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iHealth Rapid Antigen Test Implementation Toolkit

Steps

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STEP 1: Apply for CLIA waiver
(Please skip to Step 2 if your school district already has a CLIA waiver)

What is a CLIA waiver?
A CLIA waiver (Clinical Laboratory Improvement Amendment) is a certification that allows a facility to legally examine a person through waived tests for the purpose of diagnosis, treatment, or prevention of disease. Waived tests are simple laboratory examinations and procedures, like a rapid antigen test, that have an insignificant risk of an erroneous result. The antigen tests provided by DOH require that any facility administering these tests to obtain a CLIA waiver in order to legally perform the test. If you perform a test and do not have a CLIA certificate, you will be in violation of federal law.

What is the cost?
CLIA waiver certificate cost is $190. The fee received will cover the time period from the application date until the license expires in June 2023.
Do I need to list every address where I will test?
Yes, the school district should list every building in their district where testing might occur. If needed, you can include a separate sheet of paper with a list of the building names, full addresses, and phone numbers.

What if my school already has a CLIA waiver?
Many school districts across Washington state already have CLIA waivers (e.g. if a district participated in student athlete screening in spring 2021). To check if your school district has a CLIA waiver:
1. Go to the CDC’s CLIA Laboratory Search Engine
2. Enter the name of your school district into the “Laboratory Name” field and click search

If your school district already has a CLIA waiver for another rapid antigen testing technology, you do not need to reapply.

What is the CLIA waiver application process?
1. School district applies for CLIA waiver (1 application per district)
   • Fill out a Washington’s Medical Test Site License/CLIA Certificate of Waiver test site application packet
   • If testing will occur at multiple school buildings, districts must attach a list of names, addresses, and phone numbers for all the buildings covered
   • To complete the application process, districts must send hard copy ink signed original application with payment to the address on the top left-hand corner of the application form. The fee for a two-year certificate of waiver license is $190. The fee received will cover the time period from the application date until the license expires in June 2023.

CLIA application questions can be directed to lqa@doh.wa.gov.

Health Commons has a CLIA Waiver Application Template with highlighted fields and instructions, which you can reference this as you complete your own CLIA waiver.

STEP 2: Order iHealth test kits

When should I order iHealth test kits?
You can request iHealth test kits immediately after submitting your CLIA waiver application. You do not need to wait for your CLIA waiver to be formally approved or mailed to you before starting testing.

How do I order iHealth test kits?
Please coordinate with your Educational Service District to obtain iHealth test kits. They will provide you an allocation of tests based on your enrollment numbers and anticipated testing need.

How many test kits come in a box and a case? How many test kits should I request?
Each iHealth kit contains 2 tests. DOH orders and ships iHealth by the “master case,” which contains 90 kits. You can determine your daily testing needs based on the number of students and staff you screen for symptoms each day.

When will I receive my test kits?
Your Educational Service District will provide you with confirmation on pick-up and receipt date.
**STEP 3:** Communicate testing plan and collect consent to student testing

Is there a sample letter I can use to announce our testing plan to my school community?
Yes, Health Commons has a [sample announcement letter](#) for you to use. We invite you to edit this template to best fit your community.

Is there a template for a consent form?
Yes, you can use the [rapid antigen generic consent form](#). We recommend including it in your message to parents. You should also include the [iHealth Fact Sheet for Patients](#) when you send out your consent form.

**STEP 4:** Identify test observers and review iHealth training materials

**What is a test observer?**
iHealth is a rapid antigen test that can be self-administered while under observation by a trained test observer. This trained test observer needs to be age 18 or older with a high school degree (or equivalent) but does not need to be a healthcare professional. The key responsibilities of the test observer are to provide the test kit to the student, observe the sample collection, run the test for a result, and record the test results.

**Who should my test observers be?**
Test observers can be anyone — nurses, health room aides, administrative staff, etc. — that meet the above requirements. Isolation room staff most often serve as test observers. Many schools will have one test observer per test site, but this depends on your staff capacity.

**How are test observers trained?**
For iHealth, all test observers are required to review the [iHealth Instructions for Use](#). Test observers can also watch the [iHealth tutorial video](#). A iHeath tutorial video is also available in Spanish.

**STEP 5:** Receive test kits and perform quality control

**What should I do with test kits once they arrive?**
When you receive your test kits, each test observer should perform a quality control test on one of the test devices. This ensures the test kit is working as anticipated and demonstrates testing administrator competency before officially launching the tests with students.

You can find quality control procedure instructions in the [iHealth Instructions for Use](#).

**How should I store my iHealth test kits?**
The iHealth test kits should be stored in a dry place between 36°F to 86°F. Ensure all test components are at room temperature (65°F to 86°F) before use.

**When will my test kits expire?**
The iHealth test expiration date is printed on the outer packaging.
**STEP 6: Launch testing**

**When can I launch testing?**
You can begin testing as soon as your test kits have arrived and your test observers are trained. Remember to factor in a quality control test and a dry run before going live.

**What ages is this test authorized for?**
This test is authorized for observed self-collection from individuals ages 4 years and up.

**Where should I administer iHealth tests?**
Testing can take place in a variety of locations based on the purpose of the testing. For example, diagnostic testing may occur in an isolation room, while sports screening testing may take place before practice in the gym. When selecting a location to administer iHealth tests, keep in mind the test card must be flat when performing testing and should not be performed with the test card in any other position.

**What supplies should I have on hand in order to test?**
- Ensure consent is obtained for each student
- PPE (mask and gloves)
- Timer (avoid using personal cell phone to avoid contamination)
- Flat surface
- Permanent marker
- Hand sanitizer
- Disinfectant
- SimpleReport account (see Step 7)

**How should I associate a test device with a particular student while I wait the required 15 minutes for results?**
We recommend using a permanent marker to write the student’s initials on the outside of the test card along with the time the results should be read.

**Can we dispose of waste from the iHealth test kits in the regular trash?**
Used antigen tests should be discarded and sealed in a single bag, which can then be disposed of in the regular trash. Schools should contact their local public health department to determine if this meets local disposal guidance.
STEP 7: Ongoing reporting

What are the reporting requirements for iHealth?
In alignment with K-12 COVID-19 Requirements, schools must report positive rapid antigen test results administered by the school within 24 hours of the test via SimpleReport. U.S. Digital Service’s SimpleReport is a web-based reporting platform developed by the CDC that allows facilities to electronically report test results to public health departments.

If using iHealth as an LHJ-approved take-home test, results provided by participating students, staff, or parents/caregivers should NOT be reported through SimpleReport. There is no reporting requirement for schools in this scenario. The household can choose to self-report using the Self-Testing Interim Guidance from DOH, also summarized below:

“Use the state’s COVID-19 hotline: Hotline personnel will determine next steps based on zip code so results can be recorded and reported, and can guide callers through any questions they may have. The state hotline, 1-800-525-0127 (then press #), is available Monday from 6 AM to 10 PM, and Tuesday to Sunday (and observed holidays) 6 AM to 6 PM. Language assistance is available.”

How do I sign up for SimpleReport?
Each school district will have one central SimpleReport account where schools will be added as individual testing facilities within the account. Only one person from a school district needs to request access to SimpleReport. This person who is designated as the single account administrator will be responsible for adding individual schools (i.e., “testing facilities”) and test observers (“users”) to the district account.

We have a SimpleReport toolkit to help you get started, which includes account set up instructions, FAQs, user guides, and other onboarding resources.

What if my district already has a SimpleReport account?
Your district may already have a SimpleReport account if you have been using rapid antigen tests in your school community, like for athletics.

District leadership and extracurricular groups (e.g., athletics) should coordinate to determine if your district already has a SimpleReport account and — if not — who should be responsible for the initial set-up of your district’s SimpleReport account. Each school district will have one central SimpleReport account where schools will be added as individual testing facilities within the account. Only one person from each district should request access to SimpleReport.

How do I add additional test devices to my SimpleReport account?
To add a new device (e.g. iHealth) to your SimpleReport account, a person with admin privileges needs to go into to each individual testing facility and add the new testing technology at the very bottom under “Manage Devices”. You can have multiple “devices” (i.e. tests) for each facility. You also have the option to select one as a default.

If I have questions about SimpleReport, who should I ask?
You can reach out to your assigned Program Manager or reach out directly to US Digital Service using their SimpleReport support page if you are having issues using the tool.