

WHAT IT MEANS TO HAVE A CLIA PPM CERTIFICATE

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Objectives

- General overview of CLIA
- Identification of types of CLIA certificates, focusing on the certificate for provider-performed microscopy (PPM) procedures
- Identification of PPM providers
- Personnel policies for PPM

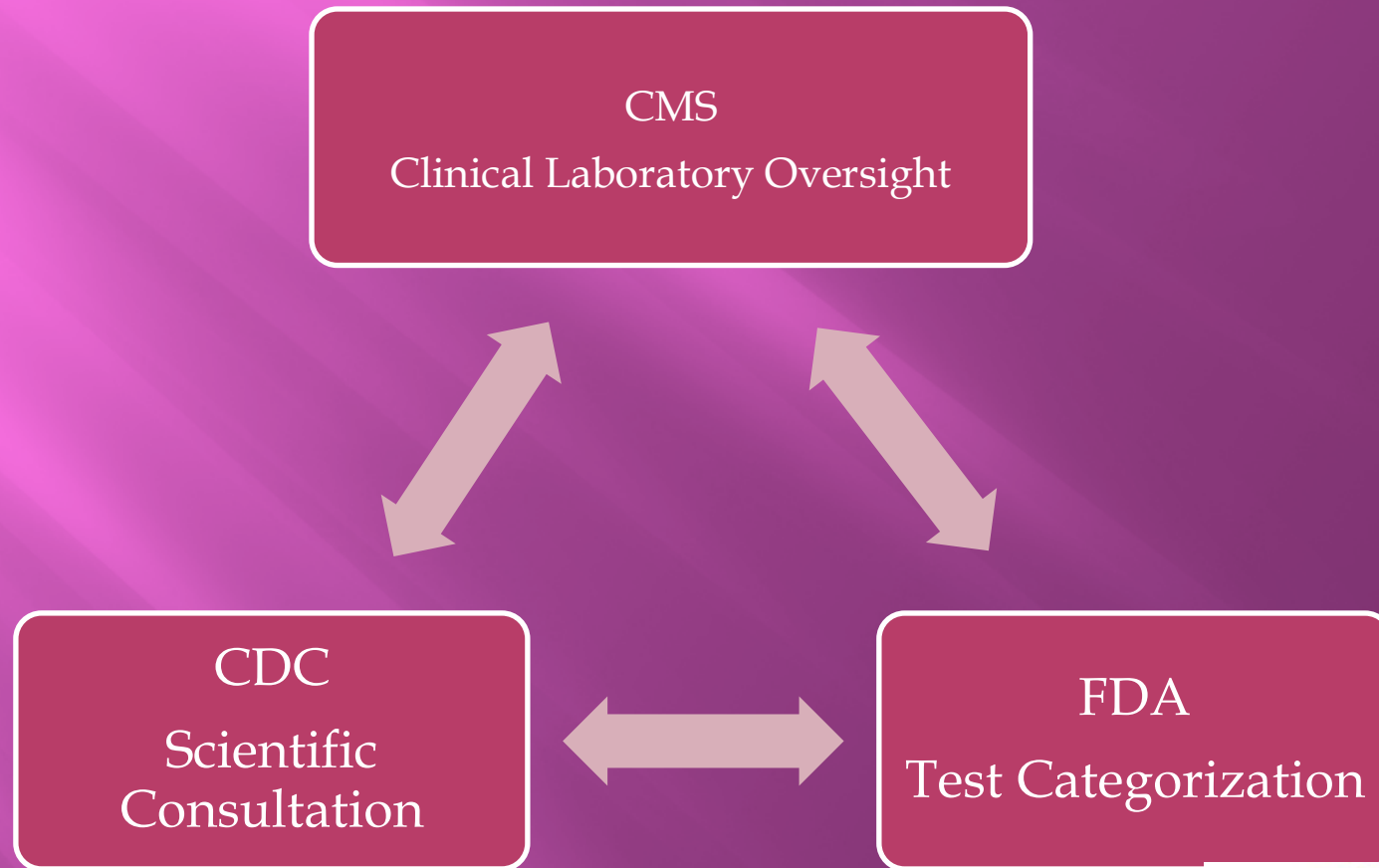
CLIA is...

- Clinical Laboratory Improvement Amendments (CLIA)
- Federal program that establishes quality laboratory standards to protect patient safety and improve health care

CLIA History

- 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 patient test results regardless of where the test was performed

CLIA Program Responsibilities



Laboratory (as defined by CLIA)

Any facility that examines human specimens 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 patient specimens must:

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

CLIA Test Complexity

- Waived testing
- Moderate complexity with subcategory of PPM procedures
- High complexity
- **Laboratories are certified at the highest level of testing performed**

CLIA Certificate Types

- Certificate of Waiver (COW)
- Certificate for Provider-Performed Microscopy (PPM) Procedures
- Certificate of Compliance (COC)
- Certificate of Accreditation (COA)

Current Enrollment Statistics

Total Number of Laboratories: 244,564

Total Non-Exempt: 236,882

- COC - 18, 959

- COA - 16,081

- PPM - 36, 784

- COW - 165,051

Total Exempt - 7,682

- NY - 3,810

- WA - 3,872



PPM History

- January 1993 – new CLIA certificate type (subcategory of moderate complexity testing)
Physician-performed microscopy
 - Allowed physicians to perform certain microscopic exams in addition to waived testing during patient's visit
 - Microscopic exams categorized as moderate complexity
 - Limited to bright-field or phase-contrast microscopy
 - Specimens labile or testing delay could compromise accuracy of results

PPM History (continued)

- Limited specimen handling or processing required
- Proficiency testing or control materials not available to monitor the entire testing process
- Not subject to routine inspections but a CLIA certificate is required
- Must meet other quality standards

PPM History (continued)

- April 1995 – Renamed to Provider-performed microscopy (PPM) to include other practitioners and to clarify tests that can be performed
 - Midlevel practitioners – licensed (if State required) nurse midwife, nurse practitioner, or physician assistant may test under physician supervision or independently if authorized by the State
 - Dentists may qualify as PPM lab directors or testing personnel

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 for vaginal or cervical mucous
- Urine sediment examinations

PPM Procedures (continued)

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

CLIA Requirements for PPM

- To obtain a Certificate for PPM, the laboratory director must be:
 - An M.D., D.O., D.P.M., or
 - D.D.S.
 - Licensed to practice in the State in which the laboratory is located
 - *Midlevel practitioner (nurse midwife, nurse practitioner, or physician assistant)*
 - *Authorized to practice independently in the State in which the laboratory is located*

CLIA Requirements for PPM (continued)

- PPM testing personnel
 - M.D., D.O., D.P.M.
 - D.D.S or
 - Midlevel practitioner under the supervision of a physician or in independent practice if authorized by the State in which the lab is located
 - If the testing personnel do NOT meet this criteria, the laboratory is performing moderate complexity testing and IS subject to routine inspections

CLIA Requirements for PPM (continued)

- All testing personnel in PPM labs are required to undergo competency assessment.
 - If a solo practitioner has a PPM lab, the solo practitioner must establish a minimal level of proficiency in order to demonstrate competency
 - PT samples could help accomplish this

CLIA Requirements for PPM (continued)

- Some things to consider for PPM competency assessment
 - Is the test actually performed during the patient's visit
 - Is the correct microscope type used (i.e. brightfield or phase contrast)
 - Does the provider perform the test and report results according to the lab's procedure

CLIA Requirements for PPM (continued)

- PPM examinations are subject to proficiency testing (PT)
 - Since there is no CMS-approved PT specifically for these examinations, labs holding a Certificate for PPM must verify the accuracy of their testing at least twice annually
 - If the labs do enroll in PT, they are subject to all of the PT requirements, including PT referral

CLIA Requirements for PPM (continued)

- Retain records for at least 2 years
- Standard operating procedure manual
- Microscope maintenance , including documentation
- Proper storage and labeling of reagents
- Documentation of room temperature

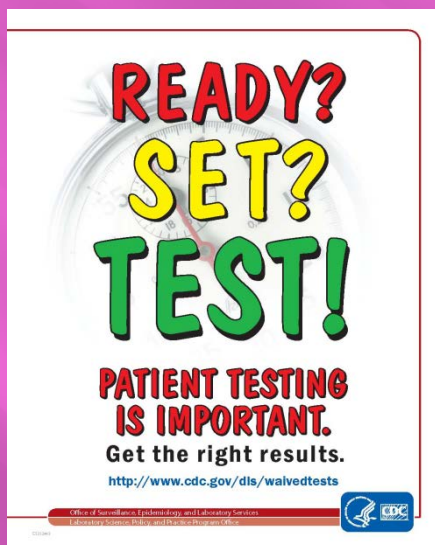
CLIA Requirements for PPM (continued)

- PPM labs can also perform waived testing
- If waived testing is included-
 - Follow the manufacturer's instructions
 - No personnel requirements for waived testing

CDC Educational Materials

- In addition to the information found on the CLIA website.....
 - CDC has published “Ready, Set, Test” booklet - describes recommended practices for physicians, nurses, medical assistants and others performing patient testing under a CLIA Waiver Certificate
 - CDC also offers an on-line training course corresponding to “Ready, Set, Test”.

Good Laboratory Practices for Waived Testing Sites



PATIENT TESTING IS IMPORTANT.
Get the right results.

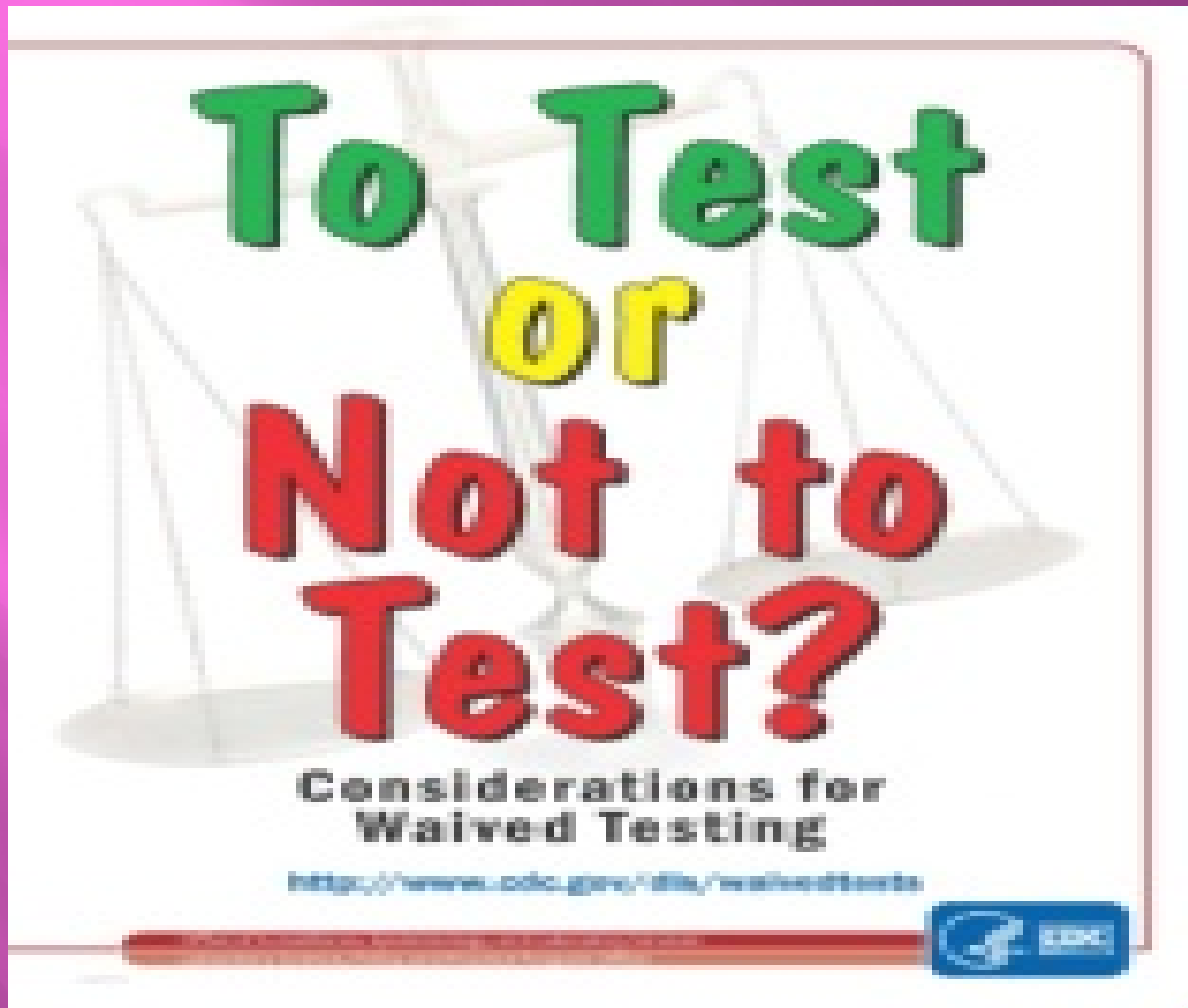
**READY?
SET?
TEST!**

- Have the latest instructions for ALL of your tests.
- Know how to do tests the right way.
- Know how and when to do quality control.
- Make sure you do the right test on the right patient.
- Make sure the patient has prepared for the test.
- Collect and label the sample the right way.
- Follow instructions for quality control and patient tests.
- Keep records for all patient and quality control tests.
- Follow rules for discarding test materials.
- Report all test results to the doctor.

<http://www.cdc.gov/dls/waivedtests>

CDC

More Food for Thought



Summary

- PPM – Provider – Performed Microscopy:
 - Includes 9 specific microscopic exams
 - Must use bright-field or phase-contrast microscope
 - Exams are performed during patient's visit
 - Exams are performed by qualified individuals

Summary (continued)

- Subject to applicable quality measures
- PT/twice yearly test accuracy verification
- Record retention (at least 2 years)
- SOPM
- If microscopy testing is performed by an individual NOT meeting provider requirements, the exams are MODERATE COMPLEXITY and the lab needs a COC or COA

Resources:

- CLIA Website
 - <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>
- CDC: Ready, Set, Test and To Test or Not to Test booklets
 - <http://www.cdc.gov/dls/waivedtests>

Resources:

- CLIA Brochure #7 - Laboratory Director Responsibilities
- CLIA Brochure # 8 - Proficiency Testing
- CLIA Brochure #10 - What Do I Need to Do to Assess Personnel Competency?
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html



THANK YOU

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