WISCONSIN DEPARTMENT of HEALTH SERVICES

Clinical Laboratory Improvement Amendments (CLIA) Laboratory Provider Forum

CLIA Overview with Focus on Certificate of Waiver (CoW) and Provider Performed Microscopy (PPM) Certified Labs

State of Wisconsin
CLIA Team

February 21, 2024

Welcome

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Objectives

Provide information so laboratories can:

- Understand the CLIA application process;
- Perform Waived testing—regulatory requirements and best practices;
- Understand Provider Performed Microscopy (PPM) regulatory requirements.

Disclaimer: The information presented in this CLIA Provider Forum is for educational purposes only. Refer to Standards and Certification: Laboratory Requirements (42 CFR 493) for official CLIA Regulations.

To Ask a Question

- Click the Q&A button
- Type your question in the Q&A box and Submit
- Please DO NOT submit questions using the Chat Button

CLIA Program Oversight and Administration

- The Centers for Medicare & Medicaid Services
- The Food and Drug Administration
- The Centers for Disease Control and Prevention

CDC, Lab Training, Introduction to CLIA

Types of CLIA Certificates

CDC, Lab Training, Introduction to CLIA

CLIA Certificate Application and Renewal Processes

Charise Mancheski, License/Permit Program Associate

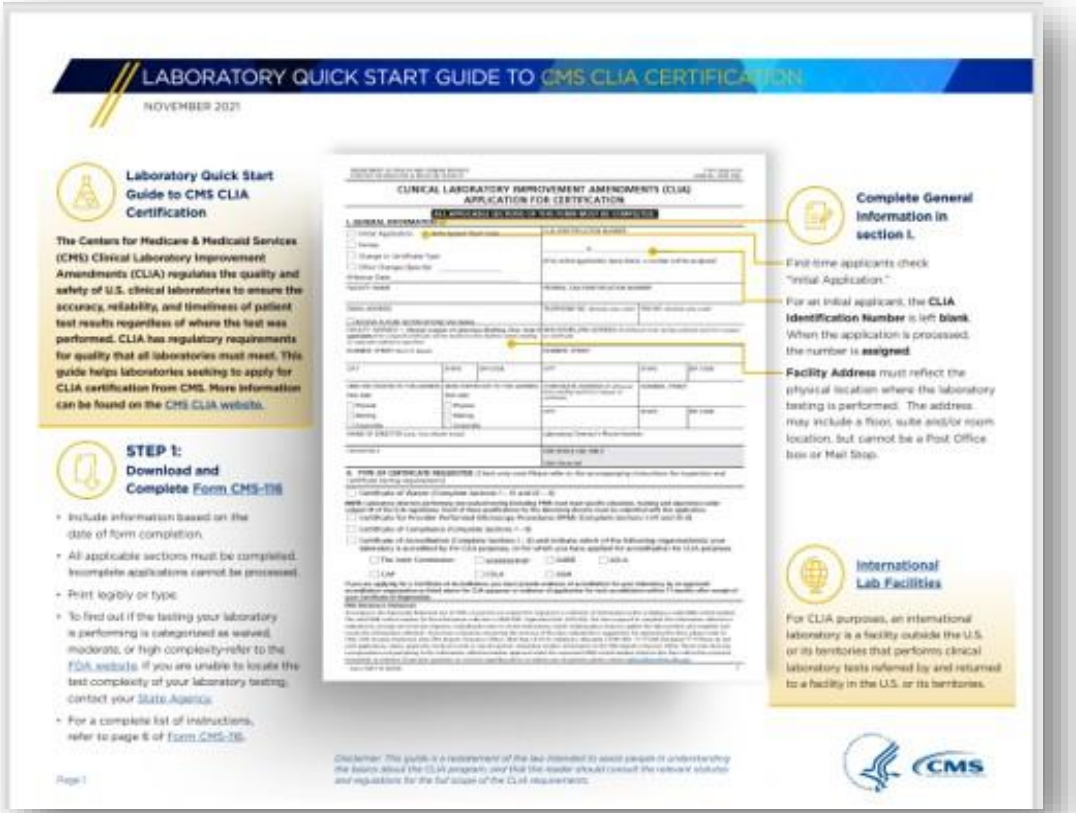
Obtaining a CLIA Certificate

- Who needs a CLIA Certificate?
  - Traditional and Non-traditional Settings
- Testing Not Subject to CLIA
  - Forensic
  - Research
  - TB Skin Testing
  - Breath Alcohol
  - Blood Collection
  - Continuous Blood Glucose Monitors

Each facility needs their own CLIA certificate.

CLIA Application “Quick Start Guide”

- Laboratory Quick Start Guide to CMS CLIA Certification
- CLIA Application CMS-116 Form
- Submit application questions or completed applications by email to: DHSDQACLIA@WI.GOV



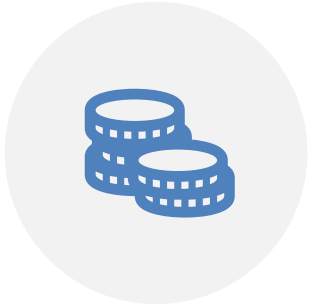
CLIA Application Hints and Tips

- Signature--Wet or Traceable Electronic
- Print Legibly or Type in On-line
- Fully completed—If updating, can request pre-populated 116 Form and just note changes.
- Example of Waived Test List Section—Covid, Drug, Blood Glucose, ICUP Alere
- Refer to FDA CLIA Database—Test Complexity Look-up website to determine the complexity level of the testing done in your laboratory--waived, moderate, or high complexity.
- Word of Caution: CLIAWaived.com
- Testing on-site and not just sample collection and/or processing.

Certificate Renewal Process

Frequency

Types of Fees Based on Certificate Type



Survey verses Certificate Fees

Certificate Fees*

- Certificate of Waiver (CoW) and Provider-Performed Microscopy (PPM) Certificates
  - CoW--$248 PPM--$297
- Certificate of Compliance (CoC) Certificate
  - Certificate Fee--$223 and up Survey Fee--$446 and up
- Certificate of Accreditation (CoA) Certificate
  - Certificate Fee--$223 and up Validation Survey Fee--$22 and up
- Certificate of Registration (CoR)
  - One-time registration for labs applying for CoC or CoA
  - Flat fee of $123 plus applicable Survey Fee for Initial Survey

**New Fee Schedule Effective January 27, 2024.*
Reach out to your State Agency for current fee schedule.

CLIA Activities with Additional Fees

- Lab adds a specialty and SA surveys outside of the CoC survey cycle to determine compliance with new testing.
- State Agency (SA) performs a follow-up survey or revisit to confirm correction of deficient practice found during a CoC survey or a validation survey of a CoA lab.
- SA performs a complaint survey and the complaint is substantiated.
- SA conducts a desk review of unsuccessful proficiency testing performance.

Fee Payments

- Payment Process
  - Invoices
  - How to Pay
    - Paying CLIA Fees Online Guide
    - Pay.gov - CLIA Laboratory User Fees

Fee Payments FAQ's

- **When can the Lab begin testing?**
  - Anytime after fees are paid and received by CMS
- **What form of payment does CMS accept?**
  - Checks sent in the mail
  - On-line payments by Credit Card, Debit Card or ACH Bank Account
  - Note: Purchase orders are not accepted for payment.

Fee Payments FAQ's (cont.)

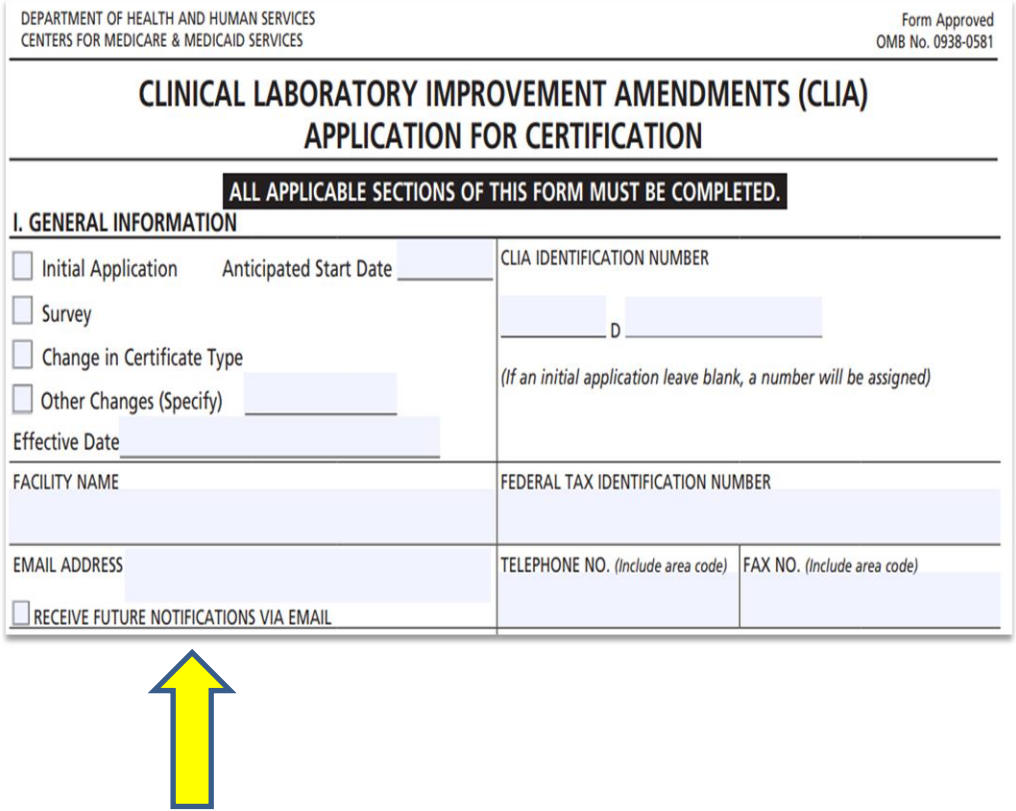
- **What happens if CMS does not receive payment?**
  - Initial—CoW & PPM will terminate for non-payment after 6 months.
  - Renewal--Certificate will expire.
    - Lab is unable to perform testing until payment is received.
    - May result in test reimbursement issues for lab.

Fee Payments FAQ's (cont.)

- **Where can a Lab get an invoice?**
  - From CMS, not the State Agency
  - CMS mails or e-mails (if Lab opted in for email notifications) invoices directly 6 months before the certificate expires—applies to CoW, PPM & CoA only.
  - Important that the mailing or e-mail address for Lab is up to date.
  - Contact the State Agency for assistance.

Electronic Certificate Availability

- CMS will email a link to your CLIA certificate when available
- Also available via the CMS / CLIA website through the 'Laboratory Demographics Lookup' S&C QCOR (cms.gov)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____
☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

Lab Changes that Require a CMS-116 Form Submission within 30 Days of Change

- Lab Director Changes for Most Certificate Types*
- Ownership
- Certificate Type
- Reinstatement or Reactivation of Certificate
- Adding a Multi-site Exception--including adding Temporary Sites

Lab Changes that Only Require Written Notification

- Laboratory Name
- Lab Location
  Physical Address Change
- Mailing/Billing and/or Corporate Address
- Tax ID (EIN)
- Specialty or Subspecialty Change
- Total Test Volume
- Telephone or Fax Number
- Email Address and/or Opt-in for Email Notifications
- Accreditation Organization
- Multi-site Information Change
- CoW Lab Director
- Voluntary Closure or Termination
- Reinstatement without Gap
  Less than 6 Months
- Technical Supervisor
  High Complexity Testing

Lab Changes that Only Require Written Notification (cont.)

- Acceptable Written Notification Formats:
  - Email Preferred—Send to DHSDQACLIA@WI.GOV.
  - Letter, Fax, CMS-116 Form
- Must Include the Following Information:
  - Laboratory Name
  - CLIA Number
  - Name of the Laboratory Director and/or Owner
  - Change(s) and Effective Date
  - If making changes for multiple CLIA certificates, may send information on a spreadsheet.

Certificate of Waiver (CoW) Laboratories

Anita Iwanski, Laboratory Certification Officer

What are Waived Tests?

- Tests that the FDA has categorized as waived testing complexity or has cleared for home use.
  - Must be simple to perform
  - Have a low risk for an incorrect result
  - Only performed on unprocessed samples
    - Examples: whole blood, urine, specimen collected on a swab, stool, saliva
  - Examples of waived tests include:
    - Glucose meters, urine dipsticks, Covid antigen testing, fecal occult blood, Prothrombin Time/INRs
    - FDA Waived Analyte List

Waived tests are not completely error-proof.
To reduce the risk of erroneous results, train personnel to perform the test according to the manufacturer's instructions and provide a safe environment where good testing practices are followed.

What are CLIA Requirements for Performing Waived Testing?

- Enroll in the CLIA program and obtain a Certificate of Waiver.
  - Pay the certificate fee every two years.
  - Notify State Agency (SA) of any changes as previously described.
  - Allow inspections/surveys by a CMS agent, typically SA Staff.
    - CoW Labs are not routinely inspected
    - May be surveyed because of a complaint--unannounced
    - Special surveys such as COVID public health reporting survey
- Follow the current manufacturer's instructions for the waived testing being performed.

Manufacturer's Instructions
aka Package Insert or Instructions for Use (IFU)

Intended Use	Sample Collection and Preparation
Summary	Test Procedure
Test Principle	Interpretation of Results
Precautions	Quality Control
Storage and Stability	Limitations
Reagents and Materials Supplied	Expected Values
Materials Required but Not Provided	Performance Characteristics

Manufacturer's Instructions—Common Components

- Intended Use, Summary, Test Principle
  - Substance detected or measured
  - Test methodology
  - Diagnostic or screening a target population
  - FDA cleared conditions for use—including professional use or self-testing
- Precautions
  - Alerts the user of practices or conditions affecting the test, potential hazards and safety precautions.
  - Ex: Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

Manufacturer's Instructions—Common Components (cont.)

- Storage and Stability
  - Recommended storage conditions—temperature and other requirements (humidity, exposure to light) affecting reagent stability
  - Ex: Store kit at 2-30°C (36-86°F). Kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.
- Reagents and Materials Supplied
- Materials Required but Not Provided
  - Ex: Clock, timer or stopwatch
  - Ex: Materials Available as an Optional Accessory--Swab Transport Tube Accessory Pack

Manufacturer's Instructions—Common Components (cont.)

- Sample Collection and Preparation
  - Detailed procedure for collecting the appropriate sample
  - Handling and storage instructions
  - Sample acceptability criteria
- Test Procedure
  - Step-by-step instructions
  - Information critical to correctly performing the test
  - Ex: Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.
  - Ex: Important: Ensure that enough blood is applied to fill the check window and it turns red.

Manufacturer's Instructions—Common Components (cont.)

- Interpretation of Results
  - Instructions on how to read or interpret the test results
  - Often includes visual aids and instructions for invalid result follow-up
  - Ex: A positive specimen will give two pink/purple-colored lines. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple-colored line is positive.
  - Ex: High Blood Glucose Readings
    - If your blood glucose is above 600 mg/dL, you will receive a "Hi." Repeat the test with a new test strip. If this message shows again, contact your healthcare professional immediately!
    - Contact your physician for advice if test results are very high (above 240 mg/dL) and/or you have symptoms of high blood glucose. These symptoms include dry mouth, thirst, frequent urination, nausea, vomiting, blurred vision, sleepiness, or abdominal pain. Symptoms will vary person to person. You may have one or all of these symptoms.

Manufacturer's Instructions—Common Components (cont.)

- Quality Control (QC)
  - Instructions for how and when to perform QC
  - Use of Internal vs External QC
  - Ext. QC Ex: Kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator.
  - Ext. QC Ex: Before testing with the ReliOn® Confirm blood glucose meter for the first time. Whenever you suspect the meter or test strips may not be functioning properly. If test results appear to be abnormally high or low or are not consistent with clinical symptoms. To check your technique. When the ReliOn® Confirm blood glucose meter has been dropped or stored below 32°F (0°C) or above 122°F (50°C).

Manufacturer's Instructions—Common Components (cont.)

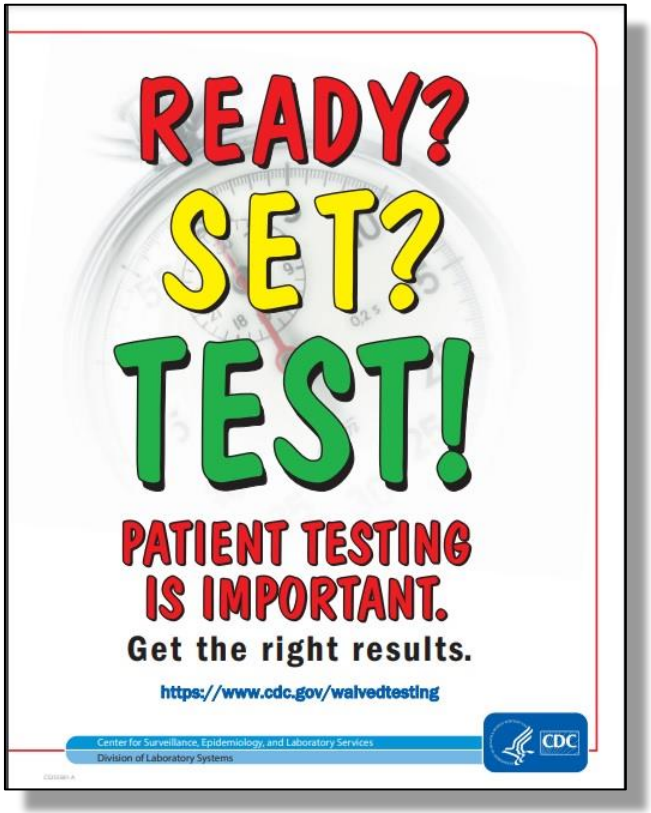
- Limitations
  - Conditions that can affect test results—Disclaimers
- Expected Values
- Performance Characteristics
  - Data and analysis for all the studies done to evaluate the test performance.

Special Case: Glucose Meters in Assisted Living and Residential Care Facilities

- Who is doing the test and follow-up?—Glucose Meter Set-up, Specimen Collection, Reagent Checks, Applying Specimen, Reading and Interpretating the Result.
  - Reads and Follows Manufacturer's Instructions
  - Follow-up for Error Codes and Abnormal Results
- Establish a Glucose Monitoring Process/Procedure for Your Facility.
  - Maintain Glucose Meters and Reagents
    - Manage Training of Staff on Manufacturer's Instructions for Glucose Meters Used in the Facility
    - Reagent Strips Stored Correctly and Not Outdated
    - Cleaning and Damaged/Broken Glucose Meters
    - External QC Requirements
  - Continuous Glucose Monitoring Systems
  - Follow-up for Abnormal Glucose Results

CDC's Ready? Set? Test!

- Ready? Set? Test! Booklet
  - Recommended practices for non-tradition laboratory personnel that perform testing under a CLIA CoW
  - Contains tips, reminders, resources, and sample forms to use at your testing site



Ready—Prepare for Testing

Good Testing Practices

- Designated testing area is well-lit with adequate space
  - Maintain patient privacy (HIPPA)
  - Safely provide testing—clean, dry, uncluttered, handy waste disposal
  - Proper temperature and ventilation for testing
  - Point-of-Care—consider bringing testing area to the patient on a cart
- Adequate inventory of reagents/kits and availability of required test materials required but not supplied
  - Reagents/kits stored according to manufacturer's instructions
    - Storage temperatures recorded and monitored for acceptability
  - Consider purchasing inexpensive digital timers if test timing is required

Ready—Prepare for Testing (cont.)

Good Testing Practices

- Track shipments and expiration dates.
  - Note "Receive Date" on packages.
  - Discard expired reagents and kits.
  - Make sure to not mix reagents from different kits.
- Use the Manufacturer's Instructions supplied with the reagents/kits.
  - Check Manufacturer's Instructions for changes with each new lot of reagents/kits. Look at the version date.
  - If changes, file old instructions with date retired and use new instructions.
  - Communicate changes in the Manufacturer's Instructions to other testing personnel.

Ready—Prepare for Testing (cont.)

Good Testing Practices

- Perform equipment maintenance and/or calibration checks as required by the manufacturer's instructions.
- Perform QC Testing and Track QC Results
  - Internal QC results can be tracked along with the test result.
  - External QC results can be tracked on separate QC log.
  - Follow-up for Unexpected QC Results
    - Manufacturer's instructions followed? New Trainee? Change in instructions?
    - Reagents/Kits stored properly and not outdated?
    - Follow troubleshooting steps in the manufacturer's instructions
    - Contact the manufacturer if unable to resolve. Have the lot number ready.

Ready—Prepare for Testing (cont.)

Good Testing Practices

- Training and Documentation
  - If more than one person will be performing testing, designate a testing lead.
  - Develop a Training Plan and Training Checklist
    - Read the Manufacturer's Instructions.
    - Utilize on-line training resources provided by the manufacturer.
    - Practice collecting the specimen as applicable.
    - Perform the test with External QC and/or a practice sample.
    - Review the entire testing process from test orders, patient preparation, specimen collection, sample labeling, testing, result reporting and documentation.

Ready—Prepare for Testing (cont.)

Good Testing Practices

- Safe Work Practices
  - Wear appropriate personal protective equipment (PPE).
  - Clean hands and change gloves between patients.
  - Follow OSHA guidelines for bloodborne pathogen exposure as applicable.
  - Do not eat, drink, or apply cosmetics in the testing area.
  - Dispose of test materials according to Manufacturer's Instructions.
  - Disinfect work surfaces before performing any test procedure, whenever there is visible contamination, and before leaving the testing area.

Set—Patient Preparation and Sample Collection

Good Testing Practices

- Test Orders
- Patient Identification
  - 2 Identifiers are best—Name and Birthdate as minimum
  - Ask patient to confirm their identity
- Patient Preparation and Questions
- Sample Collection according to Manufacturer's Instructions
- Sample or Device Labeling
  - Label at the patient's side
  - 2 Identifiers are best
  - Consider a unique sample/accession number (022124-1, 022124-2)

Test—Testing and Reporting

Good Testing Practices

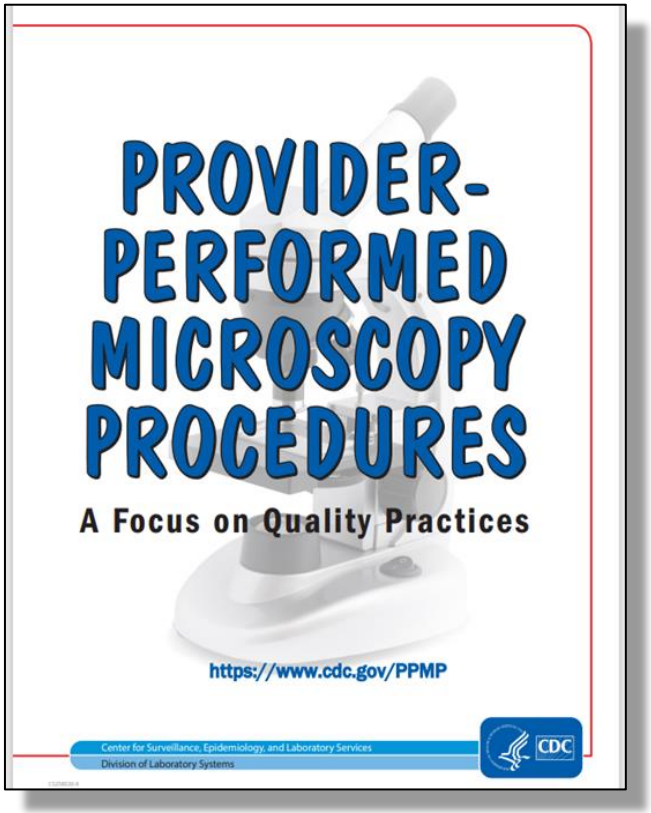
- Testing is only done by trained testing personnel.
- Check the expiration dates of the reagents/kits in use.
- Check if QC needs to be done and complete if needed.
- Bring reagents/kits to room temperature as applicable. Inspect the reagents/kits for damage or discoloration. Discard if found.
- Follow the current Manufacturer's Instructions or Quick Reference Guide in the kit and perform test on an acceptable sample.
- Record the test result on a Result Log—either paper or electronically.
- Report results per procedure and only to authorized individuals.
- Maintain records for 2 years.

Provider Performed Microscopy (PPM) Laboratories

Angela Mack, CLIA Section Manager

CDC's PPM Procedures Booklet

- Provider-Performed Microscopy Procedures: A Focus on Quality Practices
  - Contains an overview of regulatory requirements, sample forms and an overview with images of nine specific PPM procedures



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

NOTE: Under PPM, the testing site may also perform all waived tests

Who can perform PPM testing?

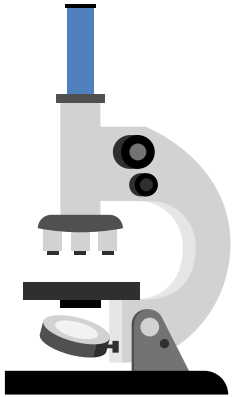
- Physician
- Mid-level Practitioner (Nurse Midwife, Nurse Practitioner, Physician Assistant)
- Dentist

All must be licensed by the State of Wisconsin

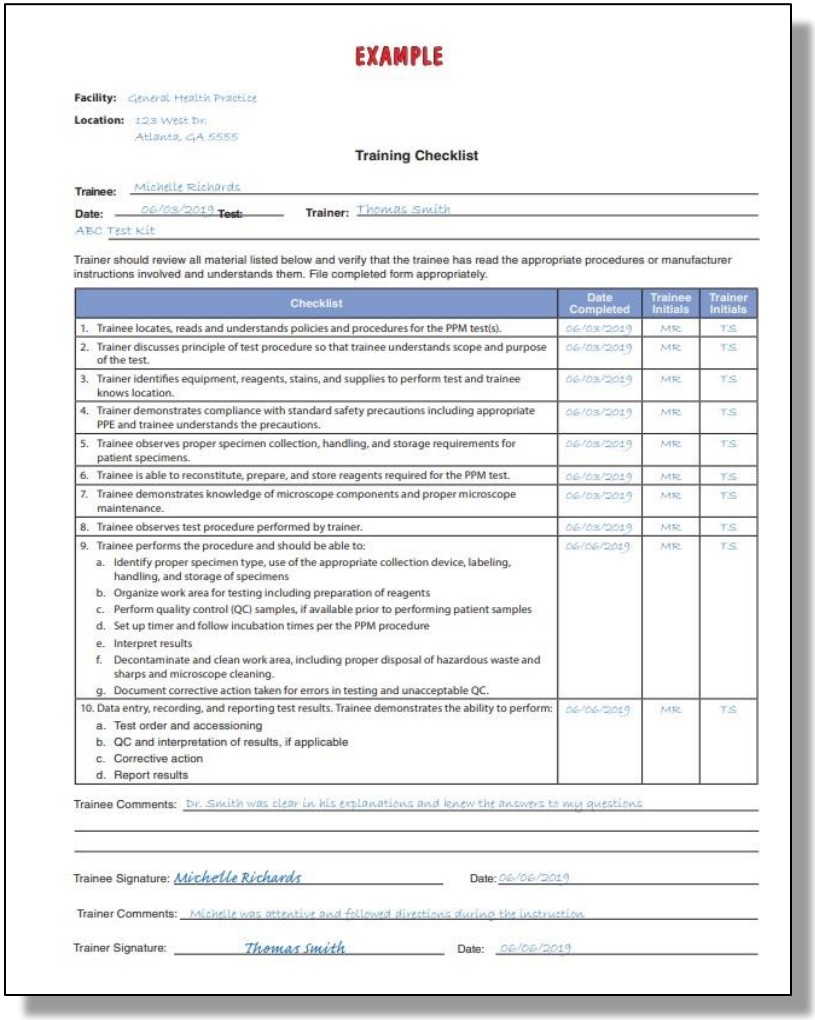
Registered Nurses (RNs), Medical Assistants (MAs), Medical Technologists (MTs/MLSs) and Technicians (MLTs) are not allowed to perform PPM testing under a PPM CLIA certificate.

Testing Personnel Training

- A Qualified Person should have Knowledge of:
  - Microscope Use and Maintenance
  - Accurate Performance of the Test(s)
  - Good Laboratory Practices
  - Safety Practices
    - Universal Precautions
    - Handling Hazardous Waste
    - Appropriate Use of Personal Protective Equipment (PPE)



Training Checklist Example



EXAMPLE

Facility: General Health Practice

Location: 123 West Dr.
Atlanta, GA 5555

Training Checklist

Trainee: Michelle Richards

Date: 06/03/2019 **Test:** ABO Test Kit **Trainer:** Thomas Smith

Trainer should review all material listed below and verify that the trainee has read the appropriate procedures or manufacturer instructions involved and understands them. File completed form appropriately.

Checklist	Date Completed	Trainee Initials	Trainer Initials
1. Trainee locates, reads and understands policies and procedures for the PPM test(s).	06/03/2019	MR	TS
2. Trainer discusses principle of test procedure so that trainee understands scope and purpose of the test.	06/03/2019	MR	TS
3. Trainer identifies equipment, reagents, stains, and supplies to perform test and trainee knows location.	06/03/2019	MR	TS
4. Trainer demonstrates compliance with standard safety precautions including appropriate PPE and trainee understands the precautions.	06/03/2019	MR	TS
5. Trainee observes proper specimen collection, handling, and storage requirements for patient specimens.	06/03/2019	MR	TS
6. Trainee is able to reconstitute, prepare, and store reagents required for the PPM test.	06/03/2019	MR	TS
7. Trainee demonstrates knowledge of microscope components and proper microscope maintenance.	06/03/2019	MR	TS
8. Trainee observes test procedure performed by trainer.	06/03/2019	MR	TS
9. Trainee performs the procedure and should be able to: a. Identify proper specimen type, use of the appropriate collection device, labeling, handling, and storage of specimens b. Organize work area for testing including preparation of reagents c. Perform quality control (QC) samples, if available prior to performing patient samples d. Set up timer and follow incubation times per the PPM procedure e. Interpret results f. Decontaminate and clean work area, including proper disposal of hazardous waste and sharps and microscope cleaning. g. Document corrective action taken for errors in testing and unacceptable QC.	06/06/2019	MR	TS
10. Data entry, recording, and reporting test results. Trainee demonstrates the ability to perform: a. Test order and accessioning b. QC and interpretation of results, if applicable c. Corrective action d. Report results	06/06/2019	MR	TS

Trainee Comments: Dr. Smith was clear in his explanations and knew the answers to my questions

Trainee Signature: Michelle Richards Date: 06/06/2019

Trainer Comments: Michelle was attentive and followed directions during the instruction

Trainer Signature: Thomas Smith Date: 06/06/2019

Testing Personnel Competency Assessment

The following six procedures are the minimum regulatory requirements for assessment of competency for all personnel performing testing:

1. **Direct observations** of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. **Monitoring** the recording and reporting of test results;
3. **Review** of intermediate test results or worksheets, QC records, PT results, and preventive maintenance and corrective action records;
4. **Direct observations** of performance of instrument maintenance (microscopes) and function checks;
5. **Assessment of test performance** through testing previously analyzed specimens, internal blind testing samples or external PT samples; and
6. **Assessment of problem-solving skills**

PPM Competency Assessment FAQ's

- **Do all six procedures of competency assessment need to be performed at the same time each year?**
  - No, competency assessment can be done throughout the entire year.
  - Coordinate the competency assessment with routine practices and procedures to minimize impact on workload.
- **May I use Proficiency Testing (PT) performance to assess competency?**
  - Yes, PT performance may be used as part of your competency assessment; but use of PT performance alone is not sufficient to meet all six required procedures.

PPM Competency Assessment FAQ's (cont.)

- **I am a sole practitioner and perform all of my own laboratory testing; does CLIA require that I have written policies for assessing my own competency?**
  - Need to establish a minimal level of proficiency to demonstrate your competency
  - Accomplished via proficiency testing or comparisons with a peer entity
  - Need to ensure that you maintain the required competency

PPM Competency Assessment FAQ's (cont.)

- **My laboratory performs only provider-performed microscopy (PPM) and a mid-level practitioner performs the testing; do I need to perform a competency assessment on this person?**
  - Yes, if the individual is performing this type of non-waived testing.
  - The competency assessment should include all six elements.

Preparation and Equipment

- Adequate Space with Clean Work Surfaces and Good Lighting
- Privacy
- Flat Surface for Microscope
- Environmental Requirements such as Temperature and Humidity
- Storage and Supplies

Test Order and Specimen Collection

Before Collecting a Specimen, Confirm:

- Test Order: Written or Electronic Order from Authorized Person
- Patient Identification

SPECIMEN COLLECTION

- Specimen Type
- Collection Method
- Proper Labeling of Specimen

Performing the Test

- Test Procedures: Procedure manual must include specific instructions for each PPM procedure.
- Quality Control: Perform as recommended per regulations and laboratory policies.
- Recording Results: Need to be legible and reported in a timely manner.
- Reporting Results: Only report to authorized persons and document verbal reports which should be followed by a written report.

Proficiency Testing (PT) and Quality Assessment (QA)

- PT: Verifies accuracy and reliability of tests
  - Lab must verify accuracy of testing at least twice per year.
  - PT is a good tool to meet this regulatory requirement.
- QA: Lab must develop a quality system that includes an ongoing QA component that monitors, identifies, evaluates, and resolves problems as appropriate for PPM testing.

Document communication and complaint issues. Use problems or issues to improve quality.

CLIA Resources

CLIA Resources

- Standards and Certification: Laboratory Requirements (42 CFR 493)
- Survey Procedures and Interpretive Guidelines for Laboratories
  - Also know as the State Operations Manual (SOM), Appendix C
- DHS Survey Guide for Clinical Laboratories
- CLIA Brochures
  - How to Obtain a CLIA Certificate of Waiver
  - What Do I Need to Do to Assess Personnel Competency?
- FDA CLIA Database—Test Complexity Look-up

CLIA Resources

- Department of Health Services (DHS) CLIA Webpage
  - The "Memos, Publications, & Resources" tab has links to many of the CLIA Survey Resources and additional federal resources.

Just type "CLIA" in the DHS Search box to get to the CLIA pages.

CLIA Educational Resources

- CDC Division of Laboratory Systems (DLS)

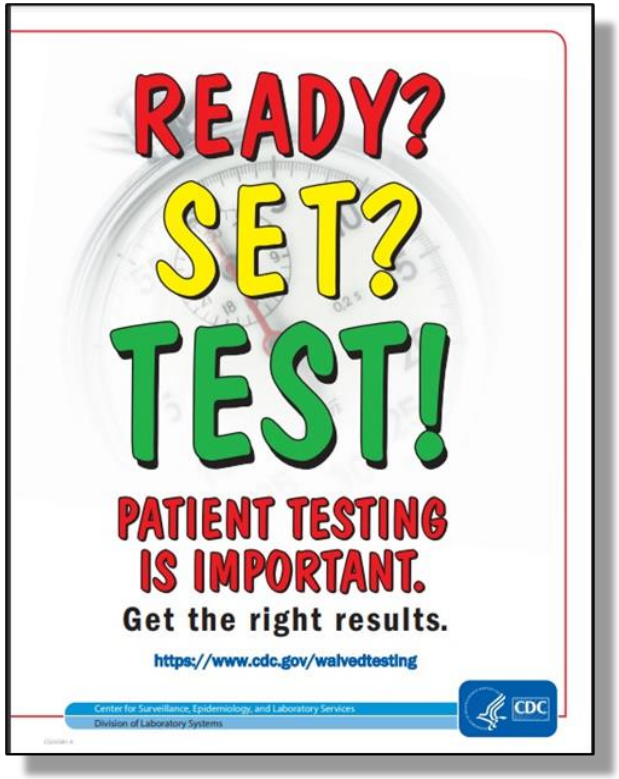
- Association of Public Health Laboratories (APHL) CLIA Resources

APHL recently launched their Learning Center. Sign up for a free account to access on-demand laboratory related training and resources

CDC Waived Testing Resources

CDC Waived Testing Webpage

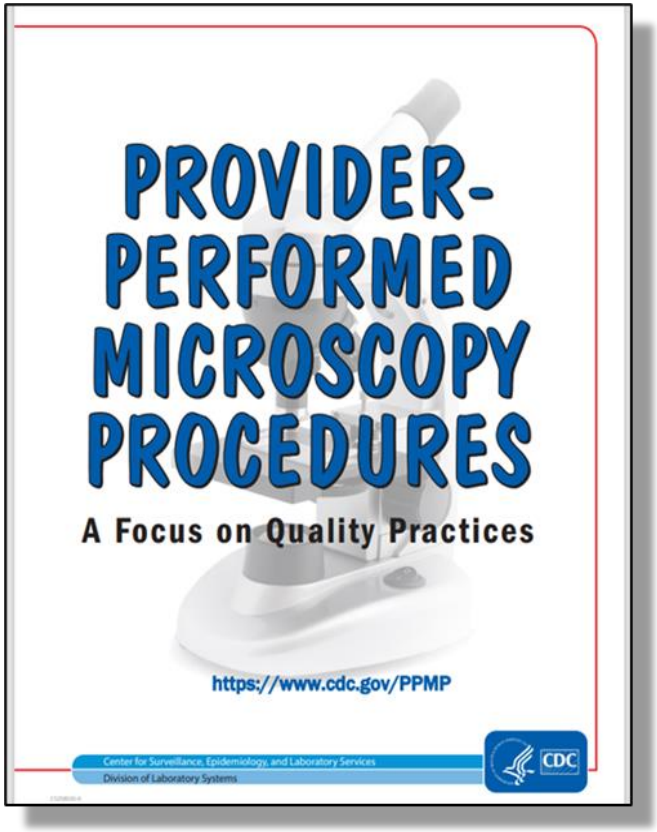
- MMWR Good Laboratory Practices for Waived Testing Sites
- Ready? Set? Test! Booklet
- Ready? Set? Test! Online Course
- Self-Assessment for Good Testing Practices



CDC PPM Testing Resources

CDC PPM Testing Webpage

- Provider-Performed Microscopy Procedures
- Provider-Performed Microcopy Procedures: An Introduction Online Course
- CDC Basic Microscopy Online Course
- Basic Microscopy Training Videos:
  - Microscope Components
  - Setting up a Microscope
  - Cleaning the Microscope
  - Focusing the Microscope



CLIA Educational Resources (cont.)

- CDC OneLab™

OneLab™
A Unified Response to Training Needs

CLIA Updates and Correspondence

- DHS GovD CLIA Message
  - Sign up to receive email notices about DQA and CMS CLIA memos, DQA Quarterly Information Updates, and health care policy-related information.
  - Join our email list *Look for the sign-up on the DHS CLIA Webpage.*
- DHS CLIA Mailbox
  - Email for all of your CLIA questions and correspondence.
  - DHSDQACLIA@WI.GOV

Questions and Answers

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DHS CLIA Forums Webpage

Webinar Recordings and Presentation Slides Posted

- **Forum I--November 29, 2023**
- Certificate of Compliance (CoC) Laboratory Survey Preparation and Process Part I
  - Survey Readiness and Organization of Documents and Records for Review
  - CMS-116 CLIA Application and CMS-209 Laboratory Personnel Report
  - Laboratory Personnel Responsibilities and Qualifications

- **Forum II--January 24, 2024**
- Certificate of Compliance (CoC) Laboratory Survey Preparation and Process Part II
  - CMS-2567 Statement of Deficiencies (SOD), Immediate Jeopardy, Response Requirements and Commonly Cited Deficiencies
  - Competency Assessment
  - Proficiency Testing and PT Referral
  - New Test Performance Verification

Thank You!