

CLIA WAIVER APPLICATION INFORMATION FROM DHHS

If you do not yet have a Clinical Laboratory Improvement Amendments (CLIA) program waiver that allows you to perform certain COVID-19 tests in your facility, please consider applying for one.

For a facility to be eligible to receive a free shipment of Abbott BinaxNOW antigen test cards, either from the U.S. Department of Health and Human Services (HHS) or from the Nebraska Department of Health and Human Services (DHHS), a facility must have a CLIA waiver that allows these tests to be performed on site.

The Nebraska Health Care Association (NHCA) has talked with the CLIA team at DHHS to see if there is anything a facility can do to help expedite this process and they have shared the following information:

- 1) To apply for a CLIA Certificate click on the link below to open the CMS 116 form and complete Sections I-VI and IX-X: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>
 - Make sure the name and signature of the "Owner/Director of Laboratory" on page 5 matches the "Name of the Director" on page 1.
 - Confirm the facility's Federal Tax Identification Number is accurate – should be 9 digits.
 - Make sure to include an email and phone number to contact in case of questions.

Also, complete:

- 2) CLIA Ownership Information Form:
<http://dhhs.ne.gov/licensure/Documents/CLIAOwnershipInformation.pdf>
- 3) List of Tests Performed:
http://dhhs.ne.gov/licensure/Documents/Lists_of_tests_performed.pdf
 - Test - The name of the test (**example:** COVID-19 test)
 - Method – Instrument Name (**example:** Abbott BinaxNOW AG cards, BD Veritor analyzer)
 - Specialty – Approved for waived certificate (**example:** antigen tests)
- 4) Scan and email the completed forms to our office for processing at DHHS.AcuteCareFacilities@nebraska.gov
- 5) If questions, call DHHS CLIA support: 402-471-4363

Once you submit your application:

- The DHHS CLIA team will enter the information in the CMS database (or contact you if questions).
- DHHS will email you once your facility's information is entered.
- CMS will mail you a Payment Coupon in a few days.
- Once the Coupon is received, submit your payment (\$180/two years) either by check or online.
- You may begin performing the CLIA-waived tests once your information is entered, you do not need to wait for the payment coupon or for your payment to be processed.

References:

Quick Start Guide (NEW!)

<https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf>

Link to the Nebraska Laboratory webpage for your reference:

<http://dhhs.ne.gov/licensure/Pages/CLIA-Clinical-Labs.aspx>

As a resource from the CMS Webpage the brochure "How to Obtain a CLIA Certificate of Waiver" which has some good information.

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>