

CLIA

Clinical Laboratory Improvement Amendment

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Officer

August 22, 2017

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.

Types of Certificates

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).

Certificate of Waiver (CW)

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.

Provider-Performed Microscopy (PPMP)

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

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270 82272 (Contact your Medicare carrier for claims instructions.)	Fecal occult blood	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
82962	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	Monitoring of blood glucose levels
83026	Hemoglobin by copper sulfate – non-	Various	Monitors hemoglobin level in blood

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	Abbott i-STAT Chem8+ Cartridge {Whole Blood}	i-STAT Corporation	Measures ionized calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood
80048QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc	Measures total calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc	

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)cm
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

IMPORTANT

Provider must have CLIA
Certificate on file to be
reimbursed.

Helpful Links

[CLIA Brochure: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CLIABrochure.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CLIABrochure.pdf)

[List of Approved Accreditation Organizations: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf)

[CLIA Application: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html)

[CLIA Waived Tests https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf)

Questions????