

## FAQ for OESIS RT-PCR Testing

**We have conducted testing for schools across the US.**

### **1. What is the Turn Around Time (TAT) after the sample is collected by the courier?**

We have expanded capacity and from major US cities it is now possible to obtain test results the next day except from California, where the TAT is 48 hours from pick-up. We have to coordinate transportation to make sure these TATs can be met, depending on where you are. When you set up a meeting after your application is approved, we can discuss which dates and times best fit to ensure these TATs.

### **2. What is the cost of the test per individual?**

Schools are able to host testing on a voluntary basis for their faculty and or students at no cost to the school: we are able to bill individual insurance and set up the process for this to be hosted at your school. This route can be explored in a meeting with you- [please click here](#).

The cash price of the test is \$88 and that includes the test swab, the testing analysis and data transfer. Transport is extra and will likely cost for a typical school with 250 people being tested \$10 per test (so a total of \$98 per test) with lower costs with volumes. We will consider discounts for regular volume testing.

### **3. Who has access to the results of the test?**

Generally we will have no information regarding who has been tested because you will only be providing numerical identifiers with a bar code for the sample sent: the process will require you to correlate the results you receive as a school with the numbers attributable to students and faculty tested. The anonymous results for the school will be electronically downloaded. If you go down the insurance route, you will get aggregated results but the actual individual results are communicated only to the tested patient and a doctor.

### **4. Who organizes the pick-up?**

We will coordinate all the logistics including the pick-up of the samples and delivery to its labs. We can coordinate transport costs, delivery time frames and dates. In general, the transport costs are around \$10 per sample for a typical school size.

### **5. How is the sample stored and transported?**

The sample needs to be maintained at a temperature between 36 and 46 degrees Fahrenheit. The school's process should include placing the samples in a cooler or refrigerator until pick up and will receive detailed instructions how to do so. Samples collected over two days can be picked up on the second day with the samples on Day 1 refrigerated overnight. Upon pickup, our couriers will keep samples on cool packs in a special bio-rated box for the entire transit to the lab: 800 sample vials is the maximum per bio-rated box. The box is constructed with thermal isolation chamber plates that will last up to 5 days. The boxes do not come in smaller sizes as they meet IATA Class B Biohazard requirements.

## 6. How often should we test and when?

Schools are congregate settings and generally require extra caution. Many schools are testing weekly, while others are planning every two months. The accuracy of the tests relating to false negatives for asymptomatic individuals will also be another factor how many times you test: the less accurate the tests, the more likely you will test more often. Your own context of spread and local guidelines should guide your decision. States like CT have given [specific instructions on expectations for independent and boarding schools](#), in particular, and schools in general. [The State of CA requires the regular "surveillance testing"](#) of faculty once school is reopened: here are their guidelines-

*How should schools think about testing?*

*Once schools are re-opened to at least some in-person instruction, it is recommended that surveillance testing be implemented based on the local disease trends. If epidemiological data indicates concern for increasing community transmission, schools should increase testing of staff to detect potential cases as lab testing capacity allows.*

*Who should be tested and how often?*

*School staff are essential workers, and staff includes teachers, paraprofessionals, cafeteria workers, janitors, bus drivers, or any other school employee that may have contact with students or other staff. School districts and schools shall test staff periodically, as testing capacity permits and as practicable. Examples of recommended frequency include testing all staff over 2 months, where 25% of staff are tested every 2 weeks, or 50% every month to rotate testing of all staff over time.*

## 7. What is the sensitivity and accuracy of the RT-PCR Test?

The validated studies submitted to the FDA by Centogene under its Emergency Use Authorization show 98% sensitivity and 100% specificity: EUA document control number EUA201018.

**8. What approvals are you operating under? Does it include EUA and what does that mean?**

The tests will be conducted at Centogene proprietary facilities conforming to required certifications for high throughput RT-PCR testing: Centogene labs are accredited by College of American Pathologists and certified under CLIA (Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a), to perform highly complex testing. The FDA registered swab used is a Class 1 Exempt Registered Medical Device (FDA listing number D401451) will be applied to the upper respiratory tract to obtain an oral pharyngeal sample. The Centogene SARS-CoV-2 RT-PCR test is intended for use under the Food and Drug Administration's Emergency Use Authorization.

**9. Who can take the sample?**

A nurse or EMT or equally qualified athletic trainer. This is not an at home test and must be done at a school. We provide a video on how it can be done. It can be done in a gym or in a supervised car pool line or in a field: we recommend you provide students and faculty with time windows so that they can be done in front of you, you would use a scanner we provide to record the bar codes and each person would take a screenshot with their smart phone of the sample number for their own record. As long as the samples are maintained at required temperatures, keeping overnight for additional sampling the next day is acceptable.

**10. How long do you estimate the prep, swabbing, and processing of the sample to take per specimen/ person?**

Two to three minutes. We have lots of schools that have done this now and they can share their experience.

**11. What are the pick-up days and times?**

We can work with you on this but we target pick up in the mornings. As long as the samples are maintained at required temperatures, keeping overnight for additional sampling the next day is acceptable (one night maximum to be within the shelf life of the sample). There is a weekend pick up surcharge by the biohazard couriers.

**12. Should we order swabs in advance?**

Yes, swabs are in heavy demand. Most schools are ordering the swabs themselves in advance for 2-3 extra rounds. The price of the swab is included in the \$88 total price and can be billed separately at \$10 per swab in advance.

**13. How much lead time do you recommend for confirming testing?**

We can set up testing in as little as a week but you will need to set up your processes including consents, testing strategy and more so we recommend 2-3 weeks.

**14. What results do we get?**

Positive, Negative or Failed Sample.

For further questions please email [carol.selvey@oesisgroup.com](mailto:carol.selvey@oesisgroup.com)