

COVID TESTING FAQ

What is Covid-19 pooled testing?

Pooled testing for SARS-CoV-2 processes specimens from multiple people in a single batch, saving time and resources. It is an efficient, precise, and cost-effective way to detect SARS-CoV-2 in a population such as a school. Pool members remain anonymous to the lab. In cases where the virus is detected in a pool, the paradigm shifts to diagnostic testing of the individual members of the pool to identify the positive person(s).

How will our school use a pooling strategy?

If a pooled test result is negative, then all specimens can be presumed negative with the single test. If the pooled test result is positive, the laboratory switches to an individual, diagnostic testing approach. To proceed with diagnostic testing, federal regulations require the laboratory to have to have basic information identifying individuals. When there is a positive pool result, the required identifying information associated with individuals in the pool will be automatically and securely transferred to the laboratory to facilitate immediate, individual retesting of the original sample. This diagnostic testing can usually be completed within a few hours of finding a positive pool using the same sample originally submitted to the lab. The advantages of this two-stage specimen pooling strategy include preserving testing reagents and resources, reducing the amount of time required to test large numbers of specimens, and lowering the overall cost of testing.

How often will testing occur?

Testing will occur every week once it is phased in for a school population. All staff will begin testing during the week of February 1, 2021. We plan to begin testing students at Shrewsbury High School in mid-February. The need for testing of students at other schools will be evaluated based upon virus case count data.

How does the testing process work?

The test requires everyone to submit a nasal swab sample taken from the front of the nose. Your school will provide the sample collection tools, and will train students, employees, and families regarding the sample collection process. Each sample collection day, individual will collect a sample at home in the morning. Students and employees will check in their sample at school, using a unique id and a no-contact process. Samples will be taken to a lab for analysis. Results of pooled and any diagnostic tests will be available to the school within 24-48 hours.

Will the nasal swab hurt?

The collection process is not painful and is simple enough that it was approved for self-administration. The swab is inserted no more than 1-2 cm into each nostril and rotated. Note that this approach is much less invasive and complex than nasopharyngeal swab specimen collection, which has a reputation for causing discomfort.

How are the pools selected?

Because of the co-mingling of staff and students during the school day, and the need to keep the process simple and time-efficient, we will implement random pools based upon school assignment.

Are fully remote students and staff eligible for testing?

No. Our primary focus is to create a safer school environment. To mitigate costs, we are limiting testing availability to only those students and staff who attend school in person.

Is there a cost to families and employees?

No.

Will students and employees be required to participate in the pool test process to attend school this year?

No, the testing is voluntary, but strongly encouraged since the greater participation level will create a safer school environment.

What happens if I/my student misses the sample collection?

Individuals who miss a collection event for any reason will simply participate in the following week's test cycle. Time constraints for sample efficacy and shipping times do not allow for special accommodations on the schedule.

What happens when a pool of students or faculty test positive?

If a test pool yields a positive result, each sample in the pool will immediately be tested to identify the individual or individuals who tested positive. Results for this second-stage testing will be available within a few hours. Your school will notify the individual or individuals who tested positive and trigger the appropriate contact tracing and safety protocols. Other individuals in positive pools will only be asked to quarantine if they are considered a close contact of someone who tested positive.

Should individuals who have already had Covid-19 participate in testing?

Due to the sensitivity of the PCR test, individuals who have tested positive for SARS-CoV-2 within the past 90 days should not participate in pooled testing.

Should individuals who are exhibiting symptoms participate in testing?

Pooled testing is intended for surveillance purposes. It should not be relied on to provide diagnostic results for symptomatic individuals. Instead, individuals who develop symptoms of Covid-19 should immediately begin quarantine protocols and seek an individual viral test on your own.

If our school conducts Covid-19 testing can other restrictions be relaxed?

Covid-19 testing intended to supplement and not supplant the other safety actions on campus (e. g. , mask wearing, frequent hand washing, social distancing). Using pooled testing in addition to following safety recommendations will help students and employees minimize health issues related to Covid-19, dramatically reducing the number of individuals who are covid-positive on campus.

How accurate is the test?

The test's accuracy is virtually identical to that of FDA approved individual PCR tests, which are the gold standard for SARS-CoV-2 diagnosis. Samples are analyzed using a state of the art Covid-19 rt-pcr assay. This assay exhibits expected sensitivity (the limit of detection is 10

genomic copy equivalents per reaction) and specificity (the assay was tested with 43 organisms for cross-reactivity with no false positives). When applied to pools of 16 clinical samples, validation results show that the modified assay is able to identify a single, weakly positive sample 100% of the time.

What are the limitations of Covid-19 pooled testing?

Specimen integrity can be affected by the quality of specimen collection, which could result in some specimens having limited amounts of viral genetic material for detection. Inadequate individual specimens, including those with limited amounts of viral genetic material, might not be eliminated from the pooled specimen before testing. Even if each individual specimen in a pool is adequate, the specimens in a pooled procedure are diluted, which could result in a low concentration of viral genetic material below the limit of detection of a given test. These limitations mean that monitoring the prevalence of disease and properly validating the assay and the instrumentation are important to limit the potential for false-negative results. In general, the larger the pool of specimens, the higher the likelihood of generating false-negative results. The prevalence of Covid-19 in a population also affects the efficiency of pooled testing strategies. In general, lower disease prevalence may enable a laboratory to use a larger optimal pool size.

What is the risk of false positive results?

False positives are extremely unlikely due to the test reacting with other biological material. Although very rare, false positives can occur due to anomalies in processing. Each set of samples is run with both positive and negative control samples to mitigate this possibility.

What is the risk of false negative results?

There is scientific evidence that SARS-CoV-2 testing utilizing anterior nares specimens has a similar performance to testing that utilizes nasopharyngeal specimens, provided that a high-quality anterior nares specimen is collected (see [here](#) and [here](#)). Other research has indicated that nasopharyngeal samples may catch up to 10 percent more cases than other collection methods. For a surveillance testing program, collecting gold-standard, nasopharyngeal samples are impractical for a variety of reasons, not the least of which is that people would not participate. A negative test result never completely rules out virus in an individual's system. For example, soon after infection the body does not shed the virus, meaning that at this stage of infection the individual is not infectious, and SARS-CoV-2 is not detectable by a test. The false negative rate then greatly decreases in the days following initial infection. Regular testing is thus recommended to reduce false negative rates and increase confidence. The greatest risk of a false negative is due to individuals not collecting an adequate sample. The laboratory cannot ensure the diagnostic integrity of a specimen. Detailed sample collection instructions are available in written and video form to reduce this risk.

How is my/my students privacy ensured?

JCM Analytics has created systems and protocols that meet and exceed all HIPAA privacy protections. The lab will only receive personally-identifying information in the event of a positive pool and as required by federal regulations. Samples will be used for covid-19 testing only. Samples will be retained for two years in accordance with CLIA regulations. Only approved school administrators will be able to view results. Individually identifiable information

is not shared, sold, or otherwise made available outside of the direct delivery of the contracted service.

What are the possible risks of being in the program?

There are no known health risks associated with swab-based covid-19 testing.