

How to Obtain or Renew a CLIA Certificate of Waiver in North Dakota

If you already have a CLIA Certificate of Waiver

If you want to add testing services before your next renewal, email the North Dakota State Laboratory at CLIALAB@nd.gov and include:

- Your CLIA waiver number
- Pharmacy name and location
- New tests/services being added

If you **do not have** a CLIA waiver, proceed to step #2.

1. Determine which CLIA-waived testing services you plan to offer.

2. Determine what test(s) you want to provide in your pharmacy. You will need to list these on the CLIA Certificate of Waiver application. There are a number of considerations prior to choosing a test such as: specificity/sensitivity, cost, use of/with an analyzer, what is available from your pharmacy wholesaler, sample collection, quality control requirements, processing time etc.

3. Fill out and submit your CLIA Certificate of Waiver application (CMS Form 116). Here, you will need to list the tests and manufacturers of the tests identified in step #2.

<https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf>

After you submit your application, if you change test manufacturers, you do not need to notify the state lab, but instead update this information when you renew the certificate in two years.

4. After your CLIA Certificate of Waiver is submitted to CLIALAB@nd.gov, you will receive a fee coupon (bill) via email. Pay the fee, and then your CLIA waiver will be emailed to you once payment has been processed. Processing times may vary. Contact the North Dakota State Laboratory if you have questions regarding application status

If you already have a CLIA waiver, there is a new process for renewal. Everything is now done electronically. Approximately 6 months prior to the expiration of your current certificate, you will get an email with a fee coupon. Once that is paid, you will then be provided (electronically) your updated certificate via email. If your email address is not on file, you will need to notify the ND Lab at CLIALAB@nd.gov.

Additional Resources:

[CMS CLIA Certification Quick Start Guide](#)

[North Dakota CLIA Laboratories Website](#)