## **SHIELD IL Overview:**

IDPH Funded COVID-19 Testing for School Districts

SHIELD

Target Test Tell /

I University
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## **OUR HISTORY**



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World class researchers at the University of Illinois at Urbana-Champaign created **covidSHIELD**, our innovative saliva PCR test.

- The University of Illinois is a land-grant institution tasked with supporting and serving constituents across our great state.
- The covidSHIELD test was pioneered **shortly after the pandemic began** and was deployed at the CU campus for the fall semester.
- The test was intended to be scalable so it could **benefit thousands across the state and country.**
- In 2020, the University of Illinois System deployed SHIELD Illinois to expand accessibility to the test, reopening schools, economies and saving lives across the sate.
- With nearly **2.5 million tests performed since August**, SHIELD has kept the positivity rate at UIUC below 1% since September 7, 2020.



The covidSHIELD testing process deployed at the University of Illinois' Urbana campus in early fall 2020



**ABOUT OUR TEST** 



SHIELD Illinois is a testing program that deploys the University of Illinois' innovative PCR covidSHIELD saliva test across the state.

The test has an FDA authorization (EUA) for asymptomatic & symptomatic individuals. It is a diagnostic test that can be used for screening.







IDPH will provide testing for everyone once per week and collections at little or no cost for **public middle + high schools** through Dec. 31, 2021.

Schools	Cost Per Test	One-Time Setup Fee
Tier 1 & 2 Schools	\$0	\$0
Tier 3 & 4 Schools	\$10	\$5,000

#### **Minimum Requirements to Qualify for IDPH Program**

 School commits to test 50% of
 School commits to perform

 its in-person (unvaccinated) population
 OR
 School commits to perform

 once per week
 Dec. 31, 2021



## **ABOUT OUR TEST**



	Low/ No Cost	The SHIELD Illinois saliva-based PCR test is FREE to Tier 1 and 2 schools, and \$10 per test for Tier 3 & 4 schools.
	Fast Results	Results will be sent to the individual, school and IDPH through a HIPAA-secure health records portal within 24 hours of samples reaching our lab.
<b>8</b> 6-8	Identify Infection	Our test takes a proactive approach to identify pre-symptomatic and asymptomatic individuals to allow those individuals to quarantine, reducing virus spread.
	High Accuracy	In a recent clinical trial, covidSHIELD's sensitivity (false negatives) was 96.8% and specificity (false positives) was 98.9%.
<b>8</b> 6-8	CLIA Certified	All of SHIELD Illinois' tests are processed in CLIA labs, meaning they meet federal standards for accuracy and reliability. SHIELD provides CLIA waiver doctor's order.
$\checkmark$	Easy to Collect	The covidSHIELD test is non-invasive and doesn't require a healthcare professional. A 3 <sup>rd</sup> party collection team will handle the collections.
	FDA Authorization	covidSHIELD received emergency use authorization (EUA) from the FDA. Individuals who test positive don't need to seek a second test result to confirm the result.

# Our labs are positioned across the state, allowing for quick processing and resulting







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## SHIELD ILLINOIS: WHERE WE TEST TODAY



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Safely Opening Schools. Protecting Workplaces. Saving Lives.

## **SHIELD ILLINOIS DEPLOYMENT:** K-12 SAMPLE PARTNER LIST



- Acero Charter Schools
- Baker College Prep
- Butler College Prep
- Chicago Bulls College Prep
- Chicago Jesuit Academy
- D101 McClure
- D109 Caruso Middle School
- D109 Kipling Elementary School
- D109 Shepard Middle School
- D109 South Park Elementary School
- D109 Walden Elementary School
- D365U Romeoville (HS)
- D109 Wilmot Elementary School
- D117 Lakes (HS)

- D5 Sterling (HS) D113 Deerfield HS
- D113 Highland Park HS
- D21 Cooper
- D21 Field

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- D21 Frost
- D21 Hawthorne
- D21 Holmes
- D21 Kilmore
- D21 London
- D21 Longfellow
- D126 Zion-Benton (HS)
- D209 Proviso Twp (HS)
- D40 Moline

- D21 Poe
- D21 Riley
- D21 Tarkington
- D21 Twain
- D21 Whitman
- D93 Hillside K12
- DRW College Prep
- Gary Comer College Prep
- Gary Comer College Prep Middle
- Golder College Prep
- Hansberry College Prep
- D187 Cahokia (HS)
- D201 Morton (HS)
- D4 Champaign (HS)

- ITW David Speer Academy
- J. Sterling Morton District 201
- Johnson College Prep
- Mansueto High School
- Muchin College Prep
- Noble Academy
- Noble Street College Prep
- Pritzker College Prep
- Rauner College Prep
- Rowe-Clark Math & Science Academy
- UIC College Prep
- D189 East St. Louis (HS)
- D124 Grant HS

#### Safely Opening Schools for In-Person Learning.

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## **SCHOOL TESTIMONIALS**





HILLSIDI DISTRICT 9 "We've added SHIELD testing as another layer of mitigation to keep the risk of COVID-19 transmission low. Because the test can detect positive cases when an infected person's viral load is low as well as detect those who are asymptomatic, SHIELD has been a critical component of reopening school and in giving parents the confidence to send their students to school."

- Dr. Bruce Law, Superintendent, District 113 (Deerfield + Highland Park, IL)

"In order for schools to resume normal operations, students need to be tested but testing can be expensive. covidSHIELD advances equity. With funding from the government, schools can be reopened safely at little cost. This kind of support allows under-resourced communities to continue to fight the spread of COVID-19."

- Dr. Kevin Suchinski, Superintendent, Hillside District 93 (Hillside, IL)

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- Schools: Two high schools schools located in Lake County
- Enrollment: ~3600 students
- Non-Students: ~700 faculty/staff
- Testing Strategy
  - Test everyone twice per week
  - Students tested on Tuesday and Friday (mandatory)
  - Faculty/Staff tested on Monday and Thursday (optional)







# covidSHIELD is a highly sensitive molecular RT-PCR saliva-based test.



2 spreads Etc. ...And they each infect two people Etc. ...And they each infect two people Patient 0 infects **two** Etc. people ...And they each infect two people Etc.

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Source: The Conversation, Jan. 28, 2020

• A November 2020 study in the journal PLOS One stated the R0 of SARS-CoV-2 to be 2.87, even higher than this graphic.

- Identifying infections early and isolating infected individuals breaks the chain of infection and prevents the virus from spreading.

How a virus with a reproduction number (R0) of 2 spreads



- PCR (polymerase chain reaction) creates a chain reaction that **replicates viral genetic material**, allowing detection of even low viral loads.
- covidSHIELD detects three genes of the SARS-CoV-2 virus, unlike most PCR tests, which only detect 1 gene.
  - This allows the test to identify pre-symptomatic and asymptomatic cases, as two of the genes must be present to label a sample as "positive." This makes it extremely accurate in detecting positive and negative results.
  - As the virus mutates, SHIELD's test may have superior detection abilities compared to a one-gene approach and can screen for variants of concern.
- To optimize functionality, SHIELD partnered with Thermo Fisher, the leading supplier of reagent material for PCR tests.
  - Thermo Fisher regularly updates its reagent to identify variants of the SARS-CoV-2 virus.
  - The CDC says SHIELD's test is only 1 of 3 available that is able to identify new variants.



#### Screen with covidSHIELD PCR and use Binax for symptomatic individuals

#### **Molecular tests**

- Earlier virus detection than antigen tests
- Greater sensitivity than antigen tests

#### **Antigen tests**

- Often faster results than molecular tests
- Often less expensive than molecular tests



## **TESTING FREQUENCY RECOMMENDATION**



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Testing **everyone** is critical because ~50% of spread is done by asymptomatic or pre-symptomatic individuals.



Individuals become contagious before symptoms appear covidSHIELD can detect the virus before it becomes transmissible

## **SALIVA TESTS**



If groups of people test twice

per week, SHIELD's test will

find >95% of positive cases.

Saliva PCR tests can find positives earlier than other tests, even 1-2 days before the infectious phase.



Most PCR tests are highly accurate, but saliva tests catch positives earlier than nasal swabs.



- SHIELD Illinois' collection process is quick, selfadministered and non-invasive.
- The school is responsible for **space**, an **operational plan**, **consent and communication** to constituents.
- A third-party collections team will handle everything else, including **collecting, transporting and reporting.**

## **COLLECTION SITE EXAMPLE**



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SALIVA COLLECTION STEP 3 SALIVA STATIONS STEP 1 **CHECK-IN STATION** STEP 2 SANITIZE HANDS

- A collection lane can process approximately 40-60 people per hour.
- It typically takes an individual 3-5 minutes to provide a saliva sample and complete the process.
- Patients must refrain from eating, drinking, or putting anything in their mouth for 1 hour prior to providing a sample.









## **OUTSOURCED COLLECTION PROCESS**



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Professional, trained, third-party collection team will handle the collections and reporting.



**Three Major Stakeholders** 





#### **SHIELD Illinois**

- Technology and results platform (HIPAA-secure)
- Saliva test supplies and consumables
- Training for results reporting
- CLIA waiver and doctor order
- Daily reporting to IDPH
- Trained collections partners





#### **3rd Party Collection**

- Develops operational plan
- Trained collection staff (collect and register samples)
- Transports samples to lab
- Reports positive results to patients
- Provides equipment and consumables for site and staff
- Reorders supplies



#### **School District**

- Patient consent forms
- Roster upload
- Contact tracing
- Operational plan (who, what, where; completed with 3rd party)
- Location for collection sites
- Communication to constituents



- 1. Fill out interest form <u>HERE</u>
- 2. Schedule follow-up meeting with SHIELD to review testing plan.
- 3. Sign SHIELD contract
- 4. Create consent form with district's legal team. Obtain consent from constituents.
- 5. Meet with assigned 3<sup>rd</sup> party collections partner to operationalize testing plan.
- 6. Attend SHIELD orientation.
- 7. Complete online training.
- 8. Set go-live date and start testing!

#### **Test Interest K-12 Survey**



http://bit.ly/interestedK12SHIELD



## Website:

uillinois.edu/shield

#### **Contact:**

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# **Key Terms**

## GLOSSARY



#### **TYPES OF TESTS**

- DIAGNOSTIC TEST These tests show that you have an active infection.
  - **MOLECULAR TEST** A type of diagnostic test that detects the virus' genetic material and is typically highly accurate.
    - PCR TEST Polymerase chain reaction (PCR) is a technique used to amplify small segments of DNA. PCR tests detect the presence of an antigen, in this case the SARS-CoV-2 virus.
    - **LAMP** Loop-mediated isothermal amplification is an alternative to the rt-PCR method of testing for SARS-CoV-2.
  - ANTIGEN TEST These are a type of diagnostic test that detects specific proteins on the surface of the virus. 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.
- **ANTIBODY TEST** These tests detect the presence of infection-fighting proteins that may take days or weeks to develop.

#### **USES OF TESTS**

- SCREENING Testing asymptomatic individuals regardless of exposure or signs and symptoms.
- **SURVEILLANCE** Testing on de-identified specimens so results are not linked to individuals, in order to gain information at a community level.
- **DIAGNOSTIC** Testing at the individual level when there is reason to suspect infection.

#### **TEST CHARACTERISTICS**

- 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.

## GLOSSARY



**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. Tests that have EUA do not require a second test and have liability protection through the PREP Act.

**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.

**PREP ACT** – Public Readiness and Emergency Preparedness Act, which provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency.

**OBSERVED TEST** – A test where the sample is provided in the presence of another person.

**UNOBSERVED TEST** – A test where the sample is not provided in the presence of another person.

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

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

**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

Source: FDA