

Provider-Performed Microscopy (PPM) 101

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A large, faint watermark of the CMS logo is centered on the slide. It features a stylized blue and yellow swoosh to the left of the letters 'CMS' in a large, bold, blue sans-serif font. Below the letters, the text 'CENTERS FOR MEDICARE & MEDICAID SERVICES' is written in a smaller, blue, all-caps sans-serif font.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES



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Learning Objectives

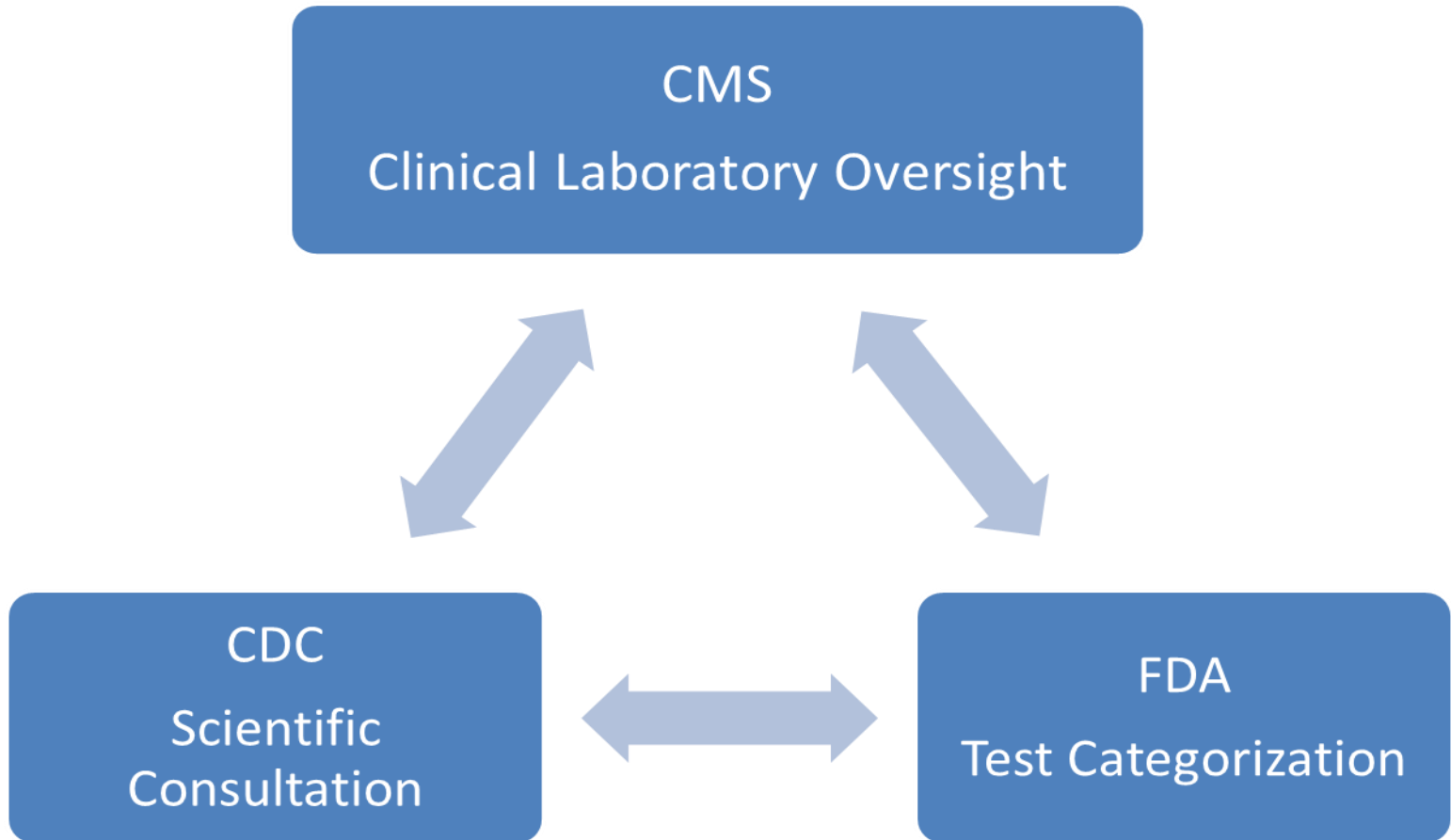
- Summarize the Clinical Laboratory Improvement Amendments (CLIA) program, including the types of CLIA certificates
- Identify the PPM examinations and the personnel required for a PPM certificate
- Identify applicable CLIA regulations for a PPM certificate

CLIA Regulation Overview

Final CLIA regulation published in Federal Register on February 28, 1992 and effective on September 1, 1992 as 42 CFR Part 493 Laboratory Requirements

Established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of laboratory test results regardless of where the test was performed

CLIA Program Responsibilities



CLIA Definition of a Laboratory

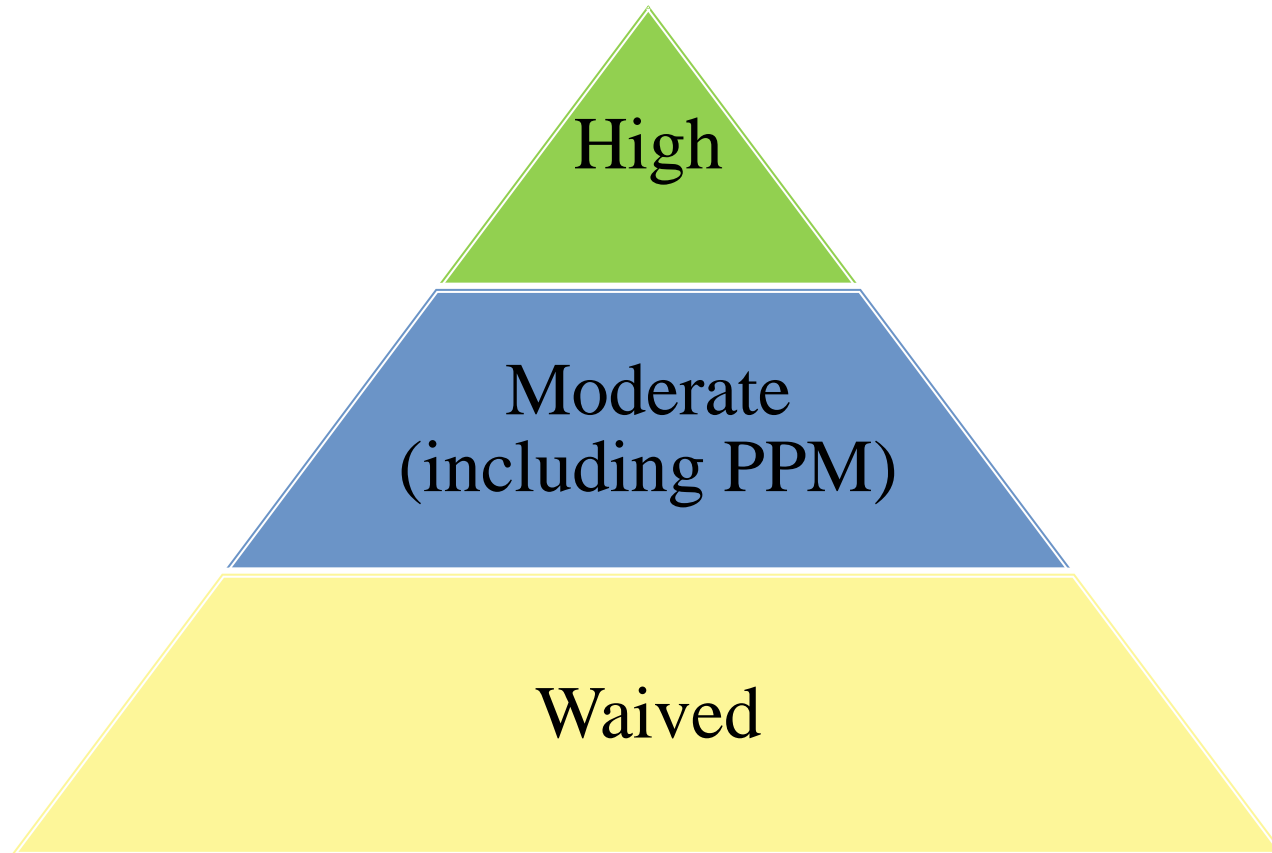
A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

All Clinical Laboratories...

that perform testing on human specimens for these purposes must:

- apply for a CLIA certificate
- pay appropriate fees and
- follow applicable CLIA requirements

CLIA Test Complexity



CLIA Certificate Types

- Certificate of Waiver (CoW)
- Certificate for Provider-Performed Microscopy (PPM) Procedures
- Certificate of Compliance (CoC)
- Certificate of Accreditation (CoA)

Certificate of Compliance (CoC)

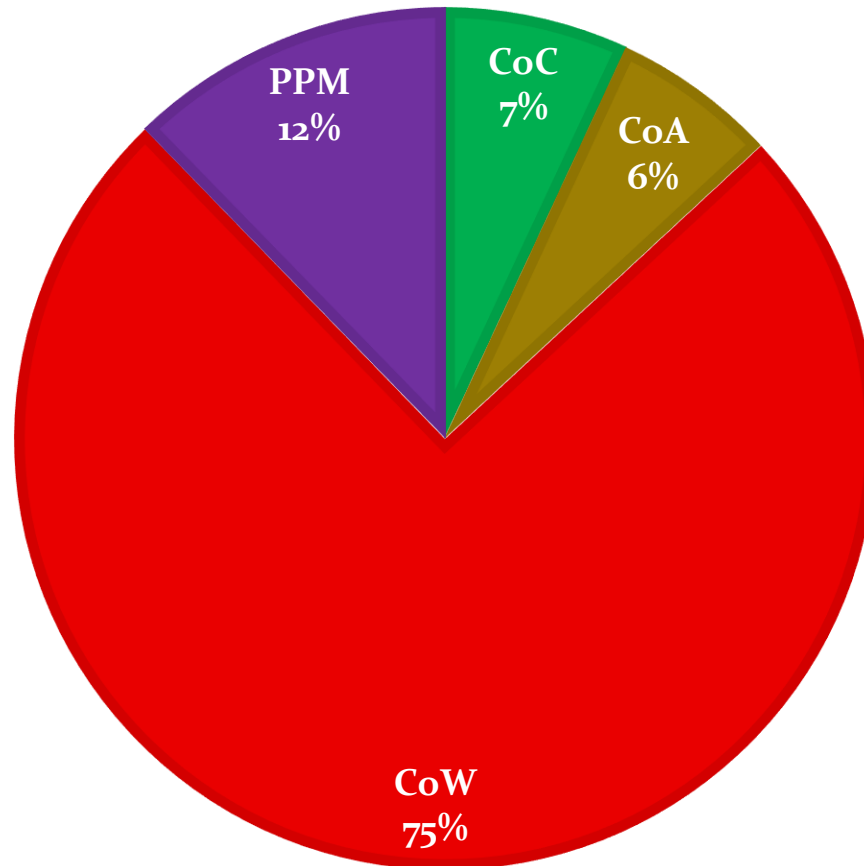
- Surveyed for compliance with the CLIA regulations
- Can perform waived, moderate and high complexity testing
- Pay biennial certificate fees
- Routinely surveyed every two years by State Agencies

Certificate of Accreditation (CoA)

- Laboratory selects Accrediting Organization (AO) at time of CLIA application
- Can perform waived, moderate and high complexity testing
- Pay biennial certificate fees
- Routinely surveyed every two years by AO survey team
- *Comply with the requirements of the approved accreditation program*

CLIA Certificate Types %

CERTIFICATE TYPES



CLIA History

- Public Law 100-578 CLIA '88 signed by President on October 31, 1988
- CLIA final rules 42 CFR part 493 (administrative processes and quality standards) published on February 28, 1992
- CLIA final rules effective on September 1, 1992
- Uniform standards to ensure accuracy, reliability and timeliness

PPM History – January 1993

New CLIA certificate type
(subcategory of moderate complexity testing)

Physician-performed microscopy procedures

- Allowed physicians to perform certain microscopic exams in addition to waived testing during patient's visit
- Microscopic examinations categorized as moderate complexity
- Limited to bright-field or phase-contrast microscopy
- Specimens that are labile or in which testing delay could compromise accuracy of results

PPM History – April 1995

- Renamed to Provider-performed microscopy (PPM) to include other practitioners, and to clarify tests that can be performed:
 - Added midlevel practitioners who are:
 - licensed by the state in which the laboratory is located, if required,
 - a nurse midwife, nurse practitioner, or physician assistant, and
 - under physician supervision unless independent practice is authorized by the State.
- Added Doctors of Dental Medicine or Surgery (D.D.M./D.D.S.) who may qualify as PPM lab directors or testing personnel if:
 - Licensed by the state in which laboratory is located

PPM Procedures

- All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- All potassium hydroxide (KOH) preparations
- Pinworm examinations
- Fern tests
- Post-coital direct, qualitative examinations of vaginal or cervical mucous
- Urine sediment examinations

April 1995 – added....

- Nasal smears for granulocytes,
- Fecal leukocytes and
- Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

What Makes PPM Procedures Special?

- **Specimens are labile** or a testing delay could compromise accuracy of results
- Limited specimen handling or processing required
- Testing **MUST** be performed during the patients' visit
- Tests performed only by qualified providers
- The equipment used is bright-field or phase-contrast microscopy
- **Control materials generally not available to monitor the entire testing process**

Laboratories Eligible to Perform PPMPs

- Not subject to routine (biennial) inspections, but a CLIA certificate is required
- Must meet applicable quality standards in CLIA
- Subject to inspection requirements as specified at 42 CFR §493.1775 (b)

PPMPs

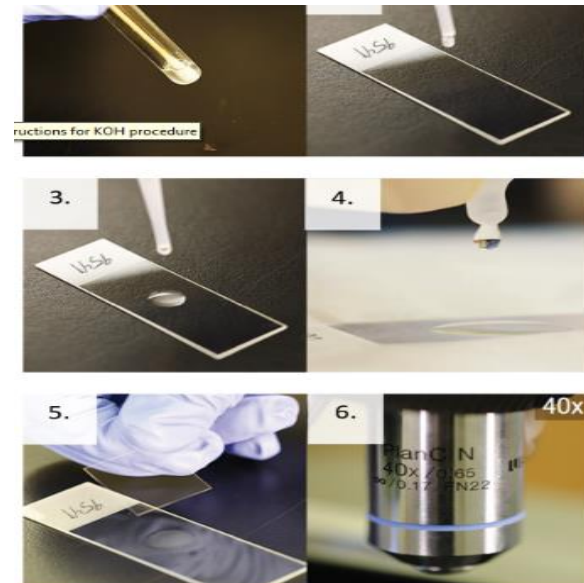
- 1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- 2) All potassium hydroxide (KOH) preparations
- 3) Pinworm examinations
- 4) Fern tests
- 5) Post-coital direct, qualitative examinations of vaginal or cervical mucous
- 6) 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)

Direct Wet Mount Preparations

Document Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All Direct Wet Mount Preparations</u>				
Scabies		Parasitology	MODERATE	09/12/1994
<u>All Direct Wet Mount Preparations</u>				
Aerobic &/or anaerobic organisms-unlimited sources		Bacteriology	MODERATE	07/26/1993
<u>All Direct Wet Mount Preparations</u>				
Trichomonas		Parasitology	MODERATE	07/26/1993
<u>All Wet Mount Preparations for Fungi</u>				
Fungi - fungal elements only		Mycology	MODERATE	07/26/1993

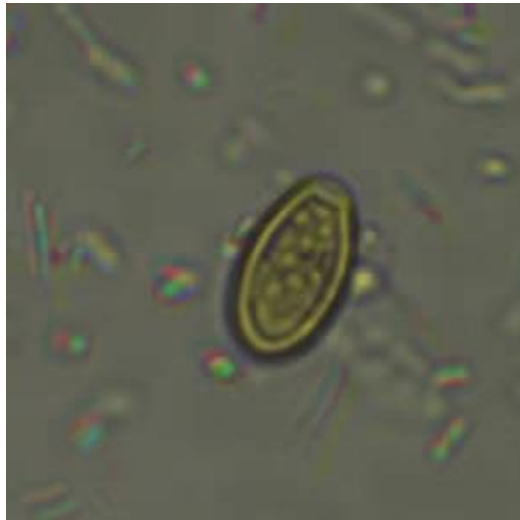
Potassium Hydroxide (KOH) Preps

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All KOH Preparations (bright-field light microscope)</u>					
		Fungi - fungal elements only	Mycology	MODERATE	07/26/1993



Pinworm Examinations

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All Pinworm Preparations</u>					
		Enterobius vermicularis	Parasitology	MODERATE	07/26/1993



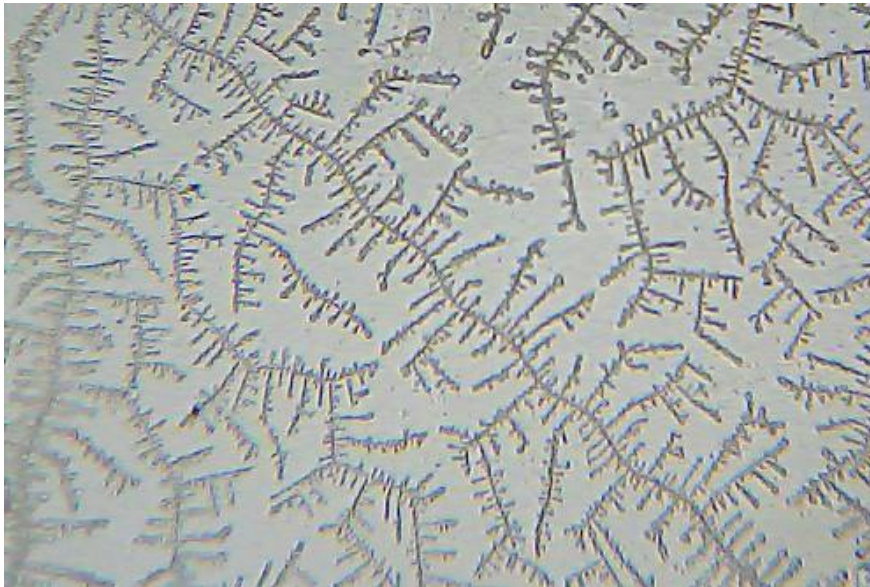
Artifact



Pinworm eggs

Fern Tests

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>Fern Test</u>		Body fluid microscopic elements	Hematology	MODERATE	07/26/1993



Microscopic view of the Fern pattern of amniotic fluid

Post-coital direct, qualitative examinations of vaginal or cervical mucus

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>Post-coital dir qualitative examination of Vag fld/Cerv Mucus (Huhner Test)</u>					
		Sperm-vaginal fluid/cervical mucus interaction	Hematology	MODERATE	01/29/1999



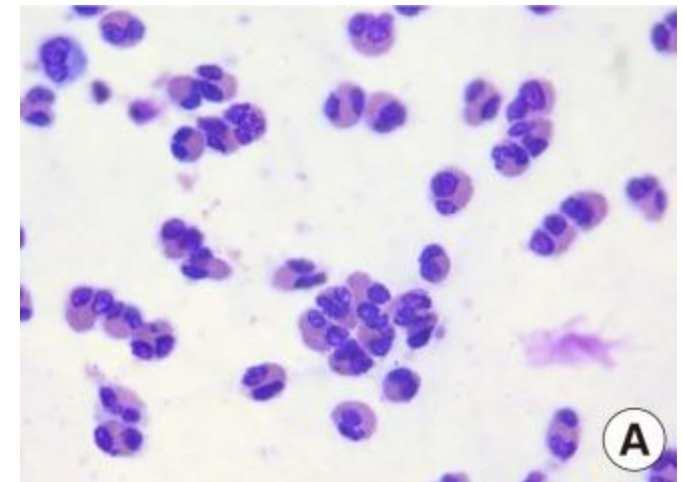
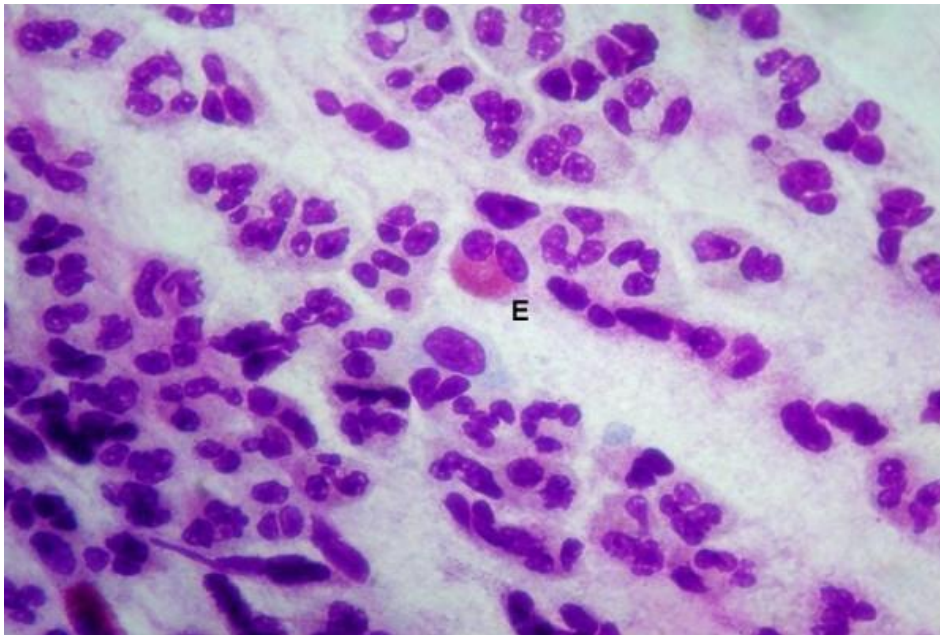
Urine Sediment Examinations

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All Manual Microscopic Analysis of Urinary Sediment</u>					
		Urinary sediment microscopic elements	Urinalysis	MODERATE	07/26/1993



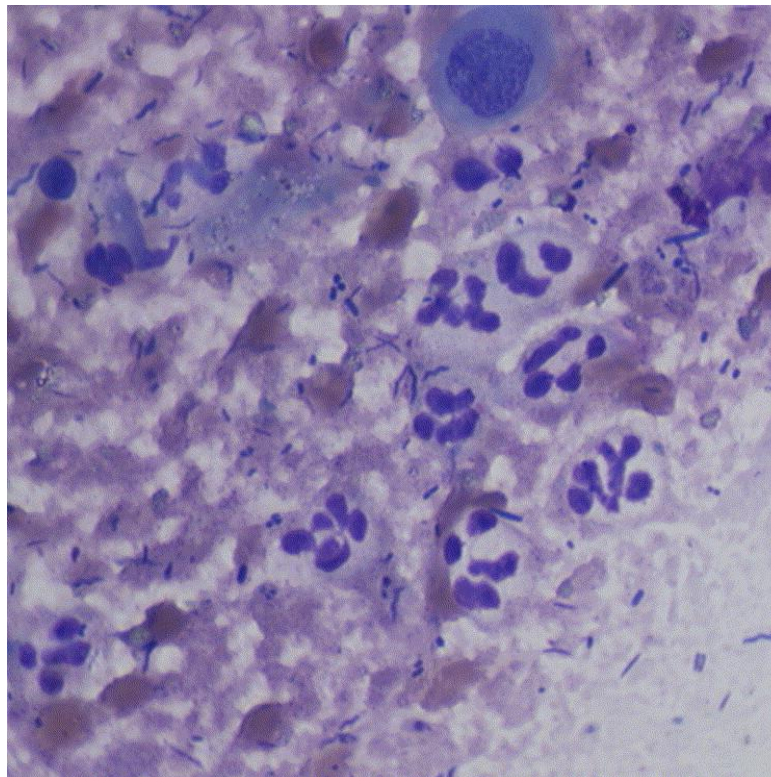
Nasal Smears for Granulocytes

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All Nasal Smears for Eosinophils</u>					
		Eosinophils	Hematology	MODERATE	07/26/1993



Fecal Leukocyte Examinations

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All Methylene Blue Wet Mount Preps for Fecal Leukocytes</u>					
		Leukocytes, fecal	Hematology	MODERATE	04/05/1996



Qualitative Semen Analysis

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
<u>All Manual Semen Analyses (presence or absence only)</u>					
		Semen	Hematology	MODERATE	07/26/1993



Including
motility

PPM Laboratory Director Qualifications

To obtain a Certificate for PPM, the laboratory director must be qualified as a:

- M.D., D.O., or D.P.M. licensed to practice in the State in which the laboratory is located,
- Midlevel practitioner (nurse midwife, nurse practitioner, or physician assistant) who is authorized to practice independently in the State in which the laboratory is located, and, if required, is also licensed to practice in that state, or
- D.D.M./D.D.S. licensed to practice in the state in which the laboratory is located.

PPM Testing Personnel Qualifications

PPM testing personnel must qualify as a:

- Physician licensed in the state in which the lab is located (M.D., D.O., or D.P.M.),
- D.D.S./D.D.M. licensed in the state in which the lab is located, or
- Midlevel practitioner (licensed if required to be so in the state in which the laboratory is located) and they are:
 - under the supervision of a physician, or
 - practicing independently if authorized to do so by the State in which the laboratory is located

If microscopy testing is performed by testing personnel that do NOT meet this criteria, the examinations are MODERATE COMPLEXITY and the laboratory needs a Certificate of Compliance (CoC) or a Certificate of Accreditation (CoA).

PPM Testing Personnel Qualifications³¹ (continued)

Unless the Medical Technologist/Clinical Laboratory Scientist qualified in one of the categories described in the prior slides, a Medical Technologist/Clinical Laboratory Scientist **Does Not** qualify as testing personnel in a laboratory with a PPM certificate.

PPM Laboratory Director Responsibilities

The laboratory director must:

- Direct no more than 5 laboratories
- Ensure that the laboratory performs only the 9 types of PPM examinations and tests categorized as waived
- Ensure that the PPM testing is performed by qualified testing personnel (i.e. qualifying M.D., D.O., D.P.M., D.D.S./D.D.M., or midlevel practitioners) during the patient's visit
- Comply with the applicable CLIA requirements

PPM Testing Personnel Responsibilities

The testing personnel are responsible for

- Specimen processing,
- Test performance, and
- Reporting test results

The testing personnel must perform the tests using either bright field or phase-contrast microscopy

PPM Laboratories

Applicable CLIA Regulations

CLIA for PPM Testing

Facility and Retention Requirements

Test Records and Test Report

Patient Confidentiality

Specimen Integrity/Identity

Competency Assessment

CLIA for PPM Testing (con't)

Procedure Manual

Equipment and Maintenance

Proficiency Testing (if available) or twice annual verification of accuracy

Quality Assessment

Facility Requirements

Environment:

- clean workspace
- sufficient lighting
- appropriate utilities
- sufficient supplies/reagents

State requirements



Retention Requirements

Retain for at least 2 years:

- Records of testing
- Written procedures
- Records of activities performed in the laboratory
- Documentation of centrifuge and microscope maintenance



Test Records & Test Report

Test Records: The identity of the PPM testing personnel must be documented in the test record.

Test Report: The laboratory has policies and procedures for monitoring and correcting problems with test reporting.

Test reports: Retain, or at least be able to retrieve a copy of the original report (including final, preliminary and corrected reports) at least 2 years after the date of reporting.

Patient Confidentiality and Specimen ID/Integrity

- Laboratory ensures confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.
- Laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of result.



Competency Assessment of Testing Personnel

The laboratory must have a mechanism for assessing testing personnel competency. This is the laboratory director's responsibility.

Competency assessment should consider:

- Training and specific skills for test performance
- Proficiency in using a microscope
- Ability to detect and identify cellular elements present in a specimen
- Ability to differentiate significant elements from debris or artifacts

Competency Assessment

The 6 elements outlined in Subpart M (Personnel) generally define competency assessment; in PPM laboratories all six elements may not be applicable.

NOTE: There is no Technical Consultant (TC) in a PPM laboratory.



PPM Competency Assessment Recommendations

Some examples of competency assessment specific to PPM testing are:

- Understanding that PPM specimens are labile; therefore, they must be examined during the patient's visit
- Is the correct microscope type used (i.e. bright field or phase contrast)
- Does the provider perform the test and report results according to the laboratory's procedure
- Are testing personnel able to distinguish cellular elements from debris

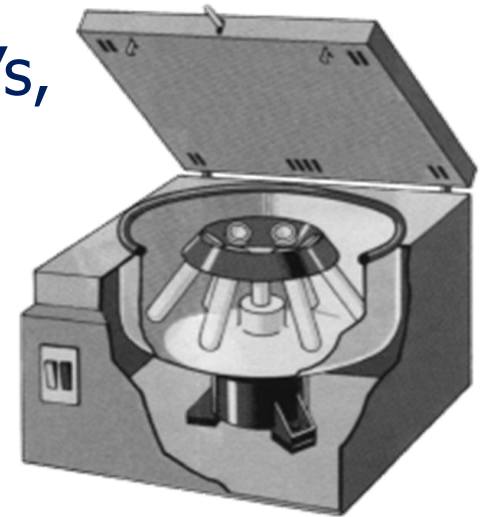
Procedure Manual, Reagents and Supplies

- The laboratory must have and follow an approved procedure manual
- The laboratory's reagents, solutions or supplies must be labeled appropriately and stored properly
- The laboratory must not use expired or deteriorated reagents, solutions or supplies



Maintenance and Function Checks

- The laboratory must perform and document maintenance on equipment (microscope, centrifuge)
- The laboratory must perform and document function checks (e.g. RPM's, timing)



Twice Annual Accuracy Verification

Twice annual accuracy verification

Any test or procedure performed that is not in Subpart I

- For a laboratory performing wet mount preparations for bacteria and fungi, KOH preparations, fern tests, post-coital direct exams of vaginal/cervical mucous, qualitative semen analysis and urine sediment examinations

Twice Annual Accuracy Verification (con't)

Twice annual accuracy verification

Any test or procedure listed in Subpart I for which compatible proficiency testing samples are not available by a CMS-approved PT program

- For a laboratory performing wet mounts for parasites and human cellular elements, pinworm examinations, nasal smears for granulocytes and fecal leukocyte examinations

Proficiency Testing Referral

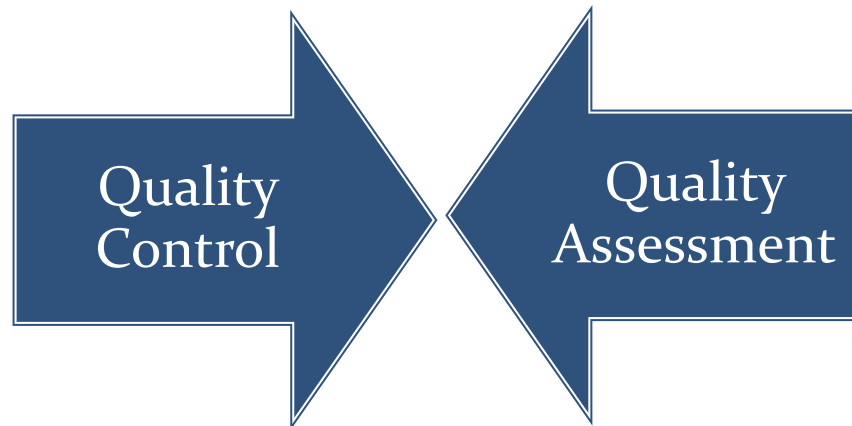
PPM laboratories can use enrollment in commercial microscopy modules to comply with verifying the accuracy of their testing at least twice annually (Commercial PPM testing modules provide two testing events annually)

- If the laboratories do enroll in PT, they are subject to all of the PT referral regulations

Quality Control

PPM examinations by definition are tests for which ***Control materials are not available to monitor the entire testing process.***

Availability of reference materials will meet the QC requirement.



Quality Assessment

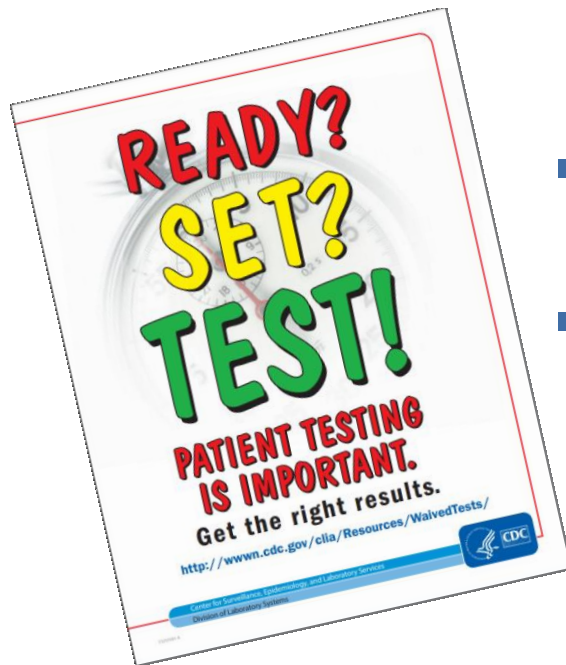
The laboratory should have an ongoing quality assessment component that monitors, identifies, evaluates, and resolves problems as appropriate for PPM testing.

CLIA Quality Assessment provides risk management to practitioners for their laboratory testing.

Waived Testing Performed with a PPMP Certificate

PPM laboratories may also perform waived testing

If waived testing is performed:



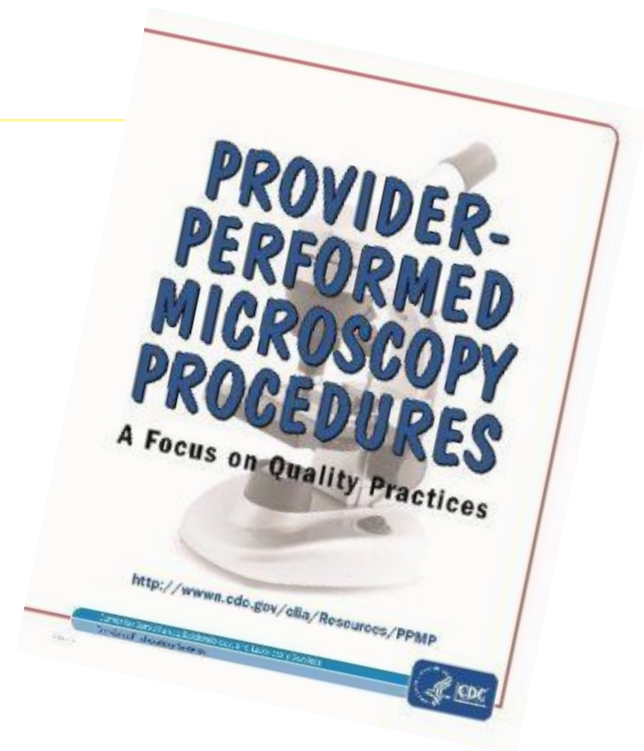
- The laboratory must have and follow the manufacturer's instructions
- For waived testing, there are no testing personnel qualification requirements

CLIA Update - The PPM Pilot Project

- There were 10 randomly selected states, (1 State per CMS Location) to participate in the pilot project
- Each state agency will survey 2% of the PPM laboratories in their State
- Surveys to begin January, 2020

CMS LOCATION/STATE
BOSTON
RHODE ISLAND
<u>NEW YORK</u>
NEW YORK
PHILADELPHIA
DELAWARE
<u>ATLANTA</u>
GEORGIA
CHICAGO
INDIANA
<u>DALLAS</u>
OKLAHOMA
<u>KANSAS CITY</u>
IOWA
<u>DENVER</u>
NORTH DAKOTA
<u>SAN FRANCISCO</u>
NEVADA
<u>SEATTLE</u>
OREGON

A Focus on Quality Practices



Tips for a PPM Laboratory



Tips

The following checklist summarizes the steps to be taken when implementing and overseeing PPM testing.

GENERAL REQUIREMENTS

- ✓ Understand the procedures that PPM laboratories or testing sites are allowed to perform.
- ✓ Obtain a CLIA Certificate for PPM before offering testing.
- ✓ Renew the Certificate for PPM every 2 years.
- ✓ Notify your State Agency of any changes in ownership, name, address, or director within 30 days, or if you wish to add tests that are not waived or PPM procedures.
- ✓ Allow announced or unannounced on-site inspections by CMS representatives.
- ✓ Follow all applicable CLIA requirements for testing:
 - Personnel
 - Facility Administration
 - Proficiency Testing
 - Quality System
 - Inspection
 - Enforcement
- ✓ Follow all applicable state and local requirements.
- ✓ Follow regulations for confidentiality and patient privacy.

Summary & Closing Remarks

Summary of our Discussion

- Summarized the history of the PPM CLIA certificate
- *Identified the PPM examinations and the personnel required specifically for a laboratory with a PPM certificate*
- Identified applicable CLIA regulations for a PPM certificate

Resources

[CMS CLIA Website](#)

[List of Provider-performed Microscopy Procedures](#)

[Interpretive Guidelines for Laboratories](#)

[Policy & Memos to States and Regions](#)

[List of Proficiency Testing Programs](#)

Resources (con't)

CDC Provider-Performed Microscopy (PPM) Procedures

CDC Waived Tests

CDC Free Educational Materials for Public Health and Clinical Laboratories

FDA CLIA Medical Devices Searchable Database

More Resources

Proficiency Testing & Competency Assessment Resources

AAFP 2020 PT Catalog

<https://www.aafp.org/practice-management/labs/about.html>

MLE 2020 PT Catalog

<https://www.acponline.org/practice-resources/business-resources/laboratory-proficiency-testing-program>

WSLH 2020 PT Catalog

<http://www.slh.wisc.edu/proficiency/clinical-pt-catalog-and-ordering/>

API 2020 PT Catalog

<https://www.api-pt.com/catalog.aspx>

CAP 2020 PT Catalog

<https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping>

AAB 2020 PT Catalog

<https://www.aab-pts.org/>

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Questions concerning this webinar may be sent to the following mailbox

LabExcellence@cms.hhs.gov

THANK YOU