## Department of Elementary and Secondary Education &

## Department of Public Health

## **Frequently Asked Questions – COVID-19 Testing, June 9, 2022**

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, have been extended at least until fall 2022. CIC Health is sending schools 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.

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.
2. **What type of testing will be offered in during the summer 2022?**

DESE/DPH will continue to provide self-tests for symptomatic testing for **school-based** summer programs (e.g., summer school, acceleration academies, ESY). Symptomatic testing may be done in school using self-tests and/or the remaining supply of BinaxNOW tests (if applicable) or by sending self-tests home with students/families. Staffing, software, and other services provided through CIC Health **will no longer be available**. Districts and schools will need to provide staffing for in-school symptomatic testing for school-based summer programs.

1. **What requirements do schools need to run symptomatic testing using self-tests and/or BinaxNOW tests over the summer 2022?**

All schools running in-school symptomatic testing either by using the remaining supply of BinaxNOW antigen tests or self-tests, 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.*

***CLIA Certificate of Waiver***: schools previously approved in the statewide testing program will continue to operate under the statewide CLIA Certificate of Waiver through summer 2022.

Schools new to the program, must fill out the statewide CLIA for all testing sites: <https://survey.alchemer.com/s3/6158268/Application-for-coverage-under-a-statewide-CLIA-Certificate-of-Waiver>. Beginning in the 2022-2023 school year, this CLIA Certificate of Waiver will not be applicable.

***Reporting positive results***: See below for information on how to report positive test results.

***Provider’s order***: Schools that were approved in the K-12 Testing Program during SY2021-22 will have the provider’s order covered by DPH through the summer 2022. (The provider’s order will be updated to reflect self-tests administered at the school.)

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

Beginning in summer 2022 and going forward, any positive 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 with their first facility at [simplereport.gov/sign-up](https://urldefense.com/v3/__http:/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/facility 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).
    - Only for summer 2022, schools should enter 22D2202157 as the CLIA number, and 1720044050 as the NPI. Beginning in the 2022-2023 school year, schools must obtain their own CLIA and NPI numbers.

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](mailto:support@simplereport.gov)

1. **Are consent forms from this school year still valid this summer? What elements should a district/school consider when developing new testing consent/opt-in forms?**

Any individual who already has consent on file (such as on the CIC Crush the Curve Platform) can receive COVID tests this summer without having to obtain consent again. Consent forms for previously consented students and staff will be available for view in the CIC Crush the Curve platform through the end of summer 2022. Any new individuals to testing will need to complete a consent form provided and tracked by the district/school. Districts and schools should obtain new consent forms for fall 2022 testing.

Elements of new consent forms:

* 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
* Demographic information required for MAVEN:
  + 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)

1. **What requirements (CLIA, reporting of positive results to DPH, provider’s order) must schools have in place to run testing program in fall 2022 and beyond?**

This depends on what kind of program the school plans on having in place. The table provided in #4 above provides the relevant information about what is required to run various types of antigen testing. Please note that while schools will continue to have access to CLIA Certificate of Waiver and provider’s orders through the state for summer 2022, they will need to make their own arrangements, as necessary, starting in fall 2022 if they want to continue to run testing programs. The information below provides an explanation of the requirements.

Please also note that pooled testing and individual (“diagnostic”) PCR tests sent to a clinical laboratory do not require CLIA coverage, but individual PCR testing does require a provider’s order.

Fall 2022 testing (please refer to the chart in question #4 above based on the type of testing the district/school will offer):

***CLIA Certificate of Waiver***: Districts or regions whose testing programs necessitate a CLIA Certificate of Waiver are highly encouraged to submit that application as soon as possible, as processing times will grow longer later in the summer and there is no guarantee of review before the start of the school year. Instructions on how to apply for a Certificate of Waiver may be found here: [Apply for a Clinical Laboratory Improvement Amendment (CLIA) Certificate | Mass.gov](https://www.mass.gov/how-to/apply-for-a-clinical-laboratory-improvement-amendment-clia-certificate)

Districts who need a CLIA Certificate of Waiver to run a COVID testing program in Fall 2022 must submit complete applications no later than August 1, 2022. Submission of applications as soon as possible is strongly encouraged to allow more time for review, processing, and feedback to the facility.

Where applicable, school districts are strongly encouraged to apply for one CLIA Certificate of Waiver that would include all schools in the district. This is less burdensome from both a submission and a review perspective.

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:

* In section I, please select “Initial Application” and under “Other Changes (Specify)” fill in “COVID 19” to alert our program that your application is a part of this distribution effort.
* In section II, please select “Certificate of Waiver” if you will be performing only the CLIA-waived tests (like the Point of Care “Professional” BinaxNOW test).
* In section III, please select “26-School/Student Health Service.”
* In section V, please select “Yes” if you are applying as a school district and have more than one school in your district.
  + In #1 in section V, please select “No” (unless there are plans to test at temporary locations).
  + In #2 in section V, please select “Yes” if criteria are met and provide requested information for each location/school.
  + In #3 in section V, please select “No.”
  + Please note that only one of the multiple site criteria may be selected.
* In section V, please select “No. If no, go to section VI” if you are applying as a school at a single site.
* In section VI, please enter the name(s) of the test(s) that will be performed under the CLIA waiver (for example, “Abbott BinaxNOW COVID-19 Ag Card Test”) and provide the Estimated Total Annual Test Volume.

Please completely fill out the other sections, as applicable, including the laboratory director signature section. If you are only performing testing for students and staff, then you do not need to obtain a state clinical laboratory license in addition to a CLIA Certificate.

Please send the completed application to The Clinical Laboratory Program at [CLIALab@mass.gov](mailto: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>

***Reporting positive results****:* See question #5 above for instructions on how to report positive results administered at school by school staff.

***Provider’s order****:* Antigen tests run at the school by school staff, as well as individual PCR tests, must be ordered by a physician. 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 past model provider’s order can be found in the Appendix below. Please note that the provider’s order may change with the type of testing being provided (symptomatic, etc.) and the type of test being used (PCR vs antigen, saliva vs nasal swab, etc.).

1. **How do I obtain a summary of all individuals that consented into the testing program in the 2021-22 school year?**

Please review [this document](https://docs.google.com/document/d/1EetkXzdXgvJlEcfVhNYv1QUsG0CdtxgUz4uyGJvcWmM/edit#heading=h.eaw7oewjos2t) for instructions on how to download a summary of all individuals that consented into your school’s testing program in the 2021-22 school year. Please note that this report will not be available beginning in fall 2022. As a reminder, once your school has access to these records, please be aware of the requirements associated with 603 CMR 23.00.

Appendix: 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 Dr. 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)