

GOOD LABORATORY PRACTICE

- CLIA NON-WAIVED TESTS MODERATELY COMPLEX PROVIDER PERFORMED MICROSCOPY PROCEDURES (PPM)

REQUIRED

- ◆ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments–1988)
- ◆ Certificate of Compliance or Certificate of Accreditation

Application at: <http://www.cms.hhs.gov/clia>
- ◆ Perform any test categorized by the FDA (Federal Drug Administration) as waived and any of nine microscopic tests
 - **Fecal leukocyte (WBCs)**
 - **Post-coital (vaginal or cervical)**
 - **Semen analysis (presence / absence)**
 - **Fern test**
 - **Urinalysis (microscopic)**
 - **Potassium hydroxide (KOH) Urinalysis – two or three glass test**
 - **Nasal smear for granulocytes**
 - **Pinworm**
 - **Wet mounts**
- ◆ Follow applicable CLIA microscopic test regulations found in the Code of Federal Regulations, Title 42, Section 493, (subparts A, C, J, K)

PERSONAL QUALIFICATIONS

See Code of Federal Regulations Title 42, Section 493

- ◆ **Director** – Sect. 493.1357 (duties Sect. 493.1407)
- ◆ **Testing Personnel** – Sect. 493.1423 (duties Sect. 493.1425)

OVERSIGHT

- ◆ **Cost** – \$200 every two years
- ◆ **Surveys** – no routine visits, complaints only

Note: Approved tests only performed by state licensed MD, DO, dentist or mid-level practitioners

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