

Montana CLIA Program

PO Box 202953, Helena MT 59620

Phone: (406) 444-2099 or (406) 438-1793 Fax: (406) 444-3456

Email: mtssad@mt.gov or jshepard@mt.gov

Certificates of Waiver FAQ

Do I need a Certificate of Waiver?

If a person is performing testing in the state of Montana which meets the CMS definition of a laboratory, you need a Montana CLIA certificate. A Certificate of Waiver covers all tests that are classified as waived by the FDA. Common examples include glucometers, occult blood, urine dipsticks, manual sedimentation rates, and waived strep/flu kits.

Who can be the Laboratory Director of a Certificate of Waiver?

Any person may be designated as Laboratory Director of a Certificate of Waiver. There are no education/experience regulations for this position for a Certificate of Waiver. Please select a stable person to minimize the paperwork to change lab directors regularly. The person designated as Laboratory Director of the CLIA certificate is responsible for ensuring the CLIA regulations are met, including that all personnel are following the manufacturer directions.

Who can perform Waived Tests?

Any person may perform waived tests. There are no education/experience regulations for performing waived tests. Each person performing waived tests **must** follow manufacturer directions.

How do I change the Laboratory Director on my CLIA certificate?

To change the Laboratory Director of a CLIA certificate, you need to fill out a CMS-116 form. Please inform the Montana CLIA program of changes in the Laboratory Director within 30 days (per the federal regulations at 42 CFR § 493.39(b)).

What are the requirements for a Certificate of Waiver?

The federal regulations for waived testing can be found at 42 CFR § 493.5-493.37.

How do I figure out if all the tests I have are waived?

The easiest way to find out if you have a CLIA waived test is to check the box and the manufacturer directions. Do they state "CLIA Waived"? If you cannot find it in the manufacturer directions, you may search the FDA [database](#) or the list of [waived tests](#) to determine if the test is classified as waived, moderate, or high complexity by the FDA. Certificates of Waiver may only perform tests that are classified as waived by the FDA. Testing above your certificate level (moderate or high) will not be reimbursed for billing and will result in adverse action by CMS for testing above your certificate.

Where is my certificate? I have not received my certificate.

New applications: Your application may take up to 10 days to process. After the application has been

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entered, a bill will be mailed to the mailing address within 7-10 days. Do not send payment with the application to the state agency. You may also pay online using the www.pay.gov system for a faster turnaround time. You will need your new CLIA number in order to use the www.pay.gov system. Once your bill has processed as Paid, your CLIA certificate will be printed and mailed to the mailing address within 1-4 weeks.

Renewing your Certificate: If your bill is paid, a new certificate will automatically be printed and mailed to you 1-3 weeks before the current certificate expires.

Please contact the Montana CLIA program with specific questions about the status of your bill or certificate mailing.

I lost my certificate.

If you cannot find your certificate or it has expired and you don't have a current one, please contact the Montana CLIA program. A letter of verification may be sent to you if a new certificate cannot be issued.

Where is my bill? I have not received my bill.

New applications: Your application may take up to 10 days to process. After the application has been entered, a bill will be mailed to the mailing address within 7-10 days. Do not send payment with the application to the state agency. You may also pay online using the www.pay.gov system for a faster turnaround time. You will need your new CLIA number in order to use the www.pay.gov system. Once your bill has processed as Paid, your CLIA certificate will be printed and mailed to the mailing address within 1-4 weeks.

Renewing your Certificate: A bill to renew your certificate will automatically be mailed to the mailing address on file six months prior to the expiration of the current certificate.

Please contact the Montana CLIA program with specific questions about the status of your bill or certificate mailing.

Do I have to fill out any forms to renew my CLIA certificate?

A bill will automatically be mailed to the mailing address on file 6 months prior to the expiration of your current certificate. You do not need to fill out any paperwork unless you have changes to the information on file. Please update the CLIA program of any changes of name, address, or laboratory director within 30 days of the change.

How much is my bill?

The cost of a Certificate of Waiver is \$180 and lasts for two years.

What if I want to get a microscope?

All microscope tests are moderate or high complexity, which is not covered by a Certificate of Waiver. If you are interested in getting a microscope and performing microscopic tests, please contact the Montana CLIA program to get the correct CLIA certificate. Testing above your certificate level will not be reimbursed and may result in CMS adverse actions.

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How do I change to a different certificate type?

In order to change to a different certificate type to perform moderate or high complexity testing, please fill out the CMS-116 form. Please contact the Montana CLIA program for the education/experience requirements of a qualified Lab Director for moderate or high complexity testing.

What if I don't follow the manufacturer directions?

The federal CLIA regulations at 42 CFR § 493.15(e)(1) require all personnel performing waived testing to follow the manufacturer directions. If the manufacturer directions are not followed, the test is re-classified by the FDA as a laboratory developed high complexity test. High complexity testing requires a different certificate type and compliance with the federal regulations at § 493.43 - 493.1777, including qualified personnel, daily quality controls, calibrations, maintenance, policies and procedures, and a quality assurance program.

My kit is waived for one sample type but not for another sample type. Can I use both?

A Certificate of Waiver only allows waived tests to be performed. If a sample type is waived, you may perform the test using that sample type. If a sample type is moderate, you may not use that sample type unless you change to a higher certificate level. For example, many kits are waived for whole blood but moderate complexity for serum or plasma. Only whole blood may be used by the Certificate of Waiver facility. Any sample processing makes the test moderate complexity.

My kit is expired. Can I still use it?

The federal CLIA regulations at 42 CFR § 493.15(e)(1) require all personnel performing waived testing to follow the manufacturer directions, including the test performance requirements such as the expiration date. Do not use your waived kits or reagents after they expire. The manufacturer will not guarantee the results and your patients may receive inaccurate test results.

I ordered a kit and it doesn't say it is waived. Can I still use it?

Read the manufacturer directions, check the FDA website, or the CMS list of waived tests to determine if the kit is waived, moderate or high complexity. Certificates of Waiver require only CLIA waived tests be performed.

I am not getting reimbursed for my tests. What can I do about it?

The Montana CLIA program does not have any billing information. Please contact your billing agency for details on billing issues. You may contact the Montana CLIA program to inquire about the status of the CLIA certificate if the billing issues state a CLIA certificate problem.

[Ready, Set, Test booklet](#)

This booklet contains basic laboratory information for waived testing and pre-made forms ready to use for ensuring quality waived testing results.

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CMS Brochure for Certificates of Waiver

[Brochure #6](#)

[Certificate of Waiver Project](#)