

FAQ for OESIS RT-PCR Testing

We have conducted testing for schools across the US.

1. 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.

2. 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.

3. 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.

4. 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. For Direct-Pay Schools, swabs cost \$10 each. Insurance-Paid testing requires completion of the [OESIS-Centogene Swab Order Form](#). This allows us to ship you swabs and a scanner in advance of your testing

5. 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.

6. 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.

7. 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 carpool 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.

For insurance-based testing, Centogene may be able to supply one contract nurse from Maxim Healthcare (per 100 tests conducted). The nurse is contracted and paid by Centogene and the school is responsible for scheduling the nurse(s) based on the test cycle start and end times. We recommend that you meet with the contracted nurse via zoom, prior to your test date to explain and understand nuances associated with your school.

8. 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.

9. 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. For Direct-Pay schools, the transport costs are usually around \$10 per sample for a typical school size. For Insurance-Paid testing, the transportation is included in the insurance fees.

10. How is the sample stored and transported?

The sample needs to be maintained at a temperature between 36° and 46°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. The box is constructed with thermal isolation chamber plates that will last up to 5 days.

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

We try schedule the transport of your samples based on your preferred testing date. Samples may be collected late in the day or early morning, long as the samples are maintained at required temperatures. You may keep samples overnight for additional sampling the next day (one night maximum to be within the shelf life of the sample).

12. How are results delivered?

Results are delivered via the secure Results portal. You designate who will be responsible for uploading test sample ID's and retrieving results. Each of you receive an invitation to join the portal. Results are delivered as individual PDF for each sample and in aggregate as a CSV (spreadsheet) file.

13. Who has access to the results of the test?

The official assigned by the school conducting the testing will be the only individuals able to tie specific test results to specific individuals.: 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 uploaded into the Results portal. If you chose the Insurance-Paid option for testing, you will share insurance ID cards for each individuals with Centogene's third party reimbursement partner, Plenum MB.

14. What results do we get?

Results will be delivered via the Results portal. There are 3 categories, Positive, Negative or Failed Sample.

15. What is the cost of the test per individual?

Schools doing Insurance Paid testing 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, which covers the cost of the swabs, scanner, transport, testing analysis and data transfer of samples. This route can be explored in a meeting with you (please do so using this link: [COVID Testing Meeting](#)).

For Direct-Pay Schools, 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.

For further questions please email carol.selvey@oesisgroup.com