Montana CLIA Program

PO Box 202953, Helena MT 59620
Phone: (406) 444-2099 Fax: (406) 444-3456
Email: mtssad@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, urine dipsticks, and waived COVID kits.

Who can be the Laboratory Director of a Certificate of Waiver?
Any individual can be appointed as the Laboratory Director for a Certificate of Waiver. This position has no CLIA personnel regulations regarding education and experience. The individual appointed as the Laboratory Director for the CLIA certificate is accountable for the facility's compliance with CLIA regulations, which includes ensuring that all staff adhere to the manufacturer's instructions.

Who can perform Waived Tests?
Any person may perform waived tests. Everyone performing waived tests must follow the manufacturer's directions.

How do I change the Laboratory Director on my CLIA certificate?
To change the Laboratory Director for a CLIA certificate, you can either fill out a CMS-116 form or provide a written notification. The written notification must include the laboratory's name, CLIA number, the name of Laboratory Director and Owner, description of the change(s) being made, date and wet signature or certified electronic signature of the Laboratory Director or Owner.
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's instructions. Do they state "CLIA Waived"? If you cannot find it in the manufacturer's instructions, 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 can I find my CLIA certificate?
Once payment is processed, a new certificate will be released to the email address on file. Once you have received a copy of your certificate electronically, additional copies of your certificate can be retrieved at this website: S&C QCOR Home Page (cms.gov) [qcor.cms.gov]
On the left-hand side, click on CLIA Laboratory Lookup.
Enter your CLIA ID and click on search.
Follow the links in blue.
The popup will have another http link that is a copy of your certificate.

Note:
How long does it take?: It can take up to 10 days to process before the lab receives a new certificate
Renewal: Once payment has been processed, a new certificate will not be released until a week before your certificate's expiration date.
Current CLIA Certificates: If the certificate details are outdated, provide either a CMS-116 form or a written notice to request updates. To obtain a certificate with updates, you must request a revised certificate for a fee. After payment, a revised certificate will be emailed, and the QCOR website will be updated.

If you cannot find your certificate or it has expired and you don't have a current one, please contact the Montana CLIA program.

Where is my bill? I have not received my bill.
CLIA fee coupons will be emailed to the email address on file. The fastest way to pay is online at the following URL: Pay CLIA Fee

Note:
Existing CLIA Certificates: A notification will be emailed to the email on file 6 months prior to the expiration of your current certificate.

How much is my bill?
The cost of a Certificate of Waiver is $248 and lasts for two years. CLIA Certificate Fee Schedule
Revised Certificates of Waiver are $95

Replacement Certificates are $75
Copies of your certificate from QCOR (S&C QCOR Home Page (cms.gov) [qcor.cms.gov]) are FREE.

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 type. Testing above your certificate level will not be reimbursed and may result in CMS adverse actions.

How do I change to a different certificate type?
To change to a different certificate type, please fill out the CMS-116 form.

What if I don't follow the manufacturer's instructions?
The federal CLIA regulations at 42 CFR § 493.15(e)(1) require all personnel performing waived testing to follow the manufacturer's instructions. If the manufacturer's instructions 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 has 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's instructions, 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's instructions, 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 may only perform tests that are classified as waived by the FDA.

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.

Additional Certificates of Waiver Information
Waived Tests | Laboratory Quality | CDC