SHIELD ILLINOIS SHIELD ILLINOIS SALIVA TEST FOR ORGANIZATIONS

SHIELD Illinois is a PCR screening testing program that utilizes the University of Illinois' innovative saliva test in order to keep your organization operating safely.

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LOW COST	The SHIELD Illinois test costs \$20-30 per test for all organizations with a 5,000-test minimum through June 2021.
FAST NOTIFICATION	Patients will receive their results within 24 hours of their sample reaching our lab, compared to a 2-3 day turnaround time for most currently available tests.
EASE OF USE	The saliva-based test is non-invasive and does not need medically trained personnel to collect samples.
CLIA CERTIFICATION	All SHIELD Illinois labs are CLIA-certified, meaning they meet federal standards for lab accuracy and reliability.
REDUCE SPREAD OF VIRUS	The SHIELD Illinois test is a nucleic acid amplification test, which the CDC recommended to reduce spread of COVID-19 by asymptomatic and presymptomatic individuals.
HIGH ACCURACY	The SHIELD Illinois test has a specificity of 99.8-99.9% and a sensitivity well above 95%, resulting in very few false positives or false negatives.
	FAST NOTIFICATION EASE OF USE CLIA CERTIFICATION REDUCE SPREAD OF VIRUS HIGH

## **KEY TERMS**

**SENSITIVITY** – The rate at which a test correctly gives a positive result when a person has the SARS-CoV-2 virus. A high rate of sensitivity means a test has very few false negatives.

**SPECIFICITY** – The rate at which a test correctly gives a negative result when a person does not have the SARS-CoV-2 virus. A high rate of specificity means a test has very few false positives.

**CLIA –** The Clinical Laboratory Improvement Amendments of 1988 statute is an amendment to the Public Health Services Act in which Congress revised the federal program for certification and oversight of clinical laboratory testing. When a lab is CLIA-certified, that means it meets certain quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health.

**SCREENING TEST** – Testing asymptomatic individuals regardless of exposure or signs and symptoms

**SURVEILLANCE TEST –** Testing to gain information at a community or population level

**DIAGNOSTIC TEST** – Testing individuals when there is a reason to suspect infection, such as symptoms or exposure.

**PCR TEST –** Polymerase chain reaction (PCR) is a technique used to amplify small segments of DNA. PCR tests detect the presence of genetic material, in this case the SARS-CoV-2 virus.

**ANTIGEN TEST** – Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies viral infection. Antigen tests for SARS-CoV-2 are generally less sensitive than real-time reverse transcription polymerase chain reaction (rt-PCR) tests for detecting the presence of viral nucleic acid.

**LAMP** – Loop-mediated isothermal amplification is an alternative to the rt-PCR method of testing for SARS-CoV-2.

**EMERGENCY USE AUTHORIZATION (EUA)** – The Food and Drug Administration is able to allow medical products or new uses of medical products that do not have full FDA approval in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, or available alternatives.



## **ATTRIBUTES OF COVID-19 TESTS**

EXAMPLE	SAMPLE	COLLECTION	FDA AUTHORIZED	SPEED OF RESULTS	соѕт	ACCURACY	EASE OF USE	CLIA LAB	ТҮРЕ	PROCESS
SHIELD ILLINOIS	SALIVA	SELF	PENDING	FAST	LOW	HIGH	EASY	YES	PCR	DIRECT
HOSPITAL/CLINIC	NASAL SWAB	CLINICIAN	YES	SLOW	MED- HIGH	нідн	HARD	YES	PCR	RNA EXTRACTION
MAIL-IN SALIVA KITS	SALIVA	SELF	YES	SLOW	MED- HIGH	HIGH	MEDIUM	YES	PCR	RNA EXTRACTION
RT-LAMP TESTS	SALIVA OR SWAB	VARIES	NO	FAST	LOW	VARIES	EASY	NO	LAMP	DIRECT
RAPID TESTS	NASAL SWAB	CLINICIAN	YES	FAST	LOW	LOW	MEDIUM	NO	ANTIGEN	DIRECT

DIRECT - Method of RT-qPCR testing without the RNA extraction step present in the standard test assay

**RNA EXTRACTION –** Costly and time-consuming step in the standard method of RT-qPCR testing requiring additional reagents that became scarce during the COVID-19 pandemic

SELF-ADMINISTERED TESTS - Tests that do not require a clinician to be present for collection of samples

OBSERVED TESTS - Tests that require the sample to be collected in the presence of another person to ensure integrity of the sample

FDA AUTHORIZED – Test operating under the authorization of the Food & Drug Administration providing blanket liability protection under the Federal PREP Act