## **Frequently Asked Questions – CLIA & General Testing Questions for Schools, Districts and School Nurses, October 3, 2022**

## **CLIA Certificate of Waiver Testing Questions**

1. **What type of tests require a CLIA Certificate of Waiver for districts and schools?**

Any K-12 district or school that will be administering CLIA-waived testing on-site to students or staff, including but not limited to certain glucose, ketone, and COVID-19 testssuch as the Abbott BinaxNOW COVID-19 Antigen Card Test, the iHealth At-Home Antigen Test, or a CLIA-waived PCR test, must be operating under a CLIA Certificate of Waiver as required by Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulations found [here](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents). This also includes testing conducted or evaluated on-site by school nurses using over-the-counter COVID-19 self-tests.

Generally, a test that has been cleared, approved, or authorized specifically for home use by the FDA is not regulated under CLIA when that test is self-administered in accordance with the FDA’s authorization and authorized labeling. If the test is either performed on-site by someone other than the individual being tested (e.g., school nurse), or the results are interpreted or reported by someone other than the individual being tested, then a CLIA certificate is required.

1. **How does a school or district apply for a CLIA Certificate of Waiver?**

A district or school administering CLIA waived tests must apply for a Certificate of Waiver through the [Department of Public Health (DPH) Clinical Laboratory Program](https://www.mass.gov/how-to/apply-for-a-clinical-laboratory-improvement-amendment-clia-certificate) by e-mailing the completed [CMS-116 CLIA application](https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf) to CLIALab@mass.gov. **DPH encourages districts to submit applications at the municipal or regional school district level whenever possible.** The application should be completed by someone knowledgeable about the testing to be performed.

Further information on applying for a CLIA Certificate of Waiver can be found in Appendix 1 at the end of this document under ‘Guidance for filling out CLIA Application’, in [this Quick Start Guide](https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf) and this [FAQ issued by CMS](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf).

1. **If a school does not have and has not applied for a CLIA Certificate of Waiver, can they perform CLIA-waived tests during the 2022-2023 school year?**

As announced in the memorandum issued October 3, 2022, DPH has obtained a statewide waiver through the 2022-2023 school year for districts and schools that would like to conduct CLIA-waived testing, including but not limited to COVID-19, glucose and ketone testing. In order to be added to this waiver, schools and districts must complete [this online form.](https://survey.alchemer.com/s3/7032448/Application-for-coverage-under-2022-2023-statewide-CLIA-Certificate-of-Waiver)

 **Districts are encouraged to submit the form at the municipal or regional school district level wherever possible.**

Districts or schools planning to administer CLIA-waived tests in and beyond Fall 2023 must still apply for their own CLIA waiver by March 31, 2023 to ensure transition to their own waiver for the 2023-2024 school year (see Question 2 and Appendix 1 for instructions). **Districts should submit applications at the municipal or regional school district level wherever possible.**

1. **Our district or school already has a CLIA Certificate of Waiver, do we need to fill out the survey to be added to the DPH statewide waiver?**

No, districts and schools that are already covered under their own CLIA Certificate of Waiver do not need to fill out the new DPH statewide waiver. Districts or schools may search the CMS website to confirm that a CLIA certificate is active: [CLIA Laboratory Search](https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp). Please note that applications processed very recently may not appear.

1. **Our district or school already has a CLIA Certificate of Waiver for certain tests; how do we add additional tests onto the certificate?**

Implementing additional CLIA-waived tests does not require notification unless doing so would put the facility over the limit of 15 different tests performed under a multiple site certificate.

See the [**FDA List of Currently Waived Analytes**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm)to determine whether a particular test is CLIA waived.

1. **Do CLIA Certificates of Waiver expire? What is the process for renewal?**

The school or district needs to renew certification every two years by paying CLIA fees. The Centers for Medicare and Medicaid Services (CMS) will send an invoice directly to the address that they have on file for the certificate.

Fee payments for certificate renewal need to be submitted to the address on the invoice or paid online at <https://www.pay.gov/public/form/start/55598674>.

Districts or schools may search the CMS website to confirm that a CLIA certificate is active: [CLIA Laboratory Search](https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp). Please note that applications processed very recently may not appear.

## **Questions regarding COVID-19 Testing**

1. **Will the iHealth self-test expiration dates be extended?**

Extended expiration dates on BinaxNOW and iHealth tests are posted on the [K-12 Testing Program section](https://www.doe.mass.edu/covid19/testing/default.html) of the DESE website. Most tests, and all iHealth tests distributed by the State, have been extended at least through fall 2022. Tests that were distributed in the Spring of 2022 came with stickers to put on test kits to make it clear that expiration dates have been extended and that there are treatment options if individuals test positive. If districts and schools require additional stickers, please contact k12covid19testing@mass.gov. Alternatively, districts and schools may create their own stickers using the information below:

*Expiration dates have been extended! Visit ihealthlabs.com/pages/news
Tested Positive? Visit mass.gov/CovidTreatment*

1. **How do we dispose of expired antigen tests (e.g., self-tests and/or BinaxNOW tests)?**Self-tests and BinaxNOW tests that are expired may be disposed in **regular trash**. Please check the extended expiration dates on the [K-12 Testing Program section](https://www.doe.mass.edu/covid19/testing/default.html) of the DESE website prior to disposing tests to avoid disposing of tests that have had their expiration dates extended.
2. **Will the state offer free tests during the 2022-23 school year?**

As announced on May 25, 2022, DESE and DPH will no longer routinely supply self-tests or other COVID-19 testing services to schools and districts. For school year 2022-23, DESE and DPH strongly recommend that schools and districts interested in implementing their own testing program limit that program to symptomatic rapid testing only. Schools and districts may purchase self-tests through the statewide contract.

Statewide contract: [COVID-19 Statewide Contract Resources for Antigen Test Kits](https://www.mass.gov/info-details/covid-19-statewide-contract-resources-for-antigen-test-kits)

1. **What requirements do schools need to run symptomatic testing using self-tests and/or BinaxNOW tests?**

All schools running in-school symptomatic or other testing must adhere to the following requirements:

|  |  |  |  |
| --- | --- | --- | --- |
| **Situation** | **CLIA Certificate of Waiver Required?** | **Reporting to DPH Required (Positives Only)?** | **Provider’s Order Required?** |
| BinaxNOW “Professional” or other official Point of Care test, any testing reason | Yes | Yes | Yes |
| Self-Test sent home, any testing reason | No | No | No |
| Self-Test performed and result interpreted at school by the individual being tested, any testing reason | No | No | No |
| Self-Test performed or result interpreted by third party (e.g. staff), any testing reason | Yes | Yes | Yes |

*For more information on when CLIA and other requirements apply, please see CMS guidance at* [*https://www.cms.gov/files/document/over-counter-otc-home-testing-and-clia-applicability.pdf*](https://www.cms.gov/files/document/over-counter-otc-home-testing-and-clia-applicability.pdf)*.*

*Children 15 or older are allowed to self-administer iHealth tests. Information about who is able to self-administer a self-test is available in the test’s package insert.*

1. **How should positive COVID-19 test results be submitted to the Department of Public Health, if required (see table in #4, above)?**

Any positive COVID-19 tests run at the school, by school staff, must be reported to the Department of Public Health using SimpleReport. Positive test results no longer need to be reported to DESE. Schools will have the option to perform a bulk upload of results into SimpleReport.

 Schools can sign up at [simplereport.gov/sign-up](https://urldefense.com/v3/__http%3A/simplereport.gov/sign-up__;!!CUhgQOZqV7M!yHknwBM51CsGkEQKnrrU_4Czi8avM8T8YiYhBL2a1C7bw9p5n_273YBSPavnTxdX8v38$)

* + As a new organization using SimpleReport, please select “My organization is new to SimpleReport” when signing up.
	+ If you have multiple testing facilities or locations within your organizations, please coordinate among the different facilities to identify an administrator to create the account for your organization.
	+ After the organization account has been established, the administrator will be able to invite additional users to be administrators for the account or as standard users.
	+ When adding a new testing location under your organization, you will need the CLIA number associated with the facility, as well as the NPI number for the Ordering Provider at the facility or for your organization. If an NPI number is not available, please enter all zeros (0000000000).

SimpleReport Resources:

* + [Setting up your SimpleReport testing workflow](https://www.simplereport.gov/assets/resources/k12-guide.pdf)
	+ [SimpleReport Training Website](https://training.simplereport.gov/app)
	+ [Bulk Result Upload Guide](https://www.simplereport.gov/assets/resources/Bulk_person_upload_guide.pdf)
	+ [CSV template for uploads](https://github.com/CDCgov/prime-simplereport/blob/main/backend/src/test/resources/test-upload.csv)
	+ For questions or issues with SimpleReport please contact support@simplereport.gov
1. **When is a provider’s order required? What should be included in a provider’s order?**

COVID-19 antigen tests and individual PCR tests administered on-site by school staff must be ordered by a health care provider. The district or school must have a provider’s order in place prior to testing. Districts and schools may obtain a standing order from a school physician or local board of health medical director.

A model provider’s order for COVID-19 tests can be found in the Appendix 2 below. Please note that the provider’s order must be adapted to reflect the type of testing being provided (symptomatic, etc.) and the type of test being used (PCR vs antigen, saliva vs nasal swab, etc.).

1. **Are COVID-19 testing consent forms from the 2021-22 school year still valid for the 2022-23 school year? What elements should a district/school consider when developing new COVID-19 testing consent/opt-in forms?**

No. Districts and schools should obtain new consent forms each school year.

Consent forms should contain the following:

* Authorization to collect a sample from an individual at school and/or to receive self-tests for at-home collection
* Authorization to report positive test results and individual’s demographic information to the Department of Public Health

For MAVEN reporting the following Demographic information is required

* + Individual’s full name
	+ Date of birth (MM/DD/YYYY)
	+ Address
	+ Race (American Indian/Alaskan Native, Asian, Black/African American, Native Hawaiian/Pacific Islander, White, Other, Prefer not to say)
	+ Ethnicity (Hispanic or Latinx, Not Hispanic or Latinx, Prefer not to say)
	+ Gender (Male, Female, Transgender, Nonbinary, Unknown, Other, Prefer not to say)

**Appendix 1: Guidance for filling out CLIA Application**

For your convenience, we are sharing some information that may help you fill out your CLIA application if your facility does not already have a CLIA Certificate of Waiver. Please note, districts and schools are required to obtain their own CLIA Certificate of Waiver by March 31, 2023 to be covered during the 2023-2024 school year.

* Name of School/School District
* Address of School/School District
* Point of Contact email
* Federal Tax Identification Number
* Telephone Number
* In Section I, please select “Initial Application”
	+ For the section requesting the Name/Credentials of the Director please input the individual who will have responsibility for oversight of the testing and ensuring compliance with CLIA requirements. Where an application is filed for multiple schools (i.e., a school district), the Director will be responsible for testing in all of the schools listed within the application. Typically, the Director will be the school nurse manager.
* In Section II, please select “Certificate of Waiver” if you will be performing only CLIA-waived tests.
* In Section III, please select the item most descriptive of your facility type, e.g. 26-School/Student Health Service.
* In Section IV, please list the times during which laboratory testing will be performed.
* In Section V, please select “No” and go to section VI, unless the organization plans to perform tests at multiple sites, e.g. a school system.
	+ If multiple site testing will apply, the organization must ensure that Section V is accurately completed. Attachment of a list of locations is acceptable if it includes all of the information requested in Section V.
* In Section VI, please enter specific testing information as in the example provided. Incomplete information may result in processing delays if applications need to be resubmitted. Districts and schools should provide the brands and manufacturers of tests being administered to the best of their ability, and once the waiver is granted, confirm that all tests being used are on the CLIA-waived list prior to administering.
* Skip Sections VII and VIII if only CLIA-waived tests will be performed.
* Complete Sections IX and X, ensuring that Type of Control and ownership information has been provided and that the Laboratory Director has signed/dated the application. **Please note:** for Type of Control in Section IX you would consider what form of control your school or district falls under, for example “city or town” or “religious affiliation”. If unsure, please consult your Head of School, Director or Superintendent. The name of the owner of the laboratory in Section X may be the entity that provides control of a public school or district, for example “Town of \_\_\_\_”.

Please completely fill out the other sections, as applicable, including the laboratory director signature section.

Please send the completed application to the Clinical Laboratory Program at CLIALab@mass.gov If you have any questions you may contact the Clinical Laboratory Program at (617) 660-5385.

A resource you may find helpful is this Quick Start Guide from CMS: <https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf>

**Appendix 2: COVID-19 Model Provider’s Order**

**Non-Patient Specific Standing Order and Protocol for obtaining a specimen for COVID-19 testing as part of testing programs for educational institutions**

In accordance with the federal PREP Act,[[1]](#footnote-2) qualified persons may collect anterior nares swab specimens from individuals that are receiving diagnostic testing for SARS-CoV-2 (“COVID-19”) as a covered countermeasure in response to the COVID-19 public health emergency (see, 42 U.S.C. § 247d- 6d(a)(1) (providing liability immunity to covered persons for covered countermeasures). All staff performing this test must be trained in specimen collection and use of proper personal protective equipment (“PPE”) specific to this test and otherwise satisfy the requirements of the PREP Act. Furthermore, in accordance with Massachusetts Department of Public Health guidance, individuals down to the age of Kindergarten may self-collect anterior nares samples.

**Non-Patient Specific Order**

**Purpose**: To permit individuals described above, in accordance with the PREP Act, to collect diagnostic specimens as a covered countermeasure to the COVID-19 public health emergency.

**Policy**: Under this non-patient specific standing order, individuals authorized in accordance with the PREP Act and/or state public health guidance may perform an anterior nares swab on individuals associated with an educational institution including on children, who have been identified by the institution and whose parent/legal guardian has consented, for COVID-19 diagnostic testing.

**Order**: Obtain an anterior nares specimen from the student to acquire the specimen.

**Non-Patient Specific Protocol**

1. Verify that the individual has been identified for diagnostic testing for COVID-19 by the institution.

2. Verify a consent is on file for the individual.

3. Review and be familiar with the PPE required to administer an anterior nares swab.

4. Review and be familiar with the procedure for performing an anterior nares swab.

5. Ensure all supplies, including specimen test kits, PPE and required forms for testing and documentation are available.

6. Record that the test was performed by documenting in accordance with state DPH policy.

**Do not attempt to obtain the specimen if:**

1. There is no consent on file.

2. The individual's lack of cooperation interferes with the procedure.

This Order shall remain in effect until rescinded or until XX. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Issued by XX

NPI Number XX

1. The PREP Act (enacted Dec. 30, 2005) amended the Public Health Service Act to provide liability immunity to a “covered person” for a “covered countermeasure”. PREP Act immunity applies to any covered person with respect to all “claims for loss” caused by, arising out of, relating to, or resulting from the “administration” or the “use” of a covered countermeasure if a Declaration has been issued by the Secretary of the U.S. Department of Health and Human Services with respect to that countermeasure. 42 U.S.C. § 247d-6d(a)(1). The Secretary issued such Declaration for covered countermeasures in the Federal Register on March 17, 2020 (see, https://www.govinfo.gov/content/pkg/FR-2020-03- 17/pdf/2020-05484.pdf). [↑](#footnote-ref-2)