

DIRECTIONS FOR THE CLIA WAIVER APPLICATION FOR EMS ORGANIZATIONS

Revised February 6, 2024

To get the CLIA Waiver Application, you can:

1. Go to the Federal Health and Human Services website by clicking on this link, or pasting it into your browser:

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

2. Contact:

Floyd Salerno, CG (ASCP), Quality Assurance Officer
Department of Health and Human Services, Division of Licensing & Certification
41 Anthony Avenue, #11 State House Station
Augusta, ME 04333-0011
PHONE: (207) 287-9339
FAX: (207) 287-5807
CLIALab.HSS@Maine.gov
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CLIA Waiver Application Instructions:

Page 1:

Section I – General Information

- a. Fill in all information that you have available.
- b. Check the reason for submission under General Information, **OR**, check “other” and specify.
 - o If this is an initial application, leave the “CLIA Identification Number” blank.
- c. Enter an Anticipated Start Date for a new certificate, **OR**, enter an effective date for updating an existing certificate.
- d. Enter a contact email address.
 - o Check “Receive Future Notifications...” if, you would like to receive an emailed certificate.
- e. Enter the responsible party for the certificate as Director.
- f. Enter a Director contact number.
 - o **NOTE: This should be the direct contact phone number, not the business main line.**
- g. Enter the responsible party’s job title under “credentials.”
- h. A Tax ID, Telephone number, and Address must be listed.

Section II – Type of Certificate Requested

- a. Check “Certificate of Waiver.”
 - o Choose only 1 certificate type of the highest level of testing being performed.
- b. Check “physical” for both mailings unless providing additional addresses. Check only one box for fee bill and only one box for certificate mail.

Page 2:

Section III – Type of Laboratory

- a. For Non-Transporting/Volunteer Services - check “Mobile Laboratory.”
- b. For Transporting Services - check “Ambulance.”

Section IV – Hours of Laboratory Testing

- a. EMS Services must provide coverage 24 hrs./day, 7 days a week. Enter 24hrs in each day of the week.

Section V – Multiple Sites

- a. Check “Yes” to indicate you are applying for a single site CLIA certificate covering multiple testing locations.
- b. Check “Yes” for exception 1
- c. Provide a list of the vehicle VIN numbers to be associated with the physical location.

Page 3:

Section VI – Waived Testing

- a. List all test systems that you are using (i.e., Glucometer, Lactate Pro, etc.).
 - o Enter the Analytes/Test, Test Name, and Manufacturer for waived testing.
- b. Enter an Estimated annual test volume (i.e., how many times you estimate using all tests).

$$\text{Test Volume} = (\text{Number of persons tested} \times \text{Planned number of times tested per week}) \times 52$$

Section VII – PPM Testing

- a. Check “no PPM” for a waived certificate. PPM is for specialist microscopic analysis.

Page 4:

Section VIII – Non-Waived Testing

- a. Skip this section, but make sure you submit the page with your application.

Page 5:

Section IX – Type of Control

- a. Check one business control type based on your service type.
 - o I.e., Municipalities (option 05) or Volunteer Services (09).
 - o If checking “Other NonProfit”, provide the type: e.g. 501c3.
- b. Check yes or no for foreign corporate ownership.
 - o If yes, enter the country name.

Section X – Director Affiliation with Other Laboratories

- a. Complete only if the director for this application is also the director for another service.

Carefully read the information below the black box. To complete the application:

- a. Print the certificate director’s name.
- b. Print the ownership person or company name above the director/owner signature.
- c. The responsible party must sign and date the application. If using an electronic signature, it must be of the type that automatically include security date and time stamps. Otherwise, page 5 must be printed and signed manually.

When submitting, include all 5 pages for audit purposes and send to: CliaLab.DHHS@maine.gov

Additional instructions are included on pages 6-10 of the [CLIA Waiver Application](#).