

Directions for Completing CLIA Certificate of Waiver Application Needed to Conduct Point-of-Care COVID-19 Testing (including BinaxNOW COVID-19 Antigen Card Tests)

NOTE: Full information on how to obtain a CLIA Certificate of Waiver can be found in the CMS document, “How to Obtain a CLIA Certificate of Waiver: <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>

Key steps for this completing the application CLIA Certificate of Waiver required to obtain and use the Abbott BinaxNOW COVID-19 Antigen Cards are outlined below:

1. Get the “CMS Certificate of Waiver Form 116”, which can be completed either as a fillable PDF form, or on paper. You can get the form in any of the following ways:
 - See PDF version of the form, attached to this email
 - Download the form from www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf
 - Contact Maine CLIA program lead, Dale Payne: Dale.Payne@maine.gov, tel. (207) 287-9339
2. If you plan to complete the form electronically, download the PDF application and save it to your computer; if you plan to complete it on paper, print off the application. Note, the application is 9 pages long, but the application itself is comprised of the first 4 pages; the remaining pages are instructions for filling out the application.
3. **Complete the form using the following steps:**

Section I. General Information

- Check box for “Initial Application”
- “CLIA Identification Number”: leave blank
- “Facility Name: Enter name of your organization
- “Federal Tax Identification Number”: Enter Federal Tax ID # for your organization
- “Email address”: Enter email for you or the primary care contact at your organization
- “Telephone No.”: Enter phone for you or primary care contact at your organization
- “Fax No.”: Enter Fax for your organization
- “Facility Address”: Enter physical location for address where testing will be done
- “Mailing/Billing Address” Enter if different from your physical address
- “Corporate Address”: Enter if different from Facility Address
- “Name of Service Director”: Name of person responsible for testing at your facility

Section II. Type of Certificate Requested:

- Check “Certificate of Waiver”

Section III. Type of Laboratory

- Check the type of facility that best reflects your entity, or enter description under “Other”

Section IV. Hours of Laboratory Testing

- Enter the hours and days that anticipate doing testing at your facility (best estimate is OK)

Section V. Multiple Sites

- Select “No” if planning to do testing only at your site
- Select “Yes” if planning to do testing at multiple sites in your organization, and complete remaining questions in this section

Section VI. Waived Testing

- Write in “Abbott BinaxNOW COVID-19 Ag Card” to test for detection of SARS-CoV-2”
- **Estimated Total Annual Test:** Fill in your best estimate of the total number of tests you predict you will be conducting annually volume at your site. You can estimate based on the number of tests received or a percentage of your population.

Section VII. Skip**Section VIII. Skip****Section IX. Type of Control:**

- Check the box that best describes the ownership type of your organization

Section X. Director Affiliation with Other Laboratories

- If the individual overseeing this testing site is also overseeing other CLIA Waived sites, please list the sites.

Signature

- Print the name and include signature for person most responsible for planned BinaxNOW Ag testing at your facility

Send your completed application via email (attach completed PDF) or paper to Maine’s CLIA program director

Dale Payne: Dale.Payne@maine.gov

Tel. (207) 287-9339

Division of Licensing & Regulatory Services

41 Anthony Avenue, Station #11

Augusta, ME 04333-0011

FAX: (207) 287-9304

[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.]