

APPLYING FOR THE CLIA WAIVER FOR POINT OF CARE COVID-19 TESTING

Click here for the CLIA form:

<https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>

At the top of page 3, click on "FORM **CMS-116**". This will take you to the form you need to complete.

CMS 116- FORM INSTRUCTIONS

Download or print off application (9 pages) you are only responsible to fill in the first 5 pages by following the instructions below.

Section I. General Information-

Check Initial Application Box

Leave CLIA Number blank

Enter the name of your organization (facility name)

Enter your SAU Federal Tax ID # (obtain from superintendent's or business office)

Enter your phone and fax numbers

Facility Address (NO PO Box)

Mailing/Billing Address **DO NOT SEND MONEY YOU WILL BE BILLED**

Send Fee and Certificate to this address: *Check physical box*

Name of Service Director (Enter school nurse or director of SBHC)

Leave corporate address box blank

Section II. Type of certificate- Check Certificate of Waiver ONLY

Section III. Type of Laboratory- Select #26 School /student health service

Section IV. Hours of Laboratory Testing- Enter the school day hours

Section V. Multiple Sites- Check no. (This waiver covers the district) Proceed to Section VI

Section VI. Waived Testing- Fill in: Abbott BinaxNOW Ag Test for the detection of SARS-CoV-2.
Scroll down to: **Estimate the total annual test** volume conducted at the site. (Estimate at least 25-30% of your student population).

Skip Sections VII. & VIII.

Section IX. Type of Control- What type is your service? Public schools choose city government. Private schools choose appropriate ownership type.

Skip Section X.

Make sure owner/director name is school district and signature is your superintendent/head of school.

For CLIA Waiver questions, you can contact:

CLIA PROGRAM
Division of Licensing & Regulatory Services
41 Anthony Avenue, Station #11
Augusta, ME 04333-0011
(207) 287-9339
FAX: (207) 287-9304
Contact: Dale Payne
CLIALAB.DHHS@Maine.gov

[Fee: Note there is a \$180 fee required for acquiring a CLIA Certificate of Waiver, but that should NOT be sent with this initial application. The state will send you an invoice for the fee once your application is reviewed and processed.]