



SHIELD Illinois Overview:

IDPH Funded COVID-19 Testing for School Districts



UNIVERSITY
OF ILLINOIS
SYSTEM

WHAT IS SHIELD ILLINOIS?



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

MISSION: *SHIELD Illinois is an example of the University of Illinois' land-grant mission, as a non-profit unit working to control the spread of COVID-19 across the state of Illinois, safely open schools, protect workplaces and save lives.*



Innovation

- Shortly after the pandemic began a **team of world class researchers at UIUC** pioneered a **saliva-based PCR test for SARS-CoV-2**.
- To safely open the University of Illinois' campus' in Fall 2020, covidSHIELD was deployed **to screen, identify, and quarantine** pre-symptomatic and asymptomatic carriers.



Protection

- With nearly **3 million tests performed** at our universities since August, SHIELD has kept the **positivity rate in Champaign county below 1%** since September 2020.
- SHIELD Illinois' expansion goal is to help **safely restart Illinois' economy** by expanding testing to schools and businesses across the state.










Scale

- Applying the university's land grant mission, the test was designed to be scalable and turnkey so it could **benefit hundreds of thousands across the state and country**.
- Built **lab infrastructure across the state** to ensure quick processing and resulting and enable expanded capacity as demand increases.

ABOUT OUR TEST



UNIVERSITY
OF ILLINOIS
SYSTEM

	Identify Infection	covidSHIELD takes a proactive approach to identify pre-symptomatic and asymptomatic individuals to allow those individuals to quarantine, reducing virus spread.
	Fast Results	Results will be sent to the school district and IDPH through a HIPAA compliant health records portal within 24 hours of samples reaching our lab.
	No Cost	The SHIELD Illinois saliva-based PCR test is FREE to public K-12 school districts.
	High Accuracy	In a recent clinical trial, covidSHIELD's sensitivity (false negatives) was 96.8% and specificity (false positives) was 98.9%.
	CLIA Certified	All of SHIELD Illinois' tests are processed in CLIA labs located throughout the state. SHIELD provides both the CLIA waiver and the doctor's order.
	Easy to Collect	The covidSHIELD test is non-invasive and doesn't require a healthcare professional. A 3 rd party operations partner will handle the collections.
	FDA Authorization	covidSHIELD received emergency use authorization (EUA) from the FDA to test symptomatic and asymptomatic individuals. Individuals who test positive don't need to seek a second test result to confirm the result.

- IDPH will provide **FREE SHIELD Illinois** testing for all **public PK-12 schools** December 31, 2021 (includes tiers 1, 2, 3 and 4).
- A third party **operations partner**, who will handle collections, transportation, and reporting, will also be provided at no cost. Certain minimums apply.
- **Free community-based testing** is available at no cost for districts looking to offer this service to their community.

Testing frequency:

IDPH currently recommends **weekly testing** for all **unvaccinated** students & staff.

Updated IDPH guidance

Modified close contact definition

- Only relevant for students participating in IDPH testing program (1x/week)
- Quarantine not required if 3+ feet and 100% masking (excludes vaccinated students/staff)

Outbreak testing

- Outbreak defined as 5+ epidemiologically-linked cases with no close contacts outside of school
- After outbreak, testing should occur 2x/week for 2+ incubation periods after outbreak with no new cases

**All quarantine decisions are to be made with the district's local health department.

GOAL OF TESTING

- Prevent transmission of COVID-19
- Curb outbreaks in school & community
- Keep students in classrooms

KEY VARIABLES

- Vaccination rates vary across state; children under 12 not yet eligible
- Potential for increased flu & respiratory illness
- Spread continues to be greater during extra-curriculars
- Risk of new variants remains

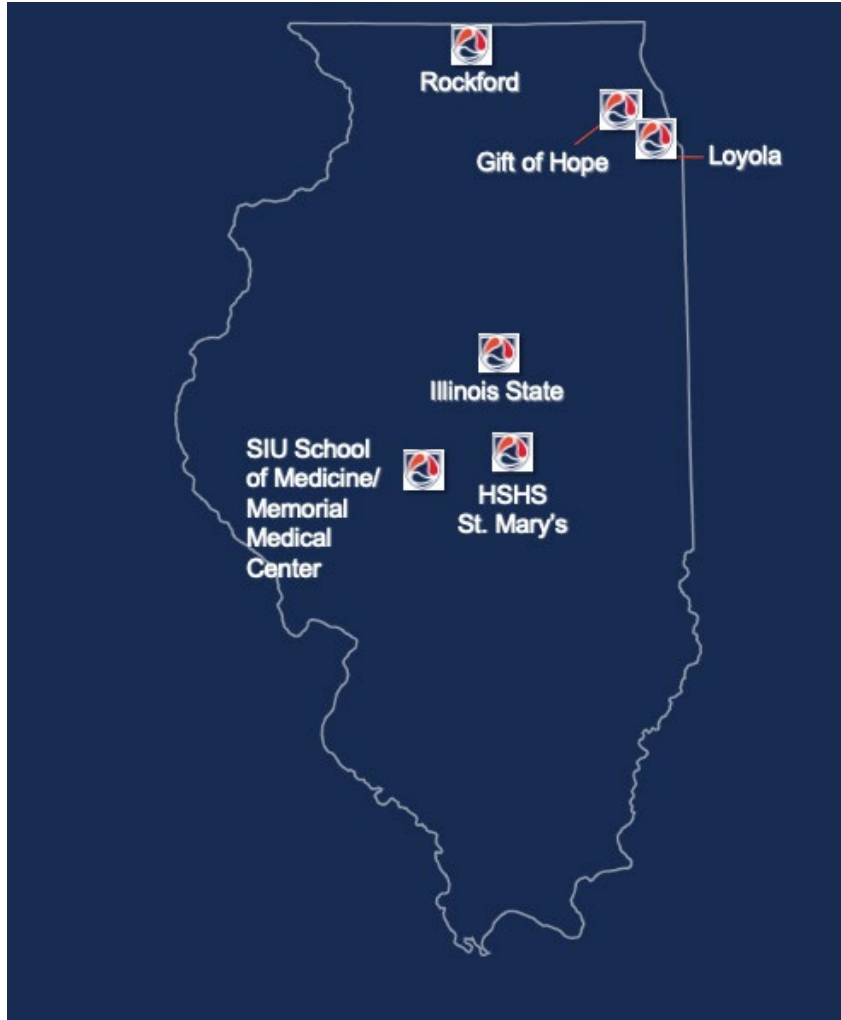
ADVANTAGES TO TESTING

- Continues to shield and protect those that are unvaccinated in school and at home
- Testing allows school to rule out Covid and keep students in classroom
- Early identification minimizes number of individuals required to quarantine
- Identifies potentially more contagious individuals earlier

SHIELD'S LAB SYSTEM



UNIVERSITY
OF ILLINOIS
SYSTEM



- 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.

(additional labs to be added in Southern IL as demand increases)

SHIELD ILLINOIS: WHERE WE TEST TODAY



UNIVERSITY OF ILLINOIS SYSTEM



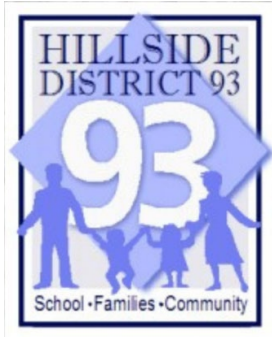
Safely Opening Schools. Protecting Workplaces. Saving Lives.

SHIELD ILLINOIS DEPLOYMENT: K-12 PARTNER LIST



UNIVERSITY
OF ILLINOIS
SYSTEM

- Acero Charter Schools
- Chicago Jesuit Academy
- Christopher House
- District 2 Triad
- District 3A Rochester
- District 4 Champaign
- District 5 McLean County
- District 5 Sterling
- District 11 Alton
- District 12 Johnsburg
- District 15 McHenry K-8
- District 15 Palatine
- District 21 Wheeling-Buffalo Grove-Arlington Heights
- District 26 River Trails K-8
- District 34 East Moline-Silvis K-8
- District 46 Grayslake
- District 47 Crystal Lake K-8
- District 50 Woodland K-8
- District 54 Schaumburg K-8
- District 63 East Maine K-8
- District 84 Rockdale
- District 92.5 Westchester K-8
- District 93 Hillside
- District 97 Oak Park K-8
- District 98 Berwyn North
- District 101 Western Springs
- District 105 LaGrange
- District 109 Deerfield K-8
- District 113 Highland Park-Deerfield HS
- District 117 Lake Villa
- District 118 Palos Park
- District 124 Grant HS
- District 124 Peru K-8
- District 127 Grayslake HS
- District 144 Prairie Hills K-8
- District 153 Homewood
- District 158 Huntley
- District 186 Springfield
- District 187 Cahokia
- District 189 East St. Louis
- District 200 Wheaton-Warrenville
- District 200 Woodstock
- District 201 Morton HS
- District 204 Joliet Twp HS
- District 205 Lockport Township HS
- District 209 Proviso Twp HS
- District 215 Lansing
- District 218 Oak Lawn HS
- District 300 Algonquin
- District 302 Kaneland
- District 365U Romeoville-Bolingbrook
- Elgin Math and Science Academy
- Illinois Math and Science Academy
- Noble Network of Charter Schools



"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)



"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)

EXAMPLE: DISTRICT 113 (DEERFIELD/HIGHLAND PARK)



- **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 (opt-out)
 - Faculty/Staff tested on Monday and Thursday (optional)



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

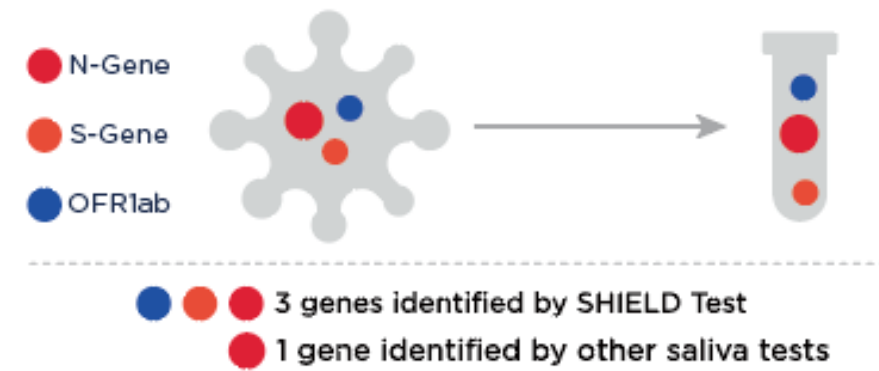
PCR (polymerase chain reaction) creates a chain reaction that **replicates viral genetic material**, allowing detection of even low viral loads.

SHIELD'S PCR TEST IS HIGHLY ACCURATE AND CAN SCREEN FOR VARIANTS



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 three 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.

ThermoFisher
S C I E N T I F I C



**SHIELD
ILLINOIS**

SHIELD IL + ANTIGEN = POWERFUL COMBINATION



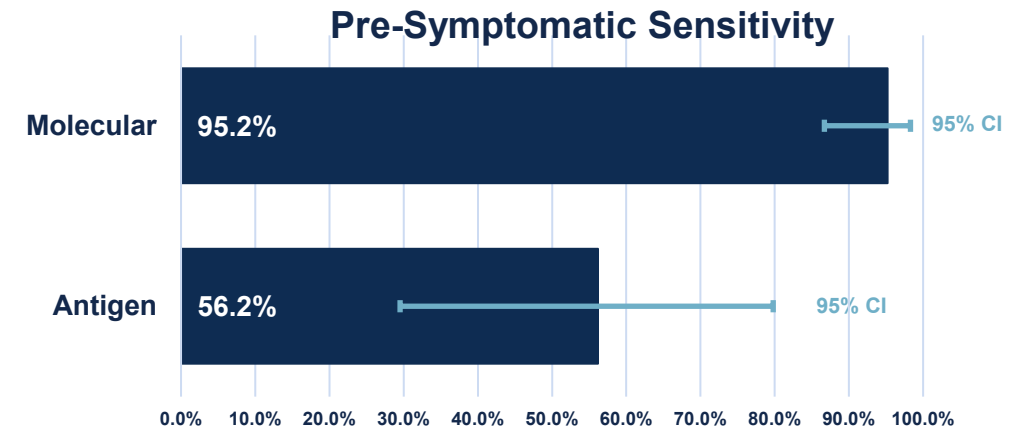
Screen with covidSHIELD PCR and use Binax for symptomatic individuals

Molecular tests

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

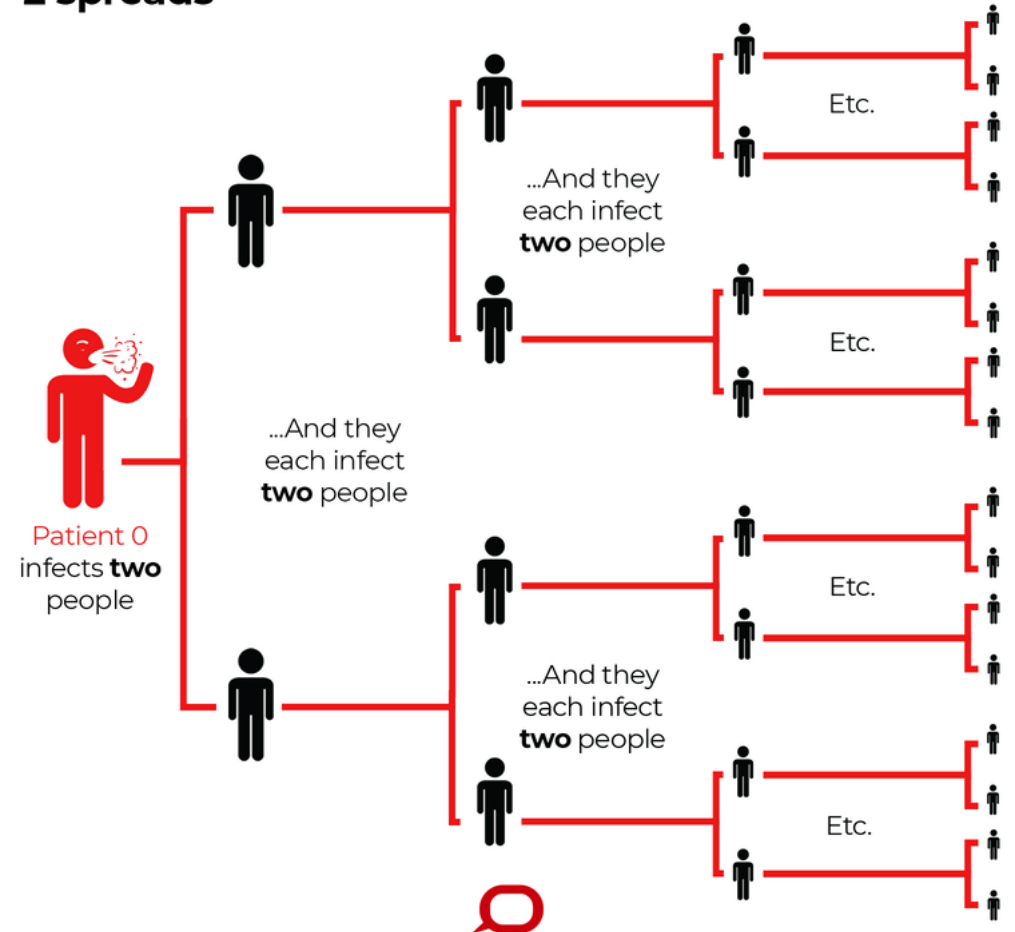
Antigen tests

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



- 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

IMPORTANCE OF FREQUENT TESTING

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

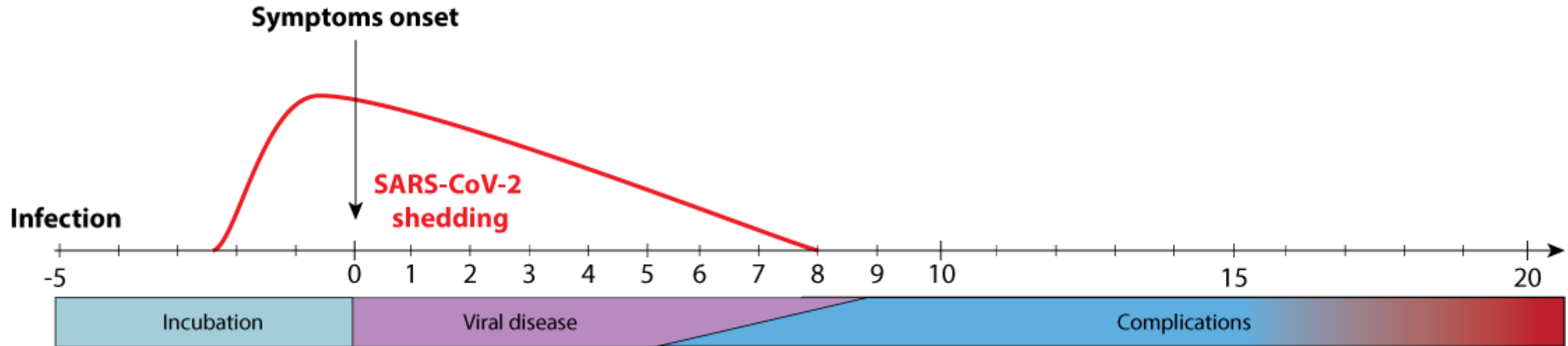
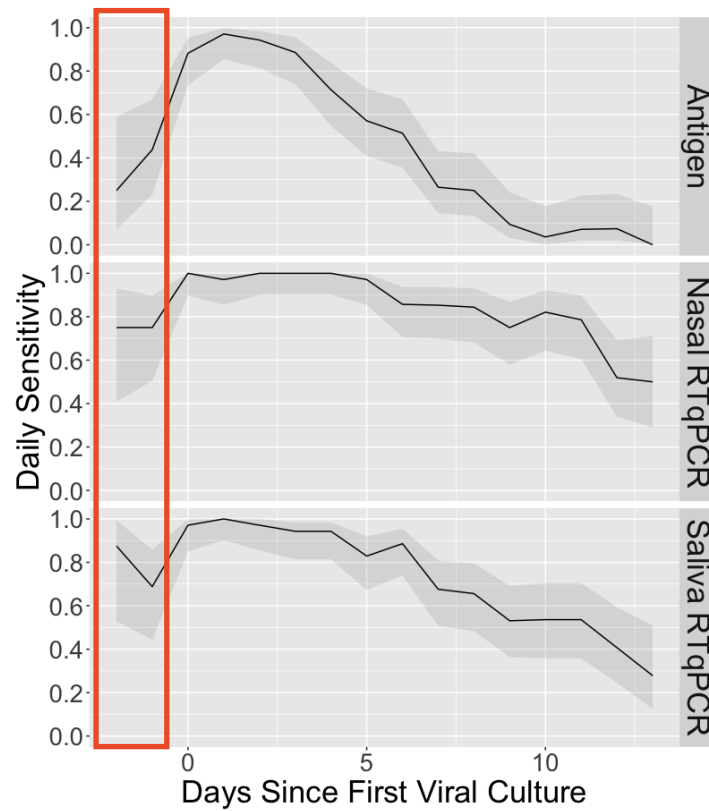


Figure from <https://viralzone.expasy.org/9116>

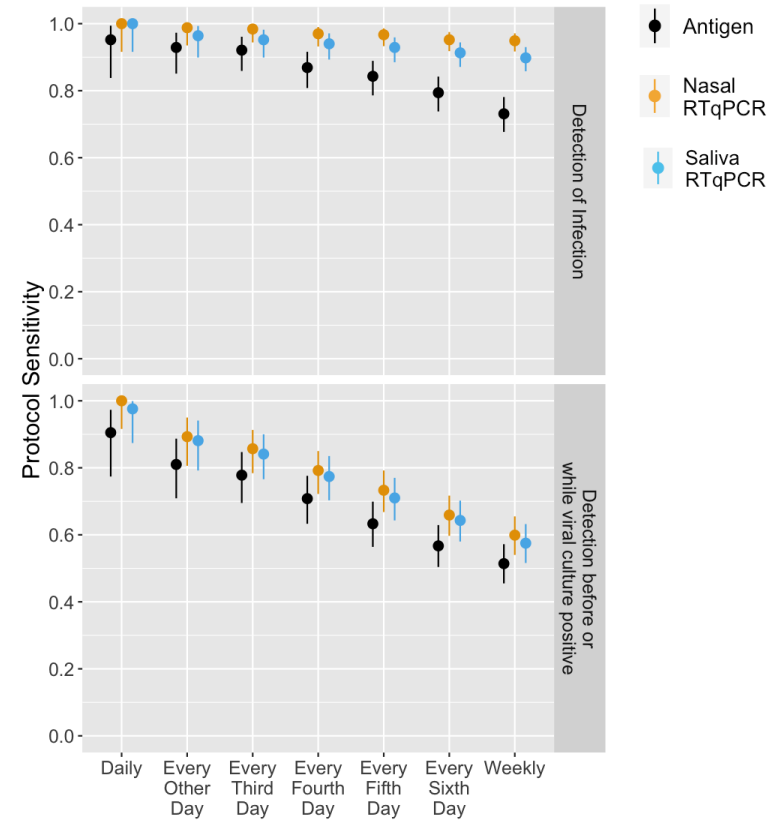
Individuals become contagious before symptoms appear
covidSHIELD can detect the virus before it becomes transmissible

Saliva 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

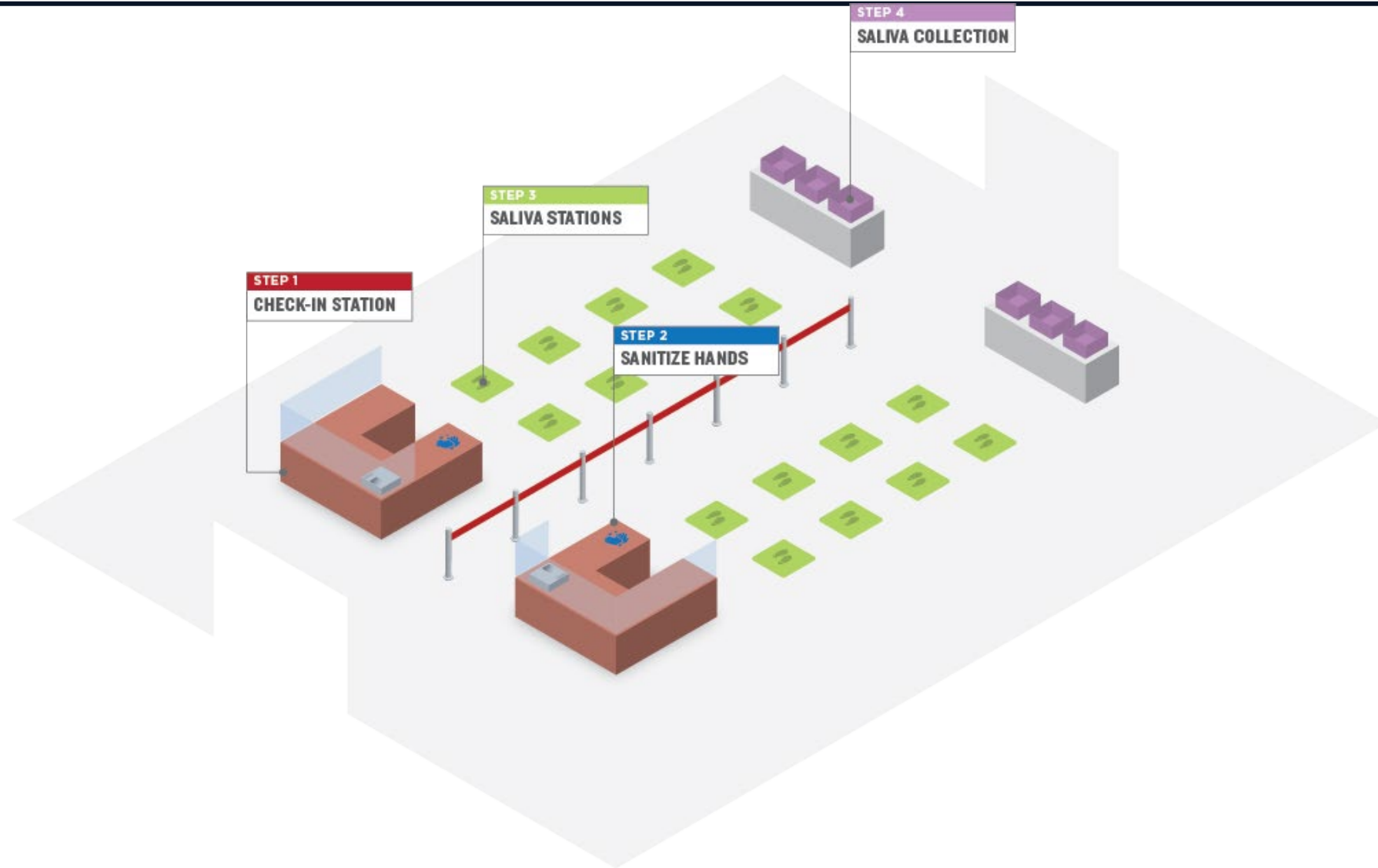
If groups of people test twice per week, SHIELD's test will find >95% of positive cases.



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

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.

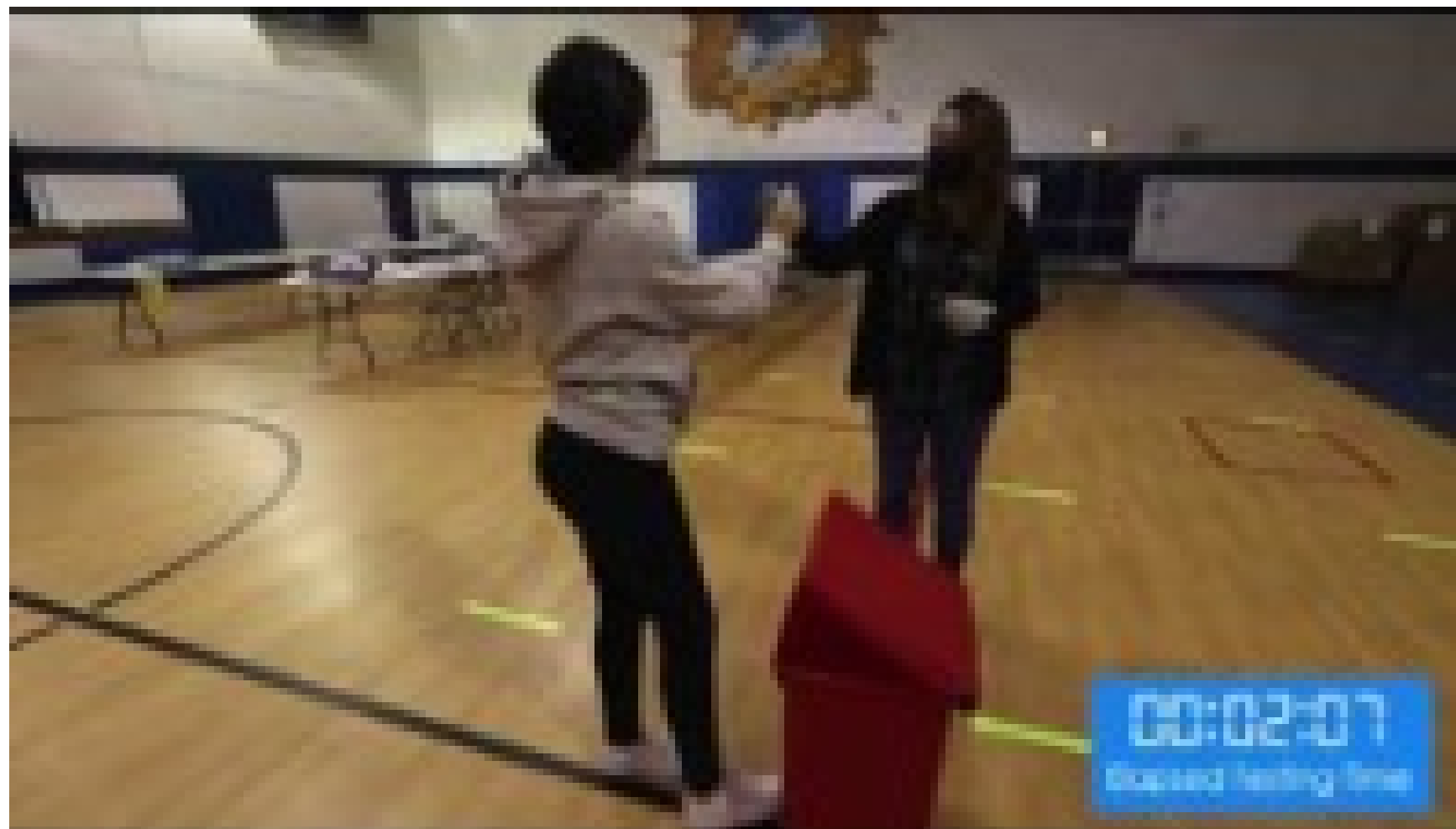




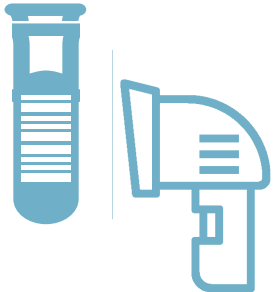
COLLECTION EXAMPLES



UNIVERSITY
OF ILLINOIS
SYSTEM



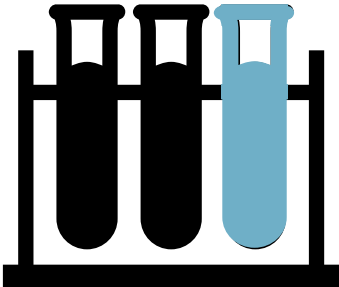
OUTSOURCED COLLECTION PROCESS



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 operations partner can handle the collections and reporting.

IDPH and SHIELD will provide most of the heavy lifting to implement testing at your school district, with three different options available.

Roles and responsibilities

IDPH/SHIELD is responsible for:

- Providing and distributing technology platform to track and identify tests
- Providing and distributing testing supplies
- Facilitating 3rd party operations partner *or* funding for school to run self-collections process

School district is responsible for:

- Setting up space and operations plan
- Receiving consent from participants
- Handling communications and contact tracing
- In some cases, running self-collections process (with funding from state)

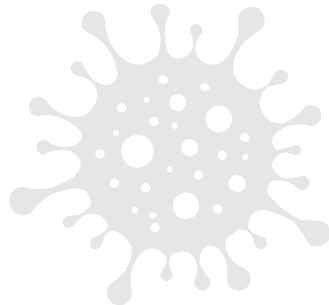
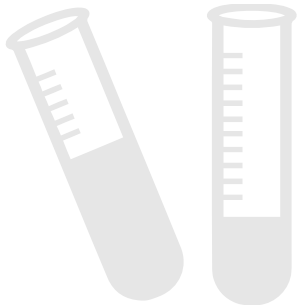
Three options available

- 1 Weekly testing with 3rd party operations partner
- 2 Weekly testing with district self collection
- 3 Emergency outbreak testing

Option 1: Weekly Screening Testing with an Operations Partner

IDPH will pay for weekly testing as well as a 3rd party operations partner who will handle collections, transportation and results reporting.

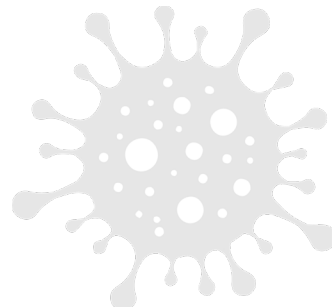
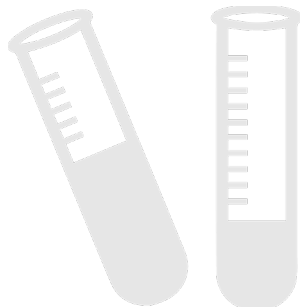
- This is the recommended option when a school district is looking to do weekly testing on unvaccinated individuals.
- 3rd party collection support requires 100 samples per deployment (day of operations).



Option 2: Weekly Screening Testing with District Collection

IDPH will pay for weekly testing and pay the district \$10/test to handle their own collections, transportation and results reporting.

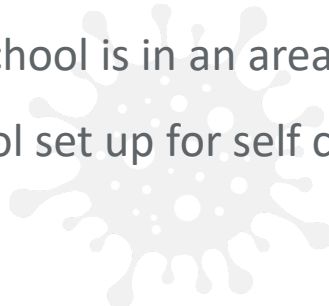
- This is the most flexible option and is recommended for districts looking to do weekly testing but have low testing consent. This option is also useful for schools that want to conduct exposure response testing.
- Collections training will be provided by SHIELD.
- Transportation can be provided by MedSpeed at an additional cost, or schools may deliver to the lab themselves.



Option 3: Outbreak Testing Preparedness

IDPH will pay for emergency response testing, which guidance defines as 2x/week testing for 28 days (2 incubation periods) for all students exposed during an outbreak.

- This option is appropriate for districts not able to operate a weekly screening program. **Emergency outbreak testing must be considered by every district regardless of interest in developing a weekly testing program.**
- IDPH recommends that schools acquire consent in advance of the start of the school year – without pre-consent the emergency response will be delayed.
- If the school is in an area where SHIELD is already deployed, a 3rd party operations partner will be provided. If the school is in an area where SHIELD is not deployed, SHIELD's mobile unit can collect for 7 days and get school set up for self collection.



REPORTING DASHBOARD: Point and Click



Overall Testing Statistics

Results By Individual

Daily Testing Trends

Positives Mapped By Zip Code

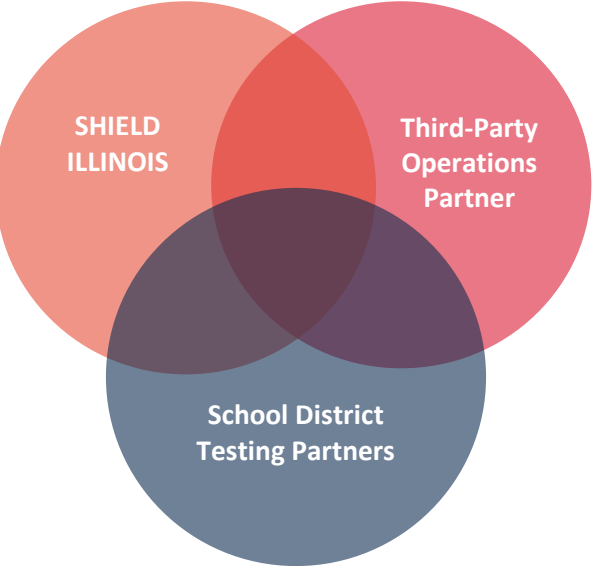
Agency	Name	Collection Date	Result
SHIELD Community Testing		5/18/2021 3:59 PM	Negative
SHIELD Community Testing		5/14/2021 10:17 AM	Negative
SHIELD Community Testing		5/12/2021 7:55 AM	Negative
SHIELD Community Testing		5/10/2021 12:02 PM	Negative
SHIELD Community Testing		5/7/2021 8:53 AM	Negative
SHIELD Community Testing		5/12/2021 8:42 AM	Negative
SHIELD Community Testing		5/21/2021 10:56 AM	Negative
SHIELD Community Testing		5/10/2021 10:12 AM	Negative
SHIELD Community Testing		5/24/2021 9:17 AM	Negative
SHIELD Community Testing		5/14/2021 10:15 AM	Negative
SHIELD Community Testing		5/25/2021 2:58 PM	Negative
SHIELD Community Testing		5/12/2021 8:08 AM	Negative
SHIELD Community Testing		5/28/2021 9:46 AM	Negative
SHIELD Community Testing		5/10/2021 8:28 AM	Negative
SHIELD Community Testing		5/17/2021 10:47 AM	Negative
SHIELD Community Testing		5/3/2021 10:28 AM	Negative
SHIELD Community Testing		5/12/2021 9:54 AM	Negative
SHIELD Community Testing		5/3/2021 8:21 AM	Negative
SHIELD Community Testing		5/24/2021 9:10 AM	Negative
SHIELD Community Testing		5/7/2021 8:32 AM	Negative
SHIELD Community Testing		5/3/2021 9:48 AM	Negative
SHIELD Community Testing		5/3/2021 9:45 AM	Negative
SHIELD Community Testing		5/3/2021 8:37 AM	Negative
SHIELD Community Testing		5/3/2021 11:13 AM	Negative
SHIELD Community Testing		5/3/2021 8:53 AM	Negative

Data available at a collection site level and aggregate level

BREAKDOWN OF RESPONSIBILITIES WITH 3RD PARTY OPERATIONS PARTNER



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



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
- Operational plan (who, what, where; completed with 3rd party)
- Location for collection sites
- Communication to constituents
- Contact tracing, as is required for all quarantined students

SCHOOL TESTIMONIALS



UNIVERSITY
OF ILLINOIS
SYSTEM



NEXT STEPS TO PURSUE TESTING



INTERESTED

1. Fill out interest form [HERE](#).
2. Schedule follow-up meeting with SHIELD to review testing details.
3. Determine if participating, identify start date*.

COMMITTED

4. Sign SHIELD contract.
5. Attend SHIELD/District Kick Off Meeting.
6. Align on consent form with school's legal team. Obtain consent from constituents.
7. Meet with assigned 3rd party operations partner to operationalize testing plan.
8. Roster students in EMR.
9. Start testing!

Test Interest K-12 Survey



<http://bit.ly/interestedK12SHIELD>

*Typically 2-3 weeks from commitment date

Website:

uillinois.edu/shield

Contact:

Beth Heller
Senior Director, External Relations
Cell: 312.953.5879
Email: bheller@uillinois.edu

Beth Milligan
Director, External Relations
Cell: 773.972.5490
Email: bmilliga@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