

Michigan Regional Laboratory System Reorganization

Obtaining a CLIA Certificate

How to determine what type of certificate is needed

NOTE

A local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing may apply for a single certificate for multiple sites

What type of testing is performed?

- Waived Tests only:
 Hemoglobin (hemocue)
 Urine Pregnancy
 Urine Dipstick
 Whole blood glucose
 Rapid Group A Strep
 Cholesterol (Cholestech)
 Lead Care II
 Rapid HIV (Clearview)
 Fecal occult blood
 OSOM Rapid Trich
 OSOM BV

Complete list of CLIA waived tests
<http://www.cms.gov/CLIA/downloads/waivetbl.pdf>

Obtain a Certificate of Waiver

- Non-waived Tests (moderate or high complexity tests)
 Gram Stain
 Lead Care I
 CLIA regulated analytes
 CLIA unregulated analytes
 (waived tests may also be performed)

Obtain a Certificate of Compliance (for moderate or high complexity tests)

- Microscopy Procedures
 Wet mount
 KOH prep
 Microscopic urine
 (waived tests may also be performed)

Who Performs Microscopy?

- Nurses
 Med Tech

Obtain a Certificate of Compliance (for moderate complexity tests)

- ONLY**
 Physician
 Nurse Practitioner
 Nurse Midwife
 Physician asst

Obtain a Certificate of Provider-Performed Microscopy Procedures

Information regarding obtaining a CLIA Certificate:
 Contact Division of Licensing and Certification, Bureau of Health Systems, Michigan Department of Licensing and Regulatory Affairs: 517-241-2648

Information regarding changes to the Michigan Regional Laboratory System:
 Contact Dr. Jeff Massey, Quality Manager, MDCH Bureau of Laboratories: 517-335-8074