



# SHIELD IL Overview:

## IDPH Funded COVID-19 Testing for School Districts



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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 state**.
- 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*



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 **Illinois public 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

1

School commits to test  
50% of its in-person  
(unvaccinated) population  
once per week

OR

2








School commits to perform  
at least 10,000 tests  
through Dec. 31, 2021



# ABOUT OUR TEST



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	<b>Low/No Cost</b>	The SHIELD Illinois saliva-based PCR test is FREE to Tier 1 and 2 schools, and \$10 per test for Tier 3 & 4 schools.
	<b>Fast Results</b>	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>Identify Infection</b>	Our test takes a proactive approach to identify pre-symptomatic and asymptomatic individuals to allow those individuals to quarantine, reducing virus spread.
	<b>High Accuracy</b>	In a recent clinical trial, covidSHIELD's sensitivity (false negatives) was 96.8% and specificity (false positives) was 98.9%.
	<b>CLIA Certified</b>	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.
	<b>Easy to Collect</b>	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.
	<b>FDA Authorization</b>	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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#### High Population Areas

Labs are located near high-population areas to increase access to testing.



#### Logistical Convenience

Locations are selected based on logistical considerations such as ease of transportation, etc.



#### Load Balancing

Ability to manage influx of samples and option to secondary locations for quick processing and resulting



#### All Labs Identical CLIA Certified

Labs must be CLIA certified and be able to process the number of tests anticipated.



# SHIELD ILLINOIS: WHERE WE TEST TODAY



# SHIELD ILLINOIS



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Safely Opening Schools. Protecting Workplaces. Saving Lives

# SHIELD ILLINOIS DEPLOYMENT: K-12 SAMPLE PARTNER LIST



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ILLINOIS**



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- 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)
- D5 Sterling (HS)
- D117 Lakes (HS)
- D109 Wilmot Elementary School
- D113 Deerfield HS
- D113 Highland Park HS
- D21 Cooper
- D21 Field
- 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

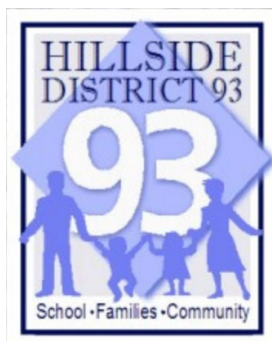
**Safely Opening Schools for In-Person Learning**





*“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)

## EXAMPLE: DISTRICT 113 (DEERFIELD/HIGHLAND PARK)



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- **Schools:** Two high 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)

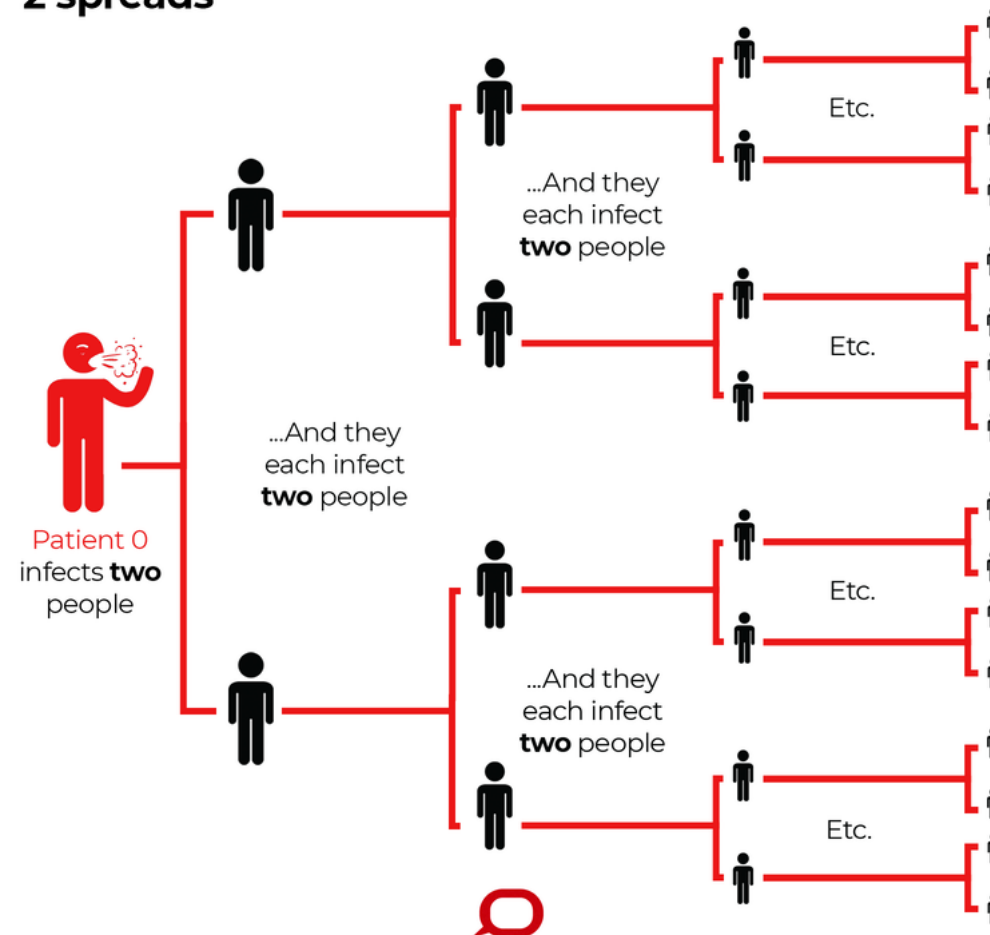


covidSHIELD is a highly sensitive molecular  
RT-PCR saliva-based test.

# HOW INFECTIONS SPREAD

- A November 2020 study in the journal PLOS One stated the  $R_0$  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 ( $R_0$ ) of 2 spreads



Source: [The Conversation](#), Jan. 28, 2020

- 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.

# SHIELD IL + ANTIGEN = POWERFUL COMBINATION



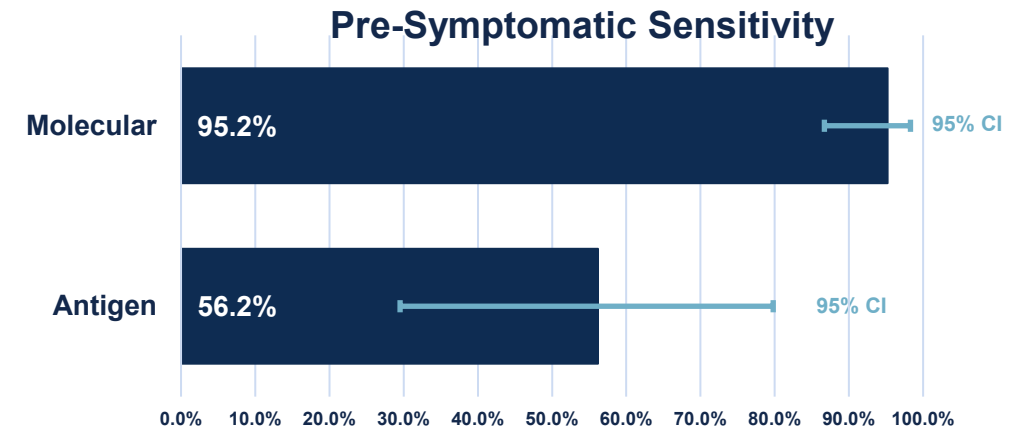
## Screen with covidSHIELD PCR and use Binax for symptomatic individuals

### 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



IDPH Recommendations	Saliva PCR Test (SHIELD Illinois)	Antigen Test (BinaxNOW)
Use Case	Screen 100% of in-person, unvaccinated population each week	Symptomatic cases
Frequency	Weekly	As needed

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

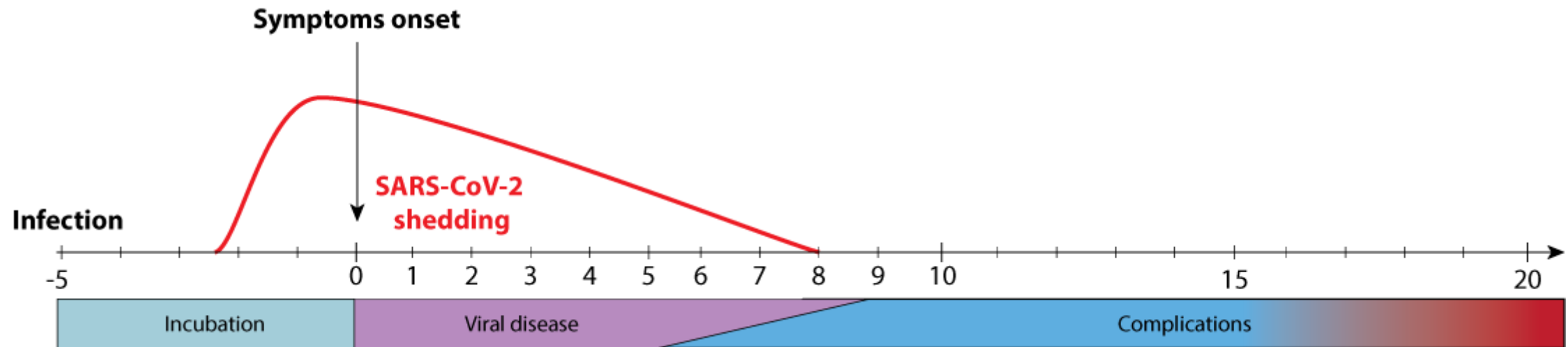
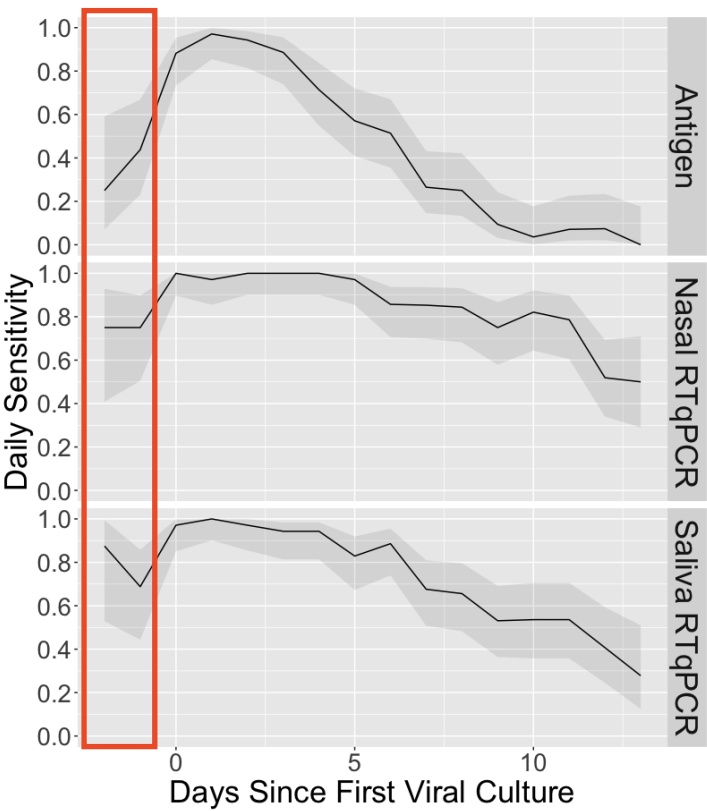


Figure from <https://viralzone.expasy.org/9116>

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

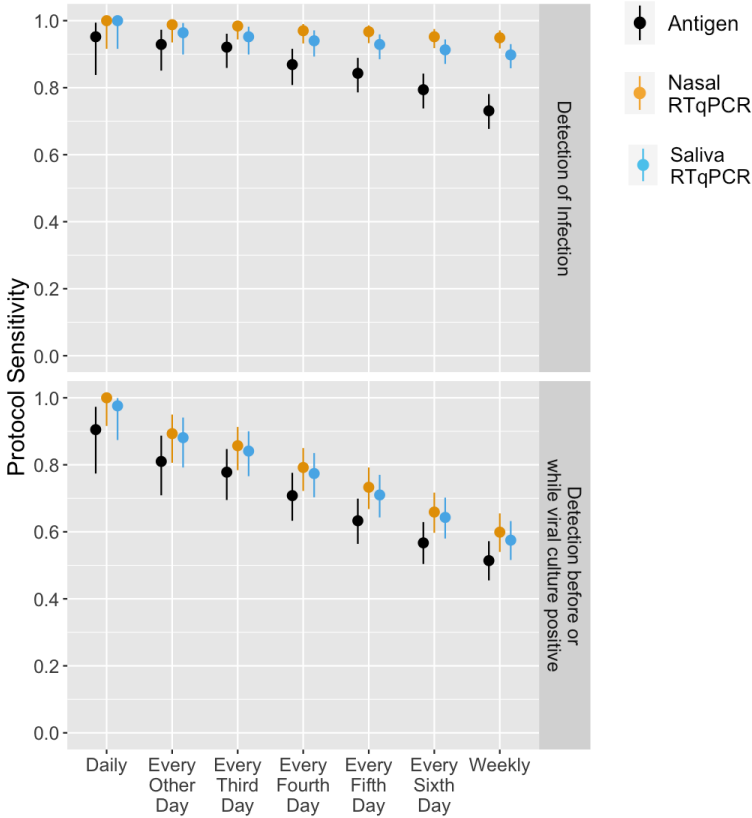
# SALIVA TESTS

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



Saliva PCR tests have 90% sensitivity before day zero

If groups of people test twice per week, SHIELD's test will find >95% of positive cases

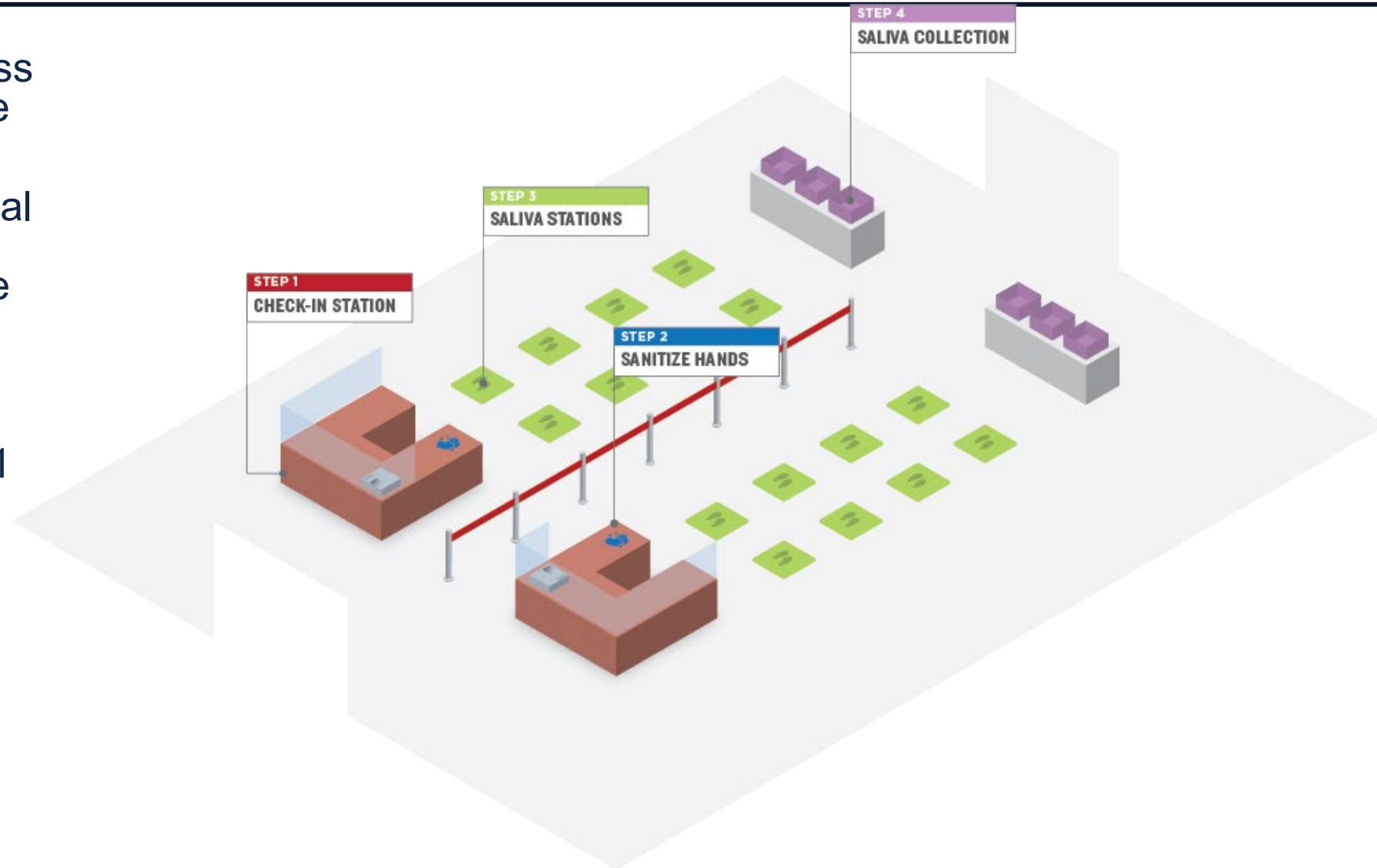


Most PCR tests are highly accurate, but saliva tests catch positives earlier than nasal swabs

- SHIELD Illinois' collection process is **quick, self-administered 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

- 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.





# COLLECTION EXAMPLES

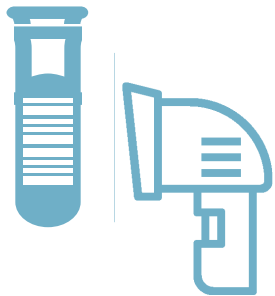


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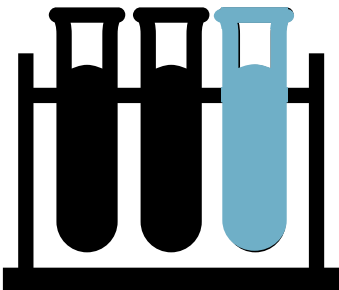
# OUTSOURCED COLLECTION PROCESS



A patient checks in by confirming their identity, then a barcoded label is associated with their sample vial



The patient deposits a small amount of saliva in a vial, then screws on the vial's cap



The patient places the vial in a rack and leaves the collection site



Samples are taken to the nearest available lab for testing



Results are delivered within 24 hours of samples reaching lab

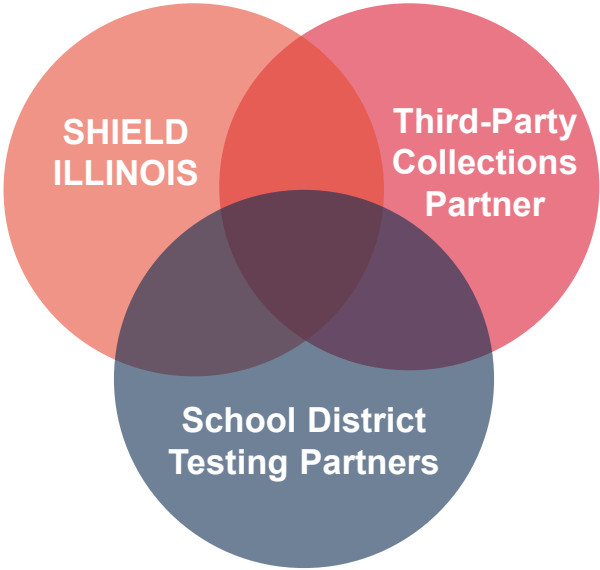
**Professional, trained, third-party collection team will handle the collections and reporting**

# BREAKDOWN OF RESPONSIBILITIES



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## Three Major Stakeholders



## Key Stakeholder Responsibilities



### 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



### 3<sup>rd</sup> 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 3<sup>rd</sup> party)
- Location for collection sites
- Communication to constituents

# NEXT STEPS TO PURSUE TESTING



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1. Fill out interest form [HERE](#)
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](https://uillinois.edu/shield)

### Contact:

Beth Heller

Director, External Relations

Cell: 312.953.5879

Email: [bheller@uillinois.edu](mailto:bheller@uillinois.edu)

## Key Terms

## 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.

Source: FDA



**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