Summer Camps 2022

COVID-19 Testing Webinar

Please input your camp name and email in the chat for future communications

Agenda

Goals

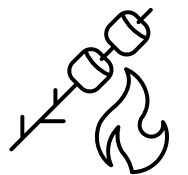Test Types Available for Order

MDHHS & CDC Partnership

CLIA Waiver Requirements

Ordering Testing Kits

Reporting COVID-19 Test Results

How to Handle Additional Tests After Camps End

*Presentation will be sent to all emails in the chat following the meeting

Goals

- Prioritize the health and safety of all campers and staff by reducing the spread of COVID-19 through testing

- Provide free testing supplies to Summer Camps

Test Types

Over the Counter COVID-19 Tests

- Types of OTC Tests
  - iHealth COVID-19 Antigen Rapid Test
  - QuickVue At-Home OTC COVID-19 Test
  - Flowflex COVID-19 Antigen Home Test
  - BinaxNOW COVID-19 Self Test
  - [OraSure InteliSwab Rapid Tests](#)

- Can be sent home or administered on site

COVID-19 Rapid Antigen Tests

- Types of Rapid Antigen Tests
  - BinaxNOW COVID-19 Antigen Test

- MUST be administered on-site by another individual

- Cannot be sent home

CLIA Waiver Requirements

Who needs a CLIA Waiver?

- Camps that are administering tests on-site

How do I complete a CLIA Waiver for our camp/site?

- For MDHHS testing program complete all sections of the CMS 116 CLIA Application.
  - Completed application can be submitted to LARA-BCHS-DHHS-COW-TESTING-APPLICATION@michigan.gov

What tests need to be listed on the CLIA Waiver?

- All test types (use official names listed on the Test Types slide)

Any CLIA questions?

- Email MDHHS-COVIDTESTINGSUPPORT@michigan.gov

MDHHS & CDC Partnership

- Support COVID-19 testing among camps servicing K-12 aged students
  - Camps do not need to be affiliated with a school to receive tests

- Offering free Antigen POC and OTC tests shipped directly to camps

- Quantity of test kits requested is meant to last the entirety of the camp

- CDC accepts these requests weekly, every Tuesday
  - You'll typically receive confirmation the Friday after the order was submitted, and tests tend to arrive 7-10 days after submission.

How to Order Test Kits

- Complete the form: Order Form for CDC Antigen or OTC COVID-19 Tests

- You can order both OTC and Antigen POC tests through the form

- Ensure you complete the entire form with <u>accurate</u> information

- Orders requesting more than 6,400 POC or 1,344 OTC will be contacted directly to complete a special delivery request

Reporting COVID-19 Test Results

Antigen and OTC tests that have been administered on-site MUST be reported to MDHHS

Test can be reported to the [Michigan Antigen Testing Results Form](#)

❑ Positive results must be reported individually within 4 hours of completion of the test

❑ Negative results may be reported as an aggregate number within 24 hours of completion of the test

Distribution of OTC tests for at-home use **does not** require reporting.

Training available online for how to complete the reporting form at [MDHHS Rapid Antigen Testing Training Series, FAQs & Resources](#).

Additional Tests Remaining

After camps have concluded, if you have any additional tests remaining:

- Distribute to partner camps

- Contact local health department and reallocate your tests to them for use

Expired test kits

- Email quantity, test type and lot # to MDHHS-COVIDTESTINGSUPPORT@michigan.gov

- Unused test kits can be disposed of as regular waste

Questions?

EMAIL: MDHHS-COVIDTESTINGSUPPORT@MICHIGAN.GOV

THANK YOU FOR YOUR PARTNERSHIP

What is a CLIA waiver?

A Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver (CoW) is a certification that allows a facility to legally examine a person through waived tests in order to assess health, diagnosis or determine treatment. The antigen tests provided by MDHHS require any facility that is administering these tests to obtain a CLIA waiver in order to legally preform the test.

No specific credentials are required to obtain a CLIA Waiver. The testing site administering the test must follow the guidelines specified under the Centers for Medicare and Medicaid Services (CMS)

Cost

CLIA waiver certificate cost is $180 for two years.

Why do I need a CLIA waiver?

To participate in MDHHS antigen testing program you must have a CLIA certificate even if you perform only one basic test. If you perform a test and do not have a CLIA certificate you will be in violation of federal law.

How do I apply?

For MDHHS testing program complete all sections of the CMS 116 CLIA Application. Completed application can be submitted to LARA-BCHS-DHHS-COW-TESTING-APPLICATION@michigan.gov.

Filling out CLIA Application for antigen testing

Section I. General information- Complete all information in section. Leave CLIA identification number blank. Be sure to select where you would like fee coupon and certificate mailed. Director will be the person responsible for the site. The director does not have to be a medical professional.

Section II. Type of Certificate Requested- Certificate of waiver

Section III. Type of Laboratory- Select your organization type. If your type is not listed select other and specify.

Section IV. Hours of Laboratory Testing- select 24 hours if your facility operates 24 hours. If you are not a 24-hour facility enter site hours of operation.

Section V. Multiple Sites- One site select no. Multiple sites can only be not for profit, federal, state, or local facilities.

Section VI. Waived Testing- List antigen test performed at site. Abbott BinaxNow COVID-19 Ag Card. Indicate estimated testing number.

Sections VII. PPM Testing- Leave Blank.

Section VIII. Non-Waived Testing- Leave Blank.

Section IX. Type of Control- Select the one most descriptive of ownership type.

Section X. Director Affiliation with other Laboratories- Permissible to skip

Print and Sign application. Electronic signature is not acceptable.

CLIA Payment and When Testing Can Begin

After the application has been successfully entered into the federal system, a fee coupon will be generated. Fee coupons and CLIA Waivers are printed and mailed by a federal contractor located in Oregon. **Fee coupons will be mailed.**

When payment has been processed, the new CLIA Waiver will be printed and mailed from Oregon via US Mail. Once the laboratory receives the CLIA certificate, they may start testing and billing (if applicable) for the test(s) performed.

> **When Can I test?**
>
> In order to perform SARS-CoV-2 POC testing and report patient-specific results, a facility must be a CLIA-certified laboratory or testing site that meets applicable regulatory requirements. **CMS is temporarily exercising enforcement discretion** under CLIA for SARS-CoV-2 POC testing when a facility has submitted a CMS-116 application for a CLIA CoW, but has not yet been assigned a CLIA number. **Specifically, facilities that have applied for a CLIA CoW to perform SARS-CoV-2 POC testing (as indicated on section VI of the submitted CMS-116) can begin SARS-CoV-2 POC testing and reporting patient-specific results as soon as they have submitted their application to their State Agency (SA).** A non-certified facility will be treated as operating under CoW while their application is being processed.
>
> Facilities that have submitted a CMS-116 application for a CLIA CoW should check with their SA before they begin testing as states may have additional licensure requirements that must be met before testing can begin.

What If I already have a CLIA waiver certificate?

Your CLIA waiver should name the specific types of tests being administered by your site. If you need to amend your CLIA Waiver to include a new type of test, amendments can be made by emailing BCHS-CLIA@michigan.gov with your CLIA identification number, name and address of the site, and changes needed. Information on amendments can be found at LARA CLIA information.

Please keep record of the amendment email sent to the email address listed above. This will serve as your proof and confirmation of amendment to your existing CLIA Waiver. You may

consider the amendment request complete and begin utilizing the test added once the email is sent.

If you are a site and want to know If a CLIA certificate is on file you can check using the [CLIA Waiver Lookup Tool](#).

Resources

[LARA CLIA information](#)

[CMS CLIA Application Guide](#)

[CLIA Waiver Lookup Tool](#)

[CMS 116 CLIA Application](#).