OVERVIEW AND UPDATES OF THE CMS CLIA PROGRAM

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Different Types of CLIA Certificates
Certificate of Waiver

- Laboratory that hold the Certificate of Waiver, may only perform those tests that have been given the “waived” status by the FDA.

- Fees for a CLIA Certificate of Waiver are $150.00 every two years.

- 5868 waived labs in Michigan
Laboratory that holds a PPMP certificate allows the providers and only the providers to use the microscope to perform laboratory tests while other staff members are able to perform the CLIA waived tests.

Examples of providers – physician or midlevel practitioner (nurse midwife, nurse practitioner, or physician assistant) or dentist 493.1357
Examples of PPMP Testing:

- Wet Mounts
- KOH Preps
- Urine Sediment Examinations
- Fern Test
- Scabies Preps
- Semen Analysis (Present/Absent)
• Fees for the Certificate of Provider Performed Microscopy Procedures are $200.00 every two years.

• 1,557 PPMP labs in Michigan
Laboratories that have a Certificate of Compliance (COC) are able to perform the waived, moderately, and highly complex tests.

Certificate of Compliance can inspect all types and levels of testing.

Laboratories are inspected every two years by the CLIA state agency inspectors.

Only pay one set of fees—only to CLIA

333 Compliance labs in Michigan
Certificate of Compliance

Total CLIA payment is billed in two parts

- Compliance fee—based on the number of tests performed by the laboratory. The invoice is sent out approx. 11 months before your certificate expires.
- Once paid, you will be surveyed.
- Once survey and deficiencies are corrected you will be billed for the certificate fee (smaller of the two).
- Once paid, the certificate will be mailed out 30 days before your current certificate expires.
Laboratories that have a Certificate of Accreditation (COA) are able to perform the waived, moderately, and highly complex tests.

Certificate of Accreditation can inspect all types and levels of testing. Exception is COLA—they are not certified to inspect Histopathology.

Laboratories are inspected every two years by one of the approved accrediting organizations.
• With a COA you are billed by your accrediting agency and by CLIA. You pay CLIA for your certificate fee and a validation fee.

• 542 COA labs in Michigan
Director Qualifications
The federal CLIA regulations do not have any qualifications for a director of a Certificate of Waiver.

One point to remember, the director is responsible for the testing performed.
Certificate of PPMP

The CLIA regulations at 493.1357 Must be one of the following:

- Physician
- Midlevel Practitioner authorized by a state to practice independently in the state in which the laboratory is located. (nurse midwife, nurse practitioner, or PA)
- Dentist

We will need a copy of the State of Michigan license
Moderate Director COC & COA

Director qualification can be found at 493.1405

- MD/DO certified in Anatomic or Clinical Pathology
- MD/DO with one year directing or supervising non-waived testing
- Complete a 20 CME director course
- Training during medical residency
- PhD that is certified by one of the boards that have been approved by CLIA
- Masters in chemical, physical, biological, clinical laboratory science or medical technology and have 1 year training or experience in non-waived testing AND 1 year supervisory laboratory experience in non-waived testing
• Bachelor’s in chemical, physical, biological, clinical laboratory science, or medical technology and have 2 years laboratory training or experience in non-waived testing AND 2 years supervisory laboratory experience in non-waived testing.
Director qualifications can be found at 493.1443

- MD/DO Certified in Anatomic or Clinical Pathology or both
- MD/DO 1 year of laboratory training during medical residency
- MD/DO with 2 years of experience directing or supervising high complex testing
- PhD and certified by one of the boards approved by CLIA
- DDS certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology
CLIA will always require copies of the supporting documents

- Medical Licenses
- Diplomas
- Board Certifications
- In some cases, documentation of experience

In some cases, if a physician is qualified as director does not mean that he/she automatically qualifies as TS/TC
REGULATIONS WAIVED VS. NON WAIVED
CLIA waived tests-two regulations

1. Have the manufacturer’s package insert for every test performed.
2. Follow the manufacturer’s instructions
Remember—a laboratory that performs PPMP is performing moderately complex testing and needs to follow the same regulations as other laboratories.
MULTIPLE SITE EXCEPTIONS
Multi Site Exceptions

- Listed on page 2 of the CLIA application CMS 116.

- Need to only answer yes to one of the three questions.
“Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using this address?”

- Things to consider—nothing is left at the location. You take all of your testing supplies (including patient charts) with you and you take it away at the end of the day.
- Examples: home health agencies, health fairs, ambulance, and mobile labs.
Is this a not-for-profit, or federal, state, or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?"

- The key points for this one is not-for-profit and a combination of not more than 15 different moderate or waived tests.
- Urine dips count as 1 test, urine drug screens—each drug is a test.
- If you include a CBC instrument, remember that can be up to 6 tests for each CBC.
“Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?”

- This is for different departments within the hospital (cath lab, OR lab, nursing units, ED lab)
- Not to be used for the professional building across the street that is attached by a crosswalk or the dialysis unit that is a separate building in the parking lot of the hospital.
PROFICIENCY TESTING
Proficiency testing: you are required to enroll in proficiency testing with one of the CLIA approved proficiency testing programs if you are performing one of the analytes off the regulated list.

Twice a Year Verification: when you perform testing that is not on the regulated analyte list you are not required to be enrolled in proficiency testing. You do have to do twice a year verification of accuracy for those tests.

- Some labs elect to just enroll in proficiency testing—it is easier
- The accrediting agencies might require you to enroll in proficiency testing regardless if it is a regulated analyte or not.
Proficiency Testing

- If you are testing one of the regulated analytes, then you are required to be enrolled in proficiency testing.

- To have it count as proficiency testing, it has to be 3 events with 5 challenges each.

- Can only use one of the CLIA approved PT providers.
Proficiency Testing and Surveys

Things we want to see on a survey when we look at PT:

- PT policy
- Rotation of samples among staff
- Testing the sample the same number of times patients are tested.
- Retention of PT documents
- Signed attestation statements by testing personnel and director/TC/TS (must meet the qualifications)
- Instrument printouts
- Signed reviews by testing personnel and director/TC/TS
- Corrective action for those results 80 % or less
Twice a year verification of accuracy policy
• It is best to spread it out throughout the year.
• Like to see it performed 5-6 samples at the beginning of the year and end of year.
• Like to see some type of log sheet where we see the original sample results and the result of the sample performed at another location and if the results agree or disagree and the corrective action taken if they disagree.
• Need to see the actual testing paperwork from both laboratories.
KOH, Wet Mounts, Urine Sediment Exams, Post Vas Semen Analysis, Fern test, and scabies are examples of PPMP testing. These are not on the regulated analyte list so you are required to perform the twice a year verification of accuracy for these tests.

Laboratories that have the PPMP CLIA certificate do not have inspections, but they are still required to follow the CLIA regulations which include the twice a year verification for the moderately complex testing performed.
CLIA has developed a competency brochure that can be found on the CLIA main web page at www.cms.hhs.gov/clia. It is brochure #10.
Six Components of a Competency Evaluation

- Direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing.
- Monitoring the recording and reporting of test results.
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
Competency Cont.

- Direct observations of performance of instrument maintenance and function checks.
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
- Assessment of problem solving skills.
How often does competency need to be assessed?

- At least semiannually during the first year of testing patient specimens.
- At least annually after that.

Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures.

Competency assessments must be performed for each test system that the testing individual performs.
Who can perform the competency assessments?

Moderately Complex Testing

The Technical Consultant or it can be delegated to someone who meets the qualifications of a technical consultant.
Highly Complex Testing

The Technical Supervisor or it can be delegated to the General Supervisor (GS) as long as the GS meets the qualifications as a GS.
Competency must also be performed and documented for individuals who are listed as the technical consultant, technical supervisor, general supervisor, and clinical consultant—even if they do not perform patient testing. If they do perform testing, the competency must include all 6 components.
If the laboratory director is the only person testing and reporting results, a minimal level of competency must be established and documented.
• CLIA does not require competency for those individuals who perform waived tests.

• Remember that PPMP certificates perform non-waived testing and competency is required. The competency must contain all 6 components for each of the midlevel practitioners.
Things we want to see when we look at competency while on survey:

- Competency Policy including the 6 components
- Six month competency records (dates-not check marks)
- Annual competency records
- Competency assessment documents for the TC, TS, GS, and CC.
WAIVED GLUCOSE TESTING
CLIA regulations for waived testing state you must follow the manufacturer’s instructions.

Most manufacturer’s package inserts for the waived glucose meters states the meters are to be used for monitoring diabetics.
Off Label Glucose Meters

If you don’t follow the manufacturer’s package insert when using the glucose meter, it is considered off label and the test becomes highly complex and no longer falls under the CLIA Certificate of Waiver.

Different qualifications for testing personnel who perform the highly complex testing.
Testing personnel qualifications

• At least an associate degree in laboratory science or medical laboratory technology
  
  OR

• Education and training equivalent to 496.1489 (b)(2)(1)
Stay tuned for more information regarding the waived glucose meter.
INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)
• IQCP is voluntary-follow the federal CLIA quality control regulations or develop and IQCP.

• IQCP applies to all specialties except: Histopathology, Oral Pathology, Cytology, and Pathology. For these specialties, the laboratory must follow the federal CLIA regulations.

• The laboratory director must make the determination if the lab follows CLIA QC regulations or develop an IQCP.
IQCP is comprised of 3 parts:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)
Risk Assessment (RA) is the identification and evaluation of potential failures and sources of errors in a testing process. The RA is comprised of 5 components.

- Specimen
- Environment
- Reagent
- Test System
- Testing Personnel
Quality Control Plan (QCP) is a document that describes the practices, resources, and procedures to control the quality of a particular test process. The QCP must at least include the number, type, frequency of testing and criteria for acceptable results of the quality control.
Quality Assessment (QA) is the review system that is established by the laboratory for the ongoing monitoring of the effectiveness of the IQCP.
Things to remember:

• IQCP is voluntary
• IQCP must be in writing
• IQCP must have written approval by the laboratory director prior to implementing.
• IQCP plan must have the 3 parts: RA, QCP, and QA.
• The RA must have the 5 components.
• The QA must show the IQCP is being monitored.
IQCP Information

CMS Web Page:  
www.cms.hhs.gov/clia

IQCP Link:  
IQCP@cms.hhs.gov
Additional CLIA Information

CLIA Web Page:
www.cms.hhs.gov/clia

State of Michigan CLIA Web Page:
www.michigan.gov/clia
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