



## **SHIELD Illinois FAQs**

**What is the University of Illinois' role in the SHIELD program?** SHIELD Illinois is a COVID-19 screening testing program and infrastructure designed to help safely open schools, protect workplaces, and save lives. This specific test was designed by University of Illinois Urbana-Champaign researchers and was supported by the university's leadership team. The testing and strategy created by these individuals was named SHIELD. Our mission as a land-grant institution is to use our capabilities and resources for the public good by deploying this method of targeting, testing, and telling beyond the University of Illinois System to the entire state of Illinois.

### **What does SHIELD stand for?**

The test developers came up with this name to evoke the concept of putting a protective shield around the University of Illinois campus.

### **What does it mean to be operating under Emergency Use Authorization (EUA)?**

The test has gone through the rigorous review process of the United States Food and Drug Administration (FDA) against an extensive set of well-established requirements/parameters, and authorization means that the covidSHIELD saliva test fulfilled all the requirements of the FDA before being authorized for use in CLIA certified laboratories for COVID testing, specifically during public health emergencies such as the current COVID-19 pandemic.

## **Testing Practices**

### **How safe are the covidSHIELD testing facilities?**

SHIELD collection sites follow a strict set of hygienic and sanitary practices to ensure that the testing facilities remain safe for both staff and test-takers.

### **Who can be tested?**

Anyone may test through their SHIELD Illinois sponsor organization (employer, school, university, governmental agency, or other organization) or at any one of our free covidSHIELD community testing sites.

Community testing sites can be found at <http://dph.illinois.gov/testing>

**Are you testing for anything else? Drugs, alcohol, etc.?**

No. The covidSHIELD test targets specific COVID-19 markers and is not able to test for other communicable disease, substances, or DNA.

**Is everything HIPPA compliant?**

Yes.

**How does the testing process work?**

The test is self-administered and non-invasive. After checking in with a collection site staff member, a patient receives a small vial and must deposit a small amount of saliva into that vial. The patient then places the vial in a collection rack and exits the collectionsite.

**How long will it take me to go through the testing process?**

The collection process is usually completed within a few minutes.

**How much saliva does a person need to produce for a covidSHIELD test?**

They will need to provide around 2mL of saliva (not bubbles) for the sample to be processed correctly (the vials used will often have a marking noting how much saliva is needed).

**What rules should I follow prior to being tested?**

You should not eat, drink, or put anything in your mouth one hour prior to taking the covidSHIELD test. This includes smoking, drinking, chewing gum, using mouth wash, etc.

**Is there anything else I should do before taking the covidSHIELD test?**

Drink lots of water and if you are able, brush your teeth one hour prior to the test.

**Why should I not put anything in my mouth or ingest anything an hour before being tested?**

Substances put in the mouth may interfere with the test and cause the sample to be invalid or rejected.

**What information is required to be tested?**

Community testers require an email address or phone number as identification to be tested and receive results.

### **Why am I asked my demographic information, including my race and date of birth?**

The laboratory that processes the tests needs to identify the sample to the individual that provided the sample, requiring a date of birth. In addition, all positive test results must be reported to the Illinois Department of Public Health in accordance with the Illinois Control of Communicable Diseases Code (77 Ill. Adm. Code 690.200(a)(5)), in which demographic information is required for this reporting process.

### **How long will it take to receive results?**

Current notification time for the saliva test is 24 hours from the time a sample received in our lab.

### **How will a group be notified of their test results?**

SHIELD Illinois supports a secure HIPAA-compliant information management system for tracking and reporting results to our collection site partners.

### **What are the possible test results one could receive from the covidSHIELD test?**

The notifications of the tests results are as follows:

Negative – The virus was not detected.

Positive – The virus was detected.

Invalid – The sample provided was non-optimal and could not produce the appropriate data during processing at the lab. (This is likely to a poor-quality sample, not adhering to the fasting requirements, or interfering material in the sample. It is recommended to have the participant retest and adhere to the one hour fasting requirements, focusing on producing the specimen from saliva, not sputum).

Inconclusive – The sample was able to be processed in the lab, but it was not able to definitively provide a detected/not detected results. (It is recommended to have the participant retest).

Rejected – The sample was not able to be processed at the lab. (This is likely due to low sample volume, the cap coming off the tube in transport or other damage to the tube, and/or extremely poor sample quality. It is recommended to have the participant retest and adhere to the one hour fasting requirements, focusing on producing the specimen from saliva, not sputum).

**Who sees the patient's results?**

Only the patient (or parent/guardian), the lab, and the ordering physician have access to individual patient results. By law, positive test records are also reported to the relevant public health department(s) for contact tracing. Sponsor organizations (e.g., school or employer) may also receive patient results at their option with patient's consent or as a part of a mandatory testing protocol for workplace health and safety.

**What happens if someone, including a child, cannot produce an acceptable saliva specimen?**

Our supportive collection site staff members can help the patient produce a sufficient saliva sample. However, to complete the test, an acceptable saliva specimen is required (i.e., no food, liquids, or other substances in the mouth for one hour prior). For younger children, we can provide a curriculum designed to guide them through the steps and the reasons for the test.

**When people drool, do the droplets stay in the air or do they disperse?**

Drooling does not generate an appreciable amount of aerosols, so there is no worry for airborne particles.

**Has there been any indication of virus spread at other collection sites?**

No. To our knowledge, there has been no collection site workers (who might spend 40 hours/week at a collection site) who have been infected at work.

**How much time should be spaced out between children testing in the same location?**

If the ventilation of the testing site is good, then minimal time is needed.

**Is my DNA kept or analyzed as part of this test?**

No. The covidSHIELD test targets specific COVID-19 markers and is not able to test for other communicable diseases, substances, or DNA.

**Can I take the covidSHIELD test at home?**

No. Currently, the covidSHIELD test must be completed in the testing room under observation of the collection staff. SHIELD must maintain chain of

custody due to FDA EUA and CLIA lab regulations.

### **How is the test specimen disposed of after testing?**

Test specimens are safely and permanently destroyed once testing is completed by being placed in biohazard containers, securely stored, and incinerated by hazardous materials personnel.

### **Where are SHIELD laboratories located?**

SHIELD Illinois has six CLIA certified laboratories throughout the state. Labs currently processing samples are in Decatur, Springfield, Normal, Rockford, Itasca, and Maywood.

### **How does the covidSHIELD test work with contact tracing?**

SHIELD Illinois reports positive results to Illinois Department of Public Health daily, which reports those results to the corresponding local health department for contact tracing purposes.

### **Are masks required in testing locations?**

Testers have the potential to be symptomatic or asymptomatic positive, so masks are required for all staff and testers to minimize exposure pursuant to CDC guidelines.

## **Testing Guidance**

### **Should you test after you are fully vaccinated?**

Those who are fully vaccinated typically do not need to be tested. However, the CDC recommends that anyone with any signs of symptoms of COVID-19 get tested, regardless of vaccination status. Regular testing is also recommended for a vaccinated person working or living in high density/congregate settings (i.e., dormitory, jail, homeless shelter, or food production plant). In addition, those working in health care settings should also be tested according to CDC's guidance.

### **Should individuals participating in sports get tested before sporting events?**

Yes. It is recommended that participants should receive a negative COVID-19 test as close to and no longer than 72 hours before competition. Individuals who are not fully vaccinated should continue with regular screening testing per Illinois Department of Public Health guidelines.

### **I have already had COVID-19, should I still get tested?**

No. Testing is not recommended for people who have recovered and are within 90 days from symptom onset or previous positive test, but testing should resume once the 90 days has passed.

### **How often should we be testing?**

Testing at least twice a week maximizes our ability to find infections early and break the transmission chain. However, with strong contact tracing weekly testing can be effective.

### **What is the difference between diagnostic testing and screening?**

The covidSHIELD test can be used for both diagnostic testing and screening. Diagnostic tests are intended to identify current infections at the individual level and are performed when a person has signs of symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known/suspected exposure to SARS-CoV-2. Screening tests are intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2.

### **What is considered outbreak testing?**

Outbreak status is when five or more cases are linked epidemiologically that do not share the same household and are not listed as close contacts of each other outside the outbreak setting. Schools should conduct twice weekly testing for unvaccinated staff and students until the school has gone two incubation periods (28 days) without identifying new cases.

### **Why does testing frequently help?**

The more frequently someone is tested, the less time they will be able to be infectious and spread the virus. When testing twice a week, an infection will be detected, on average, the day before their peak infectiousness. With weekly testing, infections will be detected, on average, one to two days after peak infectiousness. Our research also shows that testing at least twice a week means that >95% of infections will be detected; weekly testing can miss one in ten infections.

### **The positivity rate is very low in my community, why would you need to continue to test if the rate is low?**

Frequent testing helps positivity rates remain low. The covidSHIELD test is

able to catch those who are positive (whether they show symptoms or not) and are able to quarantine them in time to help reduce mass infection.

**When does an individual start shedding the virus after infection?**

It varies from person to person, but typically within three to five days after exposure.

**What day after infection do people usually start showing symptoms?**

It varies from person to person, but typically within four to seven days after exposure.

### **Test Effectiveness**

**How reliable is the covidSHIELD test?**

In a recent study, the saliva test was shown to have a specificity of 98.9% and a sensitivity of 96.8%. The FDA-authorized covidSHIELD test targets three highly conserved regions of the viral genome for detection. High specificity offered by three-target detection, combined with frequent testing makes the covidSHIELD saliva-based test extremely accurate and one of the best tests available.

**Where can I find validation data which outlines sensitivity and specificity?**

The official FDA emergency use authorization documents can be found here: <https://www.fda.gov/media/146314/download>

**Why is saliva collection better than nasal swabbing for testing and collecting?**

Saliva is more sensitive than nasopharyngeal or nasal swabs for diagnosis of asymptomatic and mild COVID-19 infection. In addition, for a nasal swab, proper sample collection technique is needed to collect a small amount of mucosal material from a specific nasal region making it error prone. Nasal swabs are invasive, and many patients find the process either difficult or uncomfortable. In comparison, no skill is needed for saliva collection. The patient simply drools saliva into a tube. The sample collection process is neither invasive nor uncomfortable. The saliva sample collection is not from a specific region and the sample size is larger than collection by nasal swab and chances of human error are minimal.

**Children are known to have low viral loads, does the covidSHIELD**

**test identify infections in children and adults with low viral loads?**

Yes. The FDA authorized covidSHIELD saliva-based test has a very low limit of detection and sensitivity of 96.8%, which means it can detect infections in patient with low viral loads.

**Can the covidSHIELD test catch active infection before infectiousness?**

Yes.

**What day does the covidSHIELD test begin to pick up the virus after infection?**

The test should be able to pick up the virus as early as two to three days after exposure.

**Will the covidShield test be able to show if someone has antibodies as well as the live virus?**

No. The test is specifically designed to detect viral genomic material (i.e., RNA) present in viral particles or free form.

**How accurately does covidSHIELD identify virus mutations?**

covidSHIELD test looks for three different SARS-CoV-2 genes. That way, even if a mutation changes one gene, the test will still be able to detect the other two genes making the covidSHIELD test particularly effective in identifying the virus regardless of variant.

**Are the covidSHIELD tests able to detect variants? And if so, which ones?**

Yes. The covidSHIELD test can detect all known variants. That ability is monitored rigorously by Thermo-Fischer, which produces the part of the test used to identify SARS-CoV-2.

**How does the covidSHIELD test know if it is a variant or the regular strain?**

The covidSHIELD test detects the presence of all COVID-19 strains regardless of variant. Only genetic sequencing can identify specific virus variants.

**If a Test is Positive**



**If I receive a positive test result from the covidSHIELD test, do I have to go and receive another test from another provider?**

No. Follow-up testing is not needed. The covidSHIELD saliva-based test is a definitive rtPCR diagnostic test authorized by the FDA.

**If a person is positive on covidSHIELD should they retest? Is there a possibility it could be a mistake?**

No. Retesting is not required or recommended. The covidShield saliva test has a specificity of 98.9% and sensitivity of 96.8%. The test targets three highly conserved regions of the viral genome for detection. High specificity offered by three-target detection, combined with frequent testing makes the SHIELD saliva-based test extremely accurate.

**What happens if a person tests positive with covidSHIELD and then gets a nasal PCR and tests negative? Which test should they trust?**

The covidSHIELD saliva test is more reliable overall compared to self-collected nasal specimens. In other words, self-collected nasal PCR has a higher false negative rate and lower sensitivity in most studies.

**What if a person tests positive, then negative, and then tests positive again? What should they do?**

Repeat testing after the initial positive test is neither required nor recommended. Patients should rely on the initial positive covidSHIELD test as definitive. They should take appropriate action to isolate and consult their healthcare provider as applicable with any questions or concerns.

**What happens if someone tests positive after testing positive sixty days prior? Should they quarantine?**

Patients should consult their healthcare provider. It is not uncommon for tests to remain positive or be intermittently positive for several weeks following a COVID illness and these individuals are not infectious to others.

**If a patient wants to get more information about a positive test result from SHIELD, what should they do?**

Patients should consult their healthcare provider. SHIELD does not provide any other information except negative/positive to the patient.

**Does SHIELD inform the patient if a positive is one of the variants?**

No. While our test can detect the presence of COVID-19 in a patient's

sample even if the person is infected with the variant, our test does not confirm which variant is present.

**Are positive test results being shared with Illinois Department of Public Health (IDPH)?**

Yes.

**What other information is being shared with Illinois Department of Public Health (IDPH)?**

Address, phone number, and demographic information are also shared with IDPH. If that person does not have a phone or email, SHIELD will share the sponsor organization's information.