

**Section 1: REGULATIONS**

**CLIA-88 TEST LEVEL LIST****Certificate of Waiver\***

1. Dipstick or Tablet Reagent Urinalysis (nonautomated) for the following:  
Bilirubin, Glucose, Hemoglobin, Ketone, Leukocyte, Nitrite, pH, Protein, Specific gravity and Urobilinogen, micro-albumin.
2. Fecal occult blood
3. Ovulation test - visual color comparison tests
4. Urine pregnancy test - visual color comparison tests
5. Erythrocyte sedimentation rate, nonautomated
6. Hemoglobin - Hemocue, Cholestek LDX or copper sulfate
7. Spun Hematocrit
8. Blood Glucose (FDA - Cleared Home Use Devices, HemoCue, Cholestek)
9. Cholesterol - using the "AccuMeter", "Advance Care" or Cholestek LDX
10. Triglycerides, HDL - Cholestek LDX
11. Rapid Strep - check company
12. H. Pylori - Pyloritek Test Kit, Quidel H. Pylori, CLOtest, Abbott Flex
13. Prothrombin Time - check company
14. A2 Hemoglobin - check company
15. Automated urinalysis - check company
16. Alcohol level - check company
17. Influenza - check company

ALL WAIVED TEST MUST STATE WAIVED ON THE MANUFACTURER INFORMATION

**Physician Performed Microscopy**

1. Wet mounts including preparation of vaginal, cervical or skin specimens
2. All potassium hydroxide preparations (KOH)
3. Pinworm examinations
4. Fern tests
5. Postcoital direct tests
6. Qualitative examination of vaginal or cervical mucous
7. Urine sediment examination
8. Fecal leukocyte examination
9. Wet mount exams of prostatic secretions
10. Qualitative semen analysis (absence or presence)

\* A complete list of approved waived tests is available by accessing the CLIA web site:  
<http://www.cms.gov/medicaid/clia/waivebl.htm>

## **CLIA PERSONNEL REQUIREMENTS**

### **WAIVED TESTING**

#### **DIRECTOR:**

1. Licensed physician

#### **TESTING PERSONNEL:**

1. Minimum: High school graduate with documented on the job training for tests performed.

### **PROVIDER PERFORMED MICROSCOPY**

#### **DIRECTOR:**

1. Licensed physician - MD or DO, Podiatrists, Dentists qualified in pathology.

#### **TESTING PERSONNEL**

1. Physician
2. Nurse midwives - documented training for tests performed
3. Physician Assistants (degree/certified) - documented training for tests performed
4. Nurse practitioners - documented training for tests performed