TOOLKIT

AccessBio CareStart
Rapid Antigen Test
IMPLEMENTATION TOOLKIT
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AccessBio CareStart Rapid Antigen Test
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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 AccessBio CareStart test kits

When should I order AccessBio CareStart test kits? 
You should order your AccessBio CareStart 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 ordering tests or starting testing.

How do I order AccessBio CareStart test kits? 
Navigate to the DOH testing order form. Complete the required fields within the order form (select “BinaxNow/AccessBio CareStart” from dropdown).

Contact Information
• Contact Name, Telephone, Email
• Facility Type: Schools K-12
• School District: Other (Not Listed)*
• School District Other: Other (Not Listed)*
• Requesting Entity: School Name
• Learn to Return Participant: Yes
• Testing Purpose/Event: Select option(s) that best represent your testing strategy

*NOTE: If you are a private school, you will put “other” for school district. Then, you will be asked to find your private school in an additional dropdown field. If you cannot find your school listed, select other.

**Shipping Information**
• Address, City, State, Zip Code, County

**Testing Supply Request**
• Supply Type: BinaxNow/AccessBio CareStart
• Amount requested: number of **TESTS** you need for the next 4 weeks (1 AccessBio CareStart master case box = 40 tests)
• CLIA Waiver: check box to indicate you are operating under a CLIA waiver
• CLIA Number: insert CLIA number if you already have it, you can leave this field blank
• Positive Reporting of Results Required: check box to indicate your understanding

**Testing Audience Additional Questions**
• Cluster Outbreak Response Request: check box if you are currently experiencing an outbreak

**Additional Information**
• Notes: We are offering [screening] / [diagnostic] rapid antigen testing for [district’s] [students] / [staff]. We have [X] number of [students] and [X] number of [staff].

**How many test kits should I order?**
Each AccessBio CareStart box contains 20 test kits. DOH orders and ships AccessBio CareStart by the “master case”, which contains 40 test kits (i.e., 2 boxes of 20 tests each). You should order the volume of tests needed for the next few months (we estimate 1-2% of your total student volume will be tested each day). You can also gauge your daily testing needs based on the number of students and staff you screen out for symptoms each day. You can use the same DOH order form to re-order additional kits if needed.

**When will I receive my test kits?**
You should receive your test kits within approximately 1 week of ordering. If you do not receive your test kits within that time frame, please email Angelea Skaggs directly at angelea.skaggs@doh.wa.gov.
**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, Health Commons has a template for consent. We recommend including it in your message to parents. You should also include the AccessBio CareStart Fact Sheet for Patients when you send out your consent form, which is linked directly in the consent form. This can also be included as a separate document, which can be downloaded [here](#).

**STEP 4:** Identify test observers and review AccessBio CareStart training materials

**What is a test observer?**
AccessBio CareStart 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 18 years 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, and record the test results.

**Who should my test observers be?**
Test observers can be anyone – nurses, health room aides, administrative staff, etc. Isolation room staff most often serve as test observers. Many schools will have 1 test observer per test site, but this depends on your staff capacity.

**How are test observers trained?**
All test observers are required to review the [AccessBio CareStart Instructions for Use](#) for anterior nasal swab (shallow nasal swab) test procedures.
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 to demonstrate testing administrator competency before officially launching with students.

You can find quality control procedure instructions in the AccessBio CareStart Instructions for Use here.

How should I store my AccessBio CareStart test kits?
The AccessBio CareStart test kits should be stored between 33.8 and 86 degrees Fahrenheit. The test device must remain in the sealed pouch until use. Do not freeze any contents of the kit.

When will my test kits expire?
Expiration dates will range up to 16 months, depending on how long they’ve been sitting on DOH shelves. You can find the expiration date on the box near the lot number. See shelf-life extension notification here.

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! Typically, it takes a district about 2 weeks to launch from your test kit order date. Remember to factor in a quality control / dry run before going live!

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

Where should I administer AccessBio CareStart tests?
Most districts opt to use their isolation room for testing. Keep in mind the test device must be flat when performing testing and should not be performed with the test device 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 marker to write the student’s initials on the outside of the test device along with the time the results should be read.

Can we dispose of waste from the AccessBio CareStart 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 AccessBio CareStart?
Schools must report positive rapid antigen test results – within 24 hours of the test via SimpleReport. US 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.

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 – called the account administrator – will be responsible to add individual schools (i.e. “testing facilities”) and test observers (“users”) after creating the district account.

We have a toolkit of onboarding resources to help you get started with SimpleReport [HERE](#), which includes account set up instructions, FAQ, 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 are already using rapid antigen testing 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 sign up and 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.

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.