

### **Clarifi COVID-19 Testing FAQs**

#### How do I enroll in pooled testing for my organization?

• If you do not already have an account set up, please contact sales@quadrantbiosciences.com to start the process. Our sales team will review contract details with you, and get you everything you need to move forward with testing.

### What information do I need to provide to participate in the pooled testing program with Quadrant Biosciences?

• <u>Testing plan</u>: A Testing Plan will need to be filled out that includes details such as the start date of your testing, how many individuals will you be testing, and how often will you test? During this step you will assign your school's organization managers.

Be sure to list your school exactly how you want it identified on the registration app (so parents can clearly identify it). Example: Chittenango CSD - Bolivar Elementary

• <u>Standing order</u>: A Standing Order needs to be signed by an MD, NP or PA authorizing the results of the tests to be released to the patient and the assigned organization manager(s).

#### How do I get testing supplies?

• Your initial order will be based on your testing plan. Once the plan has been submitted there are several ways to receive your supplies: 1) you can provide your UPS account number and we can ship them ground, 2) we can add them to our UPS account and bill you for shipping or 3) supplies can be picked up at our Syracuse warehouse located at 6251 Fly Road, East Syracuse, NY 13057

#### What testing supplies are provided?

- Barcoded collection devices (1 per student/per test)
- Instructions on how to swab
- Biohazard bags for return shipping (12 tubes per bag)

#### What do I need to provide?

- Personnel at each site to collect samples
- PPE, including gloves, fluid masks, disinfecting wipes and hand sanitizer for personnel collecting samples
- Sample collection area to include computer, scanner with USB port (optional)



#### How do we setup on test collection day?

In-school testing can be set up in two ways:

- Designated testing area such as a gym or auditorium, with collection station(s).
- Mobile room-to-room collection station
- Click <u>here</u> for a quick video overview.

#### What should we have at our collection station?

- Each collection station should be equipped with hand sanitizer, computer, scanner with USB adapter (optional), gloves, pens and a waste receptacle.
- Quadrant Biosciences will provide you with collection devices and biohazard bags.

#### How can students/faculty/staff register for Clarifi COVID-19 Testing at our school?

- Anyone who participates in the surveillance testing should register at: <u>app.clarifi-covid-19.com</u>
- Under "Organization" be sure to let parents know to register under your schools name exactly as it is listed in your testing plan.

#### What do students/faculty/staff need to bring with them the day of testing?

- Anyone being tested must have created a profile in the registration app.
- Those being tested should be instructed NOT to eat or drink anything (with the exception of water), including chewing gum, mints or lozenges, tobacco or smokeless tobacco products, within 30 minutes of reporting to the collection site.
- Mouthwash and toothpaste should NOT be used within an hour of testing.



#### How do I know when test results are ready?

- Individuals: Once your saliva test has been processed, you will receive an email notification that results are ready to review in your account at Clarifi-Covid-19.com.
- Organization Managers: Once all tests for your organization are processed, anyone listed as an Organization Manager on your testing plan will receive an email notification that results are ready to review.
  - This email will come from <u>no-reply@mail.clarifi-covid-19.com</u>

#### How do I view my results?

• Log into <u>https://app.clarifi-covid-19.com/login</u> to view your results. Results will be available on the home screen when you log in; if you have multiple profiles under your account (e.g., spouse and child), select the intended profile to view results.

#### My result says Presumed Negative - what does that mean?

- A "presumed negative" result is the terminology used to describe a negative outcome from a pooled test.
- A "reflex negative" result is the terminology used to describe a negative result from a test on a single sample (the sample was originally processed in a pool that was presumed positive).

#### My result says Reflex Positive - what does that mean?

• A "reflex positive" result is the terminology used to describe a positive result from a test on a single sample (the sample was originally processed in a pool that was presumed positive) and now has been identified as a positive result.

#### What is a reflex test?

• This is a Clinical Laboratory term that describes an automatic (reflex) follow up based on the result of another test. In the case of our pooled testing program, if there is a positive pool we automatically or reflex all samples to an individual test.

#### Do we need to collect another sample for the reflex test?

• No, there is enough liquid left in the collection device after pooling to process those samples on an individual basis.



#### Can I export registered students and test results or test status?

• You can click on "Export Results" from the "Profile Search" or "Registration Search" and get a comma separated data file (CSV) that can be imported into excel to print labels or analyze results.

#### How long do collection kits last?

• The collection kits have a shelf life of 1 year from date of manufacture kits are marked with an expiration date. Once the collection kit is "activated" by replacing the swab back into the collection tube, we can extract RNA from the sample for up to 6 days.

#### What are the storage guidelines?

• The kits, both before and after collection, should be stored at room temperature (15-25 C or 59-77 F). Avoid extreme temperatures, and extended exposure to UV light until ready for use.

#### What are the performance characteristics of this surveillance testing?

• The test kit we are using has been successful in identifying as few as 1 infected person in every 12 pooled samples.

#### My school will be delivering the pooled saliva specimens to Quadrant Biosciences. How late will Quadrant Biosciences receive samples?

• Quadrant Biosciences can receive samples from 8 am until 7 pm at the Institute for Human Performance, 505 Irving Ave., Syracuse, NY 13210.

### Where should deliveries be made? Who can I contact for more information about our specimen deliveries?

- Delivery should be made through the rear building entrance (accessible through the garage entrance facing Madison St.) Free parking is provided in the garage for up to 30 minutes.
- The campuses should contact Sarah Gentile via email at <u>Sarah.Gentile@Quadrantbiosciences.com</u> or by phone/text at 315-575-3784



#### What is the cost to students/employees?

• There is no cost to students or employees for either the pooled testing or individual reflex tests. Some insurance carriers may attempt to bill copays or deductible, this is in violation of the Families First Coronavirus Response Act (Attachment-PLAW-116bubl127) Section 6001 and the CARES Act Section 3202 (Attachment PLAW-116bubl136).

#### What about insurance?

• Insurance does not cover pooled testing, so your school is covering the costs of pooled testing through government funded grants. It does cover the individual reflex testing. The rationale is that the person is in a positive pool if they were potentially exposed to an individual with COVID. Reflex tests are submitted to insurance, insurance carriers should cover the cost of testing through the government funded, Cares Act. If for some reason the claim is denied, the insured will NOT be billed.

#### What if the student does not have insurance?

• In that case, the student can select "No Insurance" in the Insurance Section of the registration application and "NA" in the remaining insurance fields.

#### Where are the test instructions for use?

- For the ORE-100 (swab) : info.suny-covid.com/manual.pdf
- For the OME-505 (spit) : info.suny-covid.com/manual-v2.pdf

#### I am having trouble registering my account or resetting my password?

- Once started, the registration or reset process is started you will receive an email with a verification code. The code expires within 60 minutes, if the verification code expires you'll have to send a new verification code.
- If you have forgotten your password you can reset it here: <u>https://app.clarifi-covid-19.com/forgot-password</u>



#### Why do you need a standing order?

 A standing order is required for the reflex testing (not pooled testing) to comply with NYS and CLIA regulations. We also need a valid NPI number to bill many insurances. The standing order needs to be time limited, so we have set an end date to the end of the calendar year or June 30th. The ordering physician has a responsibility to ensure that a patient receives proper follow-up for a positive result, because both the school and County Health Department will also be notified and will follow up with the patient. This responsibility is mitigated from a practical perspective.

### Can a school have fewer than 12 students per pool? If yes, will there be a different cost/student?

• Saliva samples should be grouped into pools of 12 wherever possible. If on occasion it is not feasible to have a pool of 12 samples, you may create a pool with as few as 6 samples. Quadrant based the price that it is offering this testing at on most pools containing 12 samples. There may be an additional charge if there is a significant number of pools with fewer than 12 samples to cover Quadrant's increased costs in performing the testing. In no event should you create a pool of more than 12 samples.

#### What reporting will each participating school receive?

Following our laboratory processes, Quadrant Biosciences will report back to the campuses the following information:

- Results of all Students/Faculty/Staff who participated in the surveillance testing (including Last Name, First Name, and DOB); regardless of negative or positive result. Results are available in the web application.
- Results are also reported to the Health Department through ECLRS.