What is CLIA?

Congress passed CLIA in 1988 to establish quality standards for all non-research laboratory testing:

- Performed on specimens derived from humans; and
- For providing information for the diagnosis, prevention, and treatment of disease or impairment, or assessment of health.

CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate to operate.
1. Certificate of Waiver (CW);
2. Certificate for PPMP;
3. Certificate of Registration (COR);
4. Certificate of Compliance (COC); and
5. Certificate of Accreditation (COA).
The CW permits a laboratory to perform only waived tests. Waived tests are simple and accurate and there is minimal risk of error when done correctly. Examples of waived tests include:

- Certain testing methods for glucose and cholesterol;
- Fecal occult blood tests;
- Pregnancy tests; and
- Some urine tests.
A subset of the moderate complexity tests, PPMPs receive a unique classification and certification. A laboratory where a physician, mid-level practitioner, or dentist performs only certain microscopy procedures and waived tests* may receive this certificate. Examples of PPMPs are:

- Urine microscopic
- KOH smear (potassium hydroxide aka wet prep)

*If the laboratory has a Certificate for PPMP, it can perform waived tests without a Certificate of Waiver.
### CLIA Waived Test Examples

#### Tests Granted Waived Status Under CLIA

<table>
<thead>
<tr>
<th>CPT Code(s)</th>
<th>Test Name</th>
<th>Manufacturer</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>81002</td>
<td>Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen</td>
<td>Various</td>
<td>Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections</td>
</tr>
<tr>
<td>81025</td>
<td>Urine pregnancy tests by visual color comparison</td>
<td>Various</td>
<td>Diagnosis of pregnancy</td>
</tr>
<tr>
<td>82270</td>
<td>Fecal occult blood</td>
<td>Various</td>
<td>Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)</td>
</tr>
<tr>
<td>82962</td>
<td>Blood glucose by glucose monitoring devices cleared by the FDA for home use</td>
<td>Various</td>
<td>Monitoring of blood glucose levels</td>
</tr>
<tr>
<td>83026</td>
<td>Hemoglobin by copper sulfate – non-automated</td>
<td>Various</td>
<td>Monitors hemoglobin level in blood</td>
</tr>
</tbody>
</table>

#### Tests Granted Waived Status Under CLIA

<table>
<thead>
<tr>
<th>CPT Code(s)</th>
<th>Test Name</th>
<th>Manufacturer</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW</td>
<td>Abbott i-STAT Chem8+ Cartridge (Whole Blood)</td>
<td>i-STAT Corporation</td>
<td>Measures ionized calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood</td>
</tr>
<tr>
<td>80048QW</td>
<td>1. Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc) (Whole Blood)</td>
<td>Abaxis, Inc</td>
<td>Measures total calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen in whole blood</td>
</tr>
<tr>
<td></td>
<td>2. Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc) (Whole Blood)</td>
<td>Abaxis, Inc</td>
<td></td>
</tr>
</tbody>
</table>
All the Following Perform Moderate to High Complexity Tests:

* Certificate of Registration-temporary certification for laboratory to conduct moderate & high complexity tests while they complete the process. Onsite survey or verification of accreditation.
* Certificate of Compliance-Onsite survey and complies with all applicable CLIA requirements through CMS. (Federal Standards)
* Certificate of Accreditation-Meet the standards of a private non-profit accreditation organization approved by CMS. (CAP, COLA, Joint Commission)
Enrolling in the CLIA Program

1. Complete an application;
2. Pay applicable fees;
3. Be surveyed, if applicable; and
4. Meet CLIA standards and become certified.
CLIA Contacts
State Representative

Joyce Shepard, Ph.D., MLS (ASCP)
Montana CLIA Program
Phone: 406-438-1793
Fax: 406-444-3456

Mailing Address:
Montana CLIA Program
Certification Bureau-2nd floor
PO Box 202953
Helena, MT 59620

- Can answer any questions regarding CLIA
- How to apply for a CLIA Certificate
- How to change information on an existing Certificate
- Questions on a specific test
- Submit paperwork for enrollment
Federal Regional Contacts

Uniformed Public Health Service

Todd Alspach
Email: todd.alspach@cms.hhs.gov

Cara Nichols
Email: cara.nichols@cms.hhs.gov

➢ Investigate a complaint
➢ On-site visit
Provider must have CLIA Certificate on file to be reimbursed.
Helpful Links

Questions???