educational and experience requirements.

NOTE: *If the laboratory director is the only individual testing and reporting test results, they must establish and document a minimum proficiency level to maintain the required competency for accurate and reliable testing and reporting. Participating in proficiency testing, PPM continuing medical education (CME) credits, seminar training, or other external assessments are acceptable ways of establishing proficiency.*

Additional PPM Laboratory Requirements

PPM testing is a subcategory of tests that fall under moderate complexity testing, and, as such, laboratories performing them must meet the applicable CLIA quality standards for non-waived testing.

Patient Confidentiality & Specimen Identification Integrity

Laboratories must ensure confidentiality of all patient information throughout all phases of testing as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This includes patient and specimen identification, test results, and all records of testing throughout the entire testing process. In addition, positive identification and integrity of a patient's specimen must be maintained from the time of collection through completion of testing and reporting of results.

Test Request

All laboratories, including PPM laboratories/testing sites, must have a written or electronic request for patient testing from an authorized person. Verbal requests may be accepted, but a written or electronic request must be acquired within 30 days of the verbal order. The patient's chart or medical record (i.e. provider note) may be used as the test requisition.

Procedure Manual

Written procedures for every PPM test performed on-site must be available, easily accessible, and followed by all testing personnel. They must be approved, signed, and dated by the laboratory director. Refer to the 2024 3rd Quarter CLIA Corner for additional procedure manual requirements.

Reagents & Supplies

Reagents, solutions, and supplies must be appropriately labeled and properly stored according to manufacturer requirements. They must not be used beyond their expiration dates or if they are deteriorated.

Maintenance & Function Checks

Equipment maintenance must be performed and documented for microscopes and centrifuges, as applicable. Function checks must also be performed and documented for equipment (i.e. centrifuge RPM and timer checks).

Proficiency Testing (PT) Enrollment & Twice Annual Accuracy Verification

With regard to any testing performed in the laboratory, specialties, subspecialties, and analytes included in Subpart I of the CLIA Regulations are regulated. Laboratories are required to enroll in PT for any regulated testing they perform, unless there are no CMS approved PT programs available for the testing. For PPM testing that is included in Subpart I, generally, CMS-approved PT programs are unavailable and therefore the laboratory must verify accuracy at least twice annually. They must also verify the accuracy for any unregulated PPM testing they perform twice annually. This can be done by:

- Enrolling in a commercially available PT program
- Blind sample testing
- Split sample testing

Additional PPM Laboratory Requirements, continued...

Quality Control (QC)

Traditional QC materials are generally not available to monitor the entire testing process for PPM procedures, which can make it difficult to determine the accuracy of test results. Availability of reference materials will meet the QC requirement. For example, charts or pictures of all possible urine sediment components will meet QC requirements for urine sediment examinations.

Record Retention

The laboratory must retain the following for a minimum of two years:

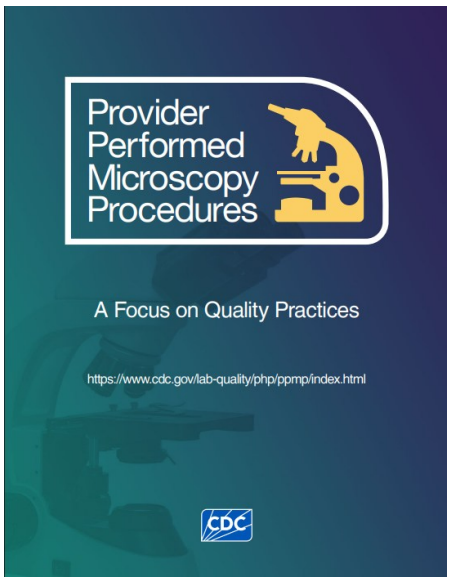
- Patient test records;
- Analytic system records (i.e. microscope maintenance and centrifuge function checks);
- Copies of test reports (from the report date)- they must be retained or retrievable and include final, preliminary, and corrected reports;
- Test procedures, which must include dates of initial use and discontinuance; and
- Quality systems assessment records.

Test Records & Test Report

Laboratories must have a system in place to guarantee the timely and accurate reporting of test results. The system must ensure test results and other patient-specific data are sent electronically or manually entered into the patient's record accurately. Testing records must include the:

- Positive identification of the specimen;
- Date and time of specimen collection and/or receipt into the laboratory;
- Date of testing; and
- Identity of the person who performed the test.

In addition, laboratories must have policies and procedures for monitoring and correcting problems with test reporting.



Additional information and educational materials can be found at the CDC's website and in the CDC's PPM Procedures Informational Booklet.

If you would like to be added to the CLIA Corner Google Group, send an email to Kristi Rotzoll & Melinda Bochmann: SHL-CLIA@uiowa.edu