



Saliva PCR Sample Collection Protocol for CCC Partner Schools

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Roles

- Administrator: Person(s) in charge of delivery and pick-up of samples, auditing samples, and PrimaryBio administration
- Sample Observer: Person(s) in charge of observing saliva administration to ensure it's done according to the protocol
- Sample Provider: Person providing the saliva

PPE Requirements for Sample Collection

- Nitrile or latex gloves
- Surgical or N95 mask

Other Materials

- | | |
|---------------------------|---|
| • Internet Access | • 2 mL test tubes with caps |
| • Laptop computer | • 70% ethanol or disinfecting wipe |
| • Barcode/QR code scanner | • Alcohol-based sanitizer or soap and water |
| • Laser jet printer | • Small holding bin for samples |
| • Printer Paper | • Permanent fine tip marker |
| • Bio-bags | |

Pre-Testing and Registration

1. District submits data file directly to Primary that includes list of all possible schools that will be tags
 - a. In these files, districts will indicate which schools may be testing on site



2. District sends out the testing registration link to all families and staff
 - a. Families should ensure they check their junk and spam folders
3. Families go through PrimaryBio registration and choose to schedule an appointment at a CCC site or to sign consent for onsite testing
 - a. Baseline on CCC sites are nasal tests
4. Districts will receive a daily report of students and staff that are currently eligible for onsite testing (e.g. have signed the latest consent form)
 - a. District contact will get one Looker report for their district and contact will divide that per school
 - b. Administrator/Nurse for each school will be responsible for creating testing cohort per day or week

Important Considerations for Saliva Collection

- Collecting saliva is easier than swabs, but saliva can be hard to test if not collected properly
- It is important to follow these instructions so that the only saliva collected is the saliva that naturally pools in the mouth - NOT sputum (mucus)
 - Saliva should be gently expelled from the mouth into the collection tube - this isn't spitting, it's "drooling" or "dribbling"
 - Coughing or spitting to generate saliva immediately prior to sample collection should be avoided
- The sample provider should not drink water **for at least 10 minutes prior** to collection.
- The individual providing the sample should avoid other drinks, food, smoking, nasal sprays, teeth cleaning, and chewing gum **for at least 30 minutes prior** to sample collection
- The individual providing the sample should only remove their mask when ready to pass their sample collection tube, replacing it immediately after sample collection.
- A large, open space where individuals can maintain safe distance while expelling saliva (e.g. a gymnasium) is an ideal collection space.

Safety Before Collection

These are important to reduce the risks of spreading virus from the individual providing a sample to the test collector, and vice versa:

- The trained personnel observing collection must be wearing personal protective equipment (PPE) (surgical or N95 masks, nitrile or latex gloves) prior to contact with the person providing the saliva sample.
- The sample collector must maintain 6 feet of distance from the individual providing the sample.
- Upon arriving, the person providing the sample should clean their hands using alcohol-based sanitizer or soap and water (no fragrances).
- It is important to make sure those providing samples continue to maintain social distancing and wear their mask while waiting to provide a sample.

Safety After Collection



- The Sample Observer should make sure that the cap of the collection tube is closed tightly
- After the sample collection process, both the sample observer and provider should clean their hands using alcohol-based sanitizer or soap and water (no fragrances).
- The sample collector can wear the same gloves for multiple sample collections. Gloves should be changed if any saliva is touched. At the end of collection, the sample collector should clean their hands using alcohol-based sanitizer or soap and water (no fragrances).
 - COVIDCheck Colorado does recommend changing gloves and cleaning hands as frequently as possible
 - If an administrator or observer is uncertain about whether or not they have touched saliva, they should change their gloves and sanitize immediately.
- If for any reason a sample needs to be disposed of (for example, if it is not of acceptable quality for testing) it should be discarded in a sealed biohazard bag into a biohazard container.
 - The biohazard bag should also be clearly marked as “Bio Hazard Waste” to ensure it is not mixed with proper samples
- If the sample collector is unsure about sample quality, they should contact CCC’s Quality Control Lead, jposner@covidcheckcolorado.org
- Samples should be placed in a biohazard container which is sealed and transported according to CCC guidelines.
- The samples can be transferred to the laboratory at room temperature. The virus RNA in saliva remains stable at room temperature for at least 7 days.

Saliva Protocol for Schools

District partners should decide how they would like to organize student and staff testing. The Saliva Protocol below outlines the steps for collection of samples for one student testing group on any given day.

Student Testing Group

1. Each school district will work with their schools to determine their testing groups by day/week

Registration

1. Process indicated above in the Pre-Testing and Registration Section

Test Preparation

1. The Administrator identifies the day’s Student Testing Group using the list showing students who have consent forms signed
2. The Administrator is responsible for applying labels to the test tubes. Each test tube label contains, 2 identifiers:
 - a. A QR code
 - b. A student’s initials that will be written by the Administrator once the individuals for that day’s Student Testing Group have been identified



3. The Administrator should ensure they apply labels to the test tubes using gloves to keep the tubes sterile

Collection

Sample providers are not allowed to drink water 10 minutes prior to collection and should not consume other drinks, food, nasal sprays, chewing gum/ tobacco for 30 minutes before sample collection. COVIDCheck Colorado recommends that districts schedule testing to ensure alignment with these guidelines (i.e. with adequate time before/after meals or snacks) COVIDCheck Colorado also strongly recommends that samples are collected in a large, open space like a gymnasium or auditorium

1. The Student Testing Group waits to enter their school collection space, standing in a socially distanced line and wearing masks
2. While in line, the Administrator or the Test Observer confirms with each student that they have not eaten or drunken anything in the last 30 minutes or had any water in the last 10 minutes. The Sample Observer also provides each student with hand sanitizer
3. As each student confirms that they have met the requirements to test, they enter the gymnasium, or designated area, with their masks on
 - a. Student who have not met the requirements are asked to wait the required amount of time or asked to test with another testing cohort
4. Upon each student's entry, they are handed a pre-labeled tube containing a QR code and their initials by the Administrator who is also wearing a mask and gloves
5. Students are then asked to spread out in the gymnasium, so that each person is standing on a number/marker that is at least 6 feet from the closest student (we recommend making "X's" on the floor for children to stand on)
6. The Observer outlines and supervises the [Sample Collection Process](#) outlined below
7. The Sample Provider raises their hand to indicate that they have collected enough sample (0.5 mL)
8. The Observer inspects the Provider's sample to ensure the sample is adequate

Check-Out (via PrimaryBio)

In the school collection space, the Administrator has an office set up including: bio bags, a computer connected to the internet, a laser jet printer connected to the computer, a barcode scanner connected to the computer, a temporary sample storage container, and the final sample storage container

1. Once it is confirmed that the Sample Provider has collected an adequate sample, the student approaches the Administrator, who is wearing gloves and a mask.
 - a. The student should also have their mask on
2. The Administrator asks the student for their first and last name and locates their ID on the printed list
3. The Administrator searches by ID (access code) in PrimaryBio
4. In PrimaryBio, the Administrator confirms first and last name, initials, and date of birth
5. The Administrator checks out the student by scanning the barcode on the test tube



6. The Administrator prints the requisition sheet
7. Using the barcode scanner, the Administrator scans the sample into Barcode ID field that they will click into and scan the barcode on the vial
 - a. If the scanner fails to work, barcodes can be manually typed in
8. The Administrator opens bio bag
9. Child drops tube into bio bag
10. Administrator places the requisition sheet into the bio bag
11. The student then exits the sample collection space, where the Sample Observer once again provides the student with hand sanitizer
12. After the student has deposited their sample and the Administrator has placed the requisition form in the bio bag; the completed bio bag is placed in the temporary sample storage container

Sample Audit

This process is described in more detail [below](#). The purpose of this audit is to ensure clear and detailed chain of custody for all samples collected on any given day.

1. At the end of the sample collection period, the Administrator opens the COVIDCheck Colorado Shipping Dashboard
2. The Administrator takes the samples in the temporary sample storage container and scans them into the CCC Shipping Dashboard application
3. After a sample is scanned in to the Shipping Dashboard, the Administrator places the sample into the final sample storage container

End of Day/Shipping

1. **COURIER:** for any location 2 hrs or closer to lab - Lab coordinates
 - 1) Confirm site drop off
 - 2) Day of delivery
 - a) Drop off package 10 min prior to courier pick up time
 - b) Sign the box into the log daily
2. **FEDEX: locations that can not use courier**
 - 1) Request Shipping Labels in the [Google Form](#) sent on Mondays
 - 2) Based on the request, your box of test materials will come with the requested number of shipping boxes **pre-labeled** for the shipment to ship back administered tests



Materials you will receive with tests



Pre-labeled box for shipping

*boxes can fit 150ish tests

- 3) Input your tracking number with your site and date of shipment for the day in the [portal](#)
- 4) Pack up your tests securely for shipping and deliver to the FEDEX location where you typically drop off your boxes.

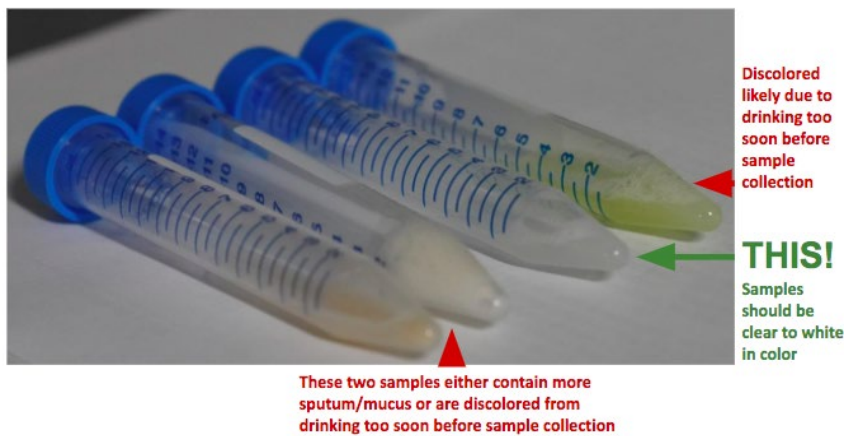
Sample Collection Process

1. While the student providing the saliva sample is still wearing their mask, the Observer will ask them to unscrew the cap of the collection tube
2. While they are still masked, ask the student providing the sample to let their saliva just start to pool in their mouth – make sure that they know not to swallow it!
 - a. Remember, Saliva is intended for the collection of *normal* saliva that naturally pools into the mouth -- it's not spitting, it's "drooling" or "dribbling." Saliva should be gently expelled from the mouth into the collection tube, so no forceful spitting is required
 - b. If someone is feeling nervous about providing a sample, their mouth may start to dry up.
3. To help with saliva production, you can encourage the person providing the sample to think about food to help to get saliva flowing, such as:
 - a. their favorite food
 - b. the last thing they ate or the next snack or meal that they're going to have
 - c. sour foods
 - d. Even just thinking about the saliva collection process itself can sometimes help.
4. It is important to give reminders to continue to work on pooling saliva in their mouth as they produce it
5. Remind them that they should not cough or sniff anything back for collection.
6. Ask the person providing the saliva sample to remove one side of their mask.



7. Standing 6ft away, ask them to hold the tube up to their mouth and gently expel the saliva which has pooled into their mouth out into the collection tube.
8. Have the person providing the saliva sample aim to collect at least 0.5 mL of saliva.
 - a. Any bubbles that also collect in the tube do NOT count towards this total volume.
 - b. If the person is struggling to produce a sample, have them close the tube, replace their mask and take a few minutes to relax and try to pool more saliva into their mouth, before trying again.
 - c. If anything other than saliva is collected (e.g. mucus, a lot of food particles), dispose of the sample, wait a few minutes and start the process again.

What does an acceptable saliva sample look like?



Sample Audit

1. Each Administrator using the shipping dashboard application needs to create an account
 - a. [Dashboard.covidcheckcolorado.org](https://dashboard.covidcheckcolorado.org)
 - b. Click “Sign In”
 - c. Don’t have an account? Click “Sign up now”
 - d. Fill out information
2. The school will inform Quality Assurance Lead of new Administrators added to dashboard
3. Quality Assurance Lead will activate the Administrators’ accounts and inform the school
4. The Administrator will login to their account and select “Containers” from the menu on the left
5. The Administrator will then select “+ ADD” to create a container and fill out information regarding:
 - a. Testing Site
 - b. Date



- c. Label - This is the name identifier for the sample and should follow the format: "[SchoolName_CollectionDate_1]"
6. The Administrator will then select "Scan Samples" and can begin scanning samples into the container
 - a. With gloves on, the Administrator will remove samples from their temporary storage container and scan them into virtual container
 - b. After sample is scanned into virtual container, the sample should be placed in the sample's permanent, physical container (most likely a zip lock bag)
7. After samples have been scanned in, the Administrator can close the bag and return to main screen
 - a. Any Administrator with a dashboard login can re-open a bag and continue scanning samples for their specific test site
 - b. Once a bag is full, it should be sealed and placed into a cooler, refrigerator, or shipping box
 - c. A full bag, placed in the cooler, refrigerator, or shipping box, should not be reopened nor have samples collected or removed from it by ANYONE on site

Data and Reporting

1. Data will continue to flow into districts current dashboards
2. Resulting will follow the same process currently in place
3. CCC will provide districts with the number of students tested in the last 2 weeks, by location

FAQ and Troubleshooting

- **What should I do if saliva has spilled on the outside of the tube?**
If this happens while the sample is being collected, have the person providing the sample sterilize the outside of the tube with 70% ethanol or a disinfecting wipe. If you notice this after the sample is collected, you should sterilize the collection tube with 70% ethanol or a disinfecting wipe.
- **What should I do if the sample has bubbles?**
Some bubbles are okay, just make sure that at least 0.5 mL of the sample is bubble-free.
- **What should a sample provider do if they have COVID-19 symptoms?**
If an individual has COVID-19 symptoms they should be referred to the nearest health care facility for proper evaluation and management and the organization conducting the testing should be made aware of the individuals symptoms.
- **What should I do if the sample provider says they have eaten or drank something less than 30 minutes before collection?**
If they only drank water more than 10 minutes before, continue with sample collection. If they have consumed other drinks, food or chewing gum the sample provider should wait until 30 minutes before sample collection.
- **Can I observe multiple sample providers at once?**



Yes! This is ideal for efficiency. One method we've found successful is to have sample providers stand distanced (e.g. with X marked on a gymnasium floor) in a semicircle, with a sample observer watching everyone.



Computer and Printer Preferences

The Administrator's computer is connected to a regular laser printer. This printer is responsible for printing the requisition form. Please ensure that the laser printer is stocked with regular printer paper (8.5 inches x 11 inches) and is connected to the computer via bluetooth or printer cable.



PrimaryBio Cheat Sheet

Student Pre-Test/Registration:

The screenshot shows the 'Student's Information' form in the 'CCC SANDBOX' environment. The form includes fields for 'Student's First Name *', 'Student's Last Name *', and 'Date of Birth *'. A note states: 'The minimum age for scheduling an appointment is 1 years old.' Below this, there are dropdown menus for 'Month', 'Day', and 'Year'. The 'Parent or Guardian Contact Information for Child's Test Results' section includes fields for 'Mobile Phone Number' and 'Email', with a 'Landline?' checkbox. A 'Continue' button is at the bottom right, and a 'Back' button is at the bottom left. A sidebar on the left contains links for 'Information', 'Questionnaire', 'Student's Information' (highlighted), 'Personal Information', 'Consent', 'Location', and 'Symptoms'. A 'Help' button is at the bottom left of the sidebar.

Check Out Flow:

1. Search for an eligible participant via 'Access Code'

The screenshot shows the 'Primary COVIDCheck COLORADO CCC SANDBOX' dashboard. At the top, there is a 'Global Search...' bar and a 'Search' button. The dashboard is divided into sections: 'General', 'Registration', and 'Results'. The 'General' section shows 'Dates' as 'Nov 03 - Dec 31', 'Locations' as 'On Site School Testing, Echo Park Stadium (Parker, 80134)', and 'Organizations' as 'COVID Check CO'. The 'Registration' section has two rows: 'Population student Registration' with a URL and a 'QR Code' button, and 'CCSD Student ID Registration' with a URL and a 'QR Code' button. The 'Results' section has a 'Results Page' with a 'QR Code' button. A sidebar on the right contains a list of links: 'Appointments', 'Participants', 'Case Report', 'Waitlists', 'Tests', 'Locations', 'Slots', 'Communications', 'Statistics', 'Templates', 'Edit', and 'Details'. A red arrow points to the 'Participants' link.



Primary Global Search... Search CCC SANDBOX

Participants for CCC SANDBOX

Access Code New Participant

Appointments Archived Appointments Participants Waitlists

Search by first name, email, or phone number Search Create Multiple Users

Name	Birth Date	Phone number	Email	Status	On Demand	Schedule	Actions
TestFirstName TestLastName	1991-01-01	(555) 555-5555	test@gmail.com	has appointment	Checkout	Schedule Appointment	Edit
Default Test	1980-01-01	(814) 823-1569	swu+1@covidcheckcolorado.org	has appointment	Checkout	Schedule Appointment	Edit
Student Test	2014-05-02	(814) 823-1569	swu+1@covidcheckcolorado.org	has appointment	Checkout	Schedule Appointment	Edit
Ed Devine	1995-07-07	(914) 263-1415	eddieddevine@gmail.com	has appointment	Checkout	Schedule Appointment	Edit
Student Test				Missing Contact Info Missing Personal Info		Schedule Appointment	Edit

Search by Access Code

Access code *

Close Search

- Confirm full registration/consent is signed and 'Checkout' button is available, click Checkout

Name	Birth Date	Phone number	Email	Status	On Demand	Schedule	Actions
Student Test	2014-05-02	(814) 823-1569	swu+1@covidcheckcolorado.org	has appointment	Checkout	Schedule Appointment	Edit
Student Test				Missing Contact Info Missing Personal Info		Schedule Appointment	Edit



- Now on the Checkout page, click on "Scan Barcode" button

Primary Global Search... Search CCC SANDBOX

Checkout for Student Test (2014-05-02)

Active Records
0 total records

COVID19 PCR (Swab) (PCR) Generate Barcode Scan Barcode

Back Save Records

- This will instantly bring up the Barcode ID field that you will click into and scan the barcode on the vial

Checkout for Student Test (2014-05-02)

Active Records
0 total records

COVID19 PCR (Swab) (PCR) Generate Barcode SCAN123456 Submit

Back Save Records

- Print Label, to be folded and placed into sample baggy front flag, along with vial

Checkout for Student Test (2014-05-02)

Active Records
0 total records

COVID19 PCR (Swab) (PCR)

Barcode ID: SCAN123456 Notes: Test Administered: Administered Not Administered

Add Another Record Print Label

Back Save Records

- Select Administered



Primary Global Search... Search CCC SANDBOX ▾

Checkout for Student Test (2014-05-02)

Active Records
0 total records

COVID19 PCR (Swab) (PCR) Print Label

Barcode ID	Notes	Test Administered
SCAN123		<div>Administered Not Administered</div>

Add Another Record

Back Save Records

7. Select Save Record

Primary Global Search... Search CCC SANDBOX ▾

Checkout for Student Test (2014-05-02)

Active Records
0 total records

COVID19 PCR (Swab) (PCR) Print Label

Barcode ID	Notes	Test Administered
SCAN123		<div>Administered Not Administered</div>

Add Another Record

Back Save Records