SHIELD Illinois Overview

University of Illinois System

WHAT IS SHIELD ILLINOIS?

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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.*

HOW IT STARTED

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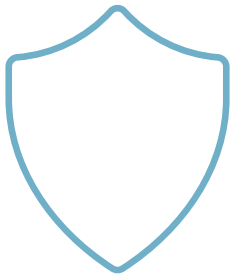
Innovation

- 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 **4.5 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

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Low Cost	The cost of the saliva-based test is $30, compared to $100+ for many other tests.
Fast Results	Results will be sent to the individual, organization and IDPH through a HIPAA-secure health records portal within 24 hours of samples reaching our lab.
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%.
CLIA Certified	All of SHIELD Illinois' tests are processed in CLIA labs, meaning they meet federal standards for accuracy and reliability.
Lab Network	SHIELD Illinois has launched a network of high-capacity labs across the state to process test samples and provide fast, accurate results.
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.

SHIELD'S LAB 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

Safely Opening Schools. Protecting Workplaces. Saving Lives

PCR: “GOLD STANDARD OF TESTING”

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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

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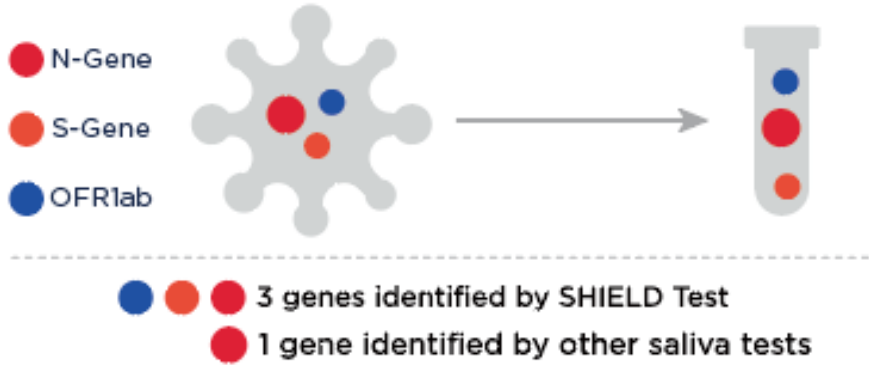
covidSHIELD detects three genes of the SARS-CoV-2 virus, unlike most PCR tests, which only detect 1 gene.

- 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.**



TYPES OF COVID-19 TESTING

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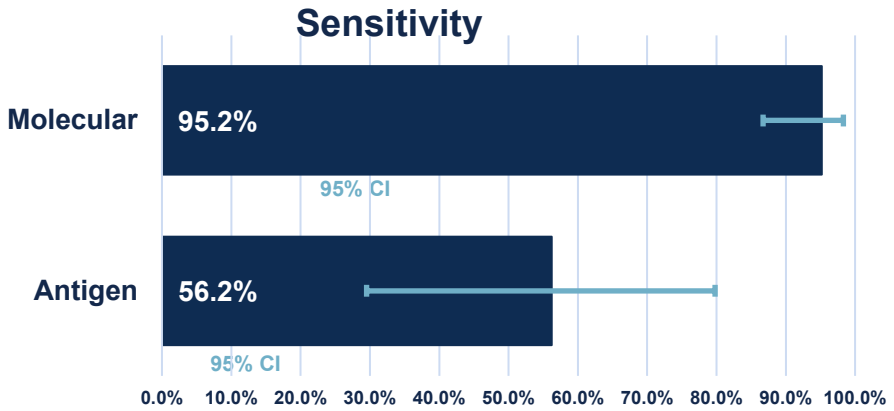
Molecular tests

- 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



HOW INFECTIONS SPREAD

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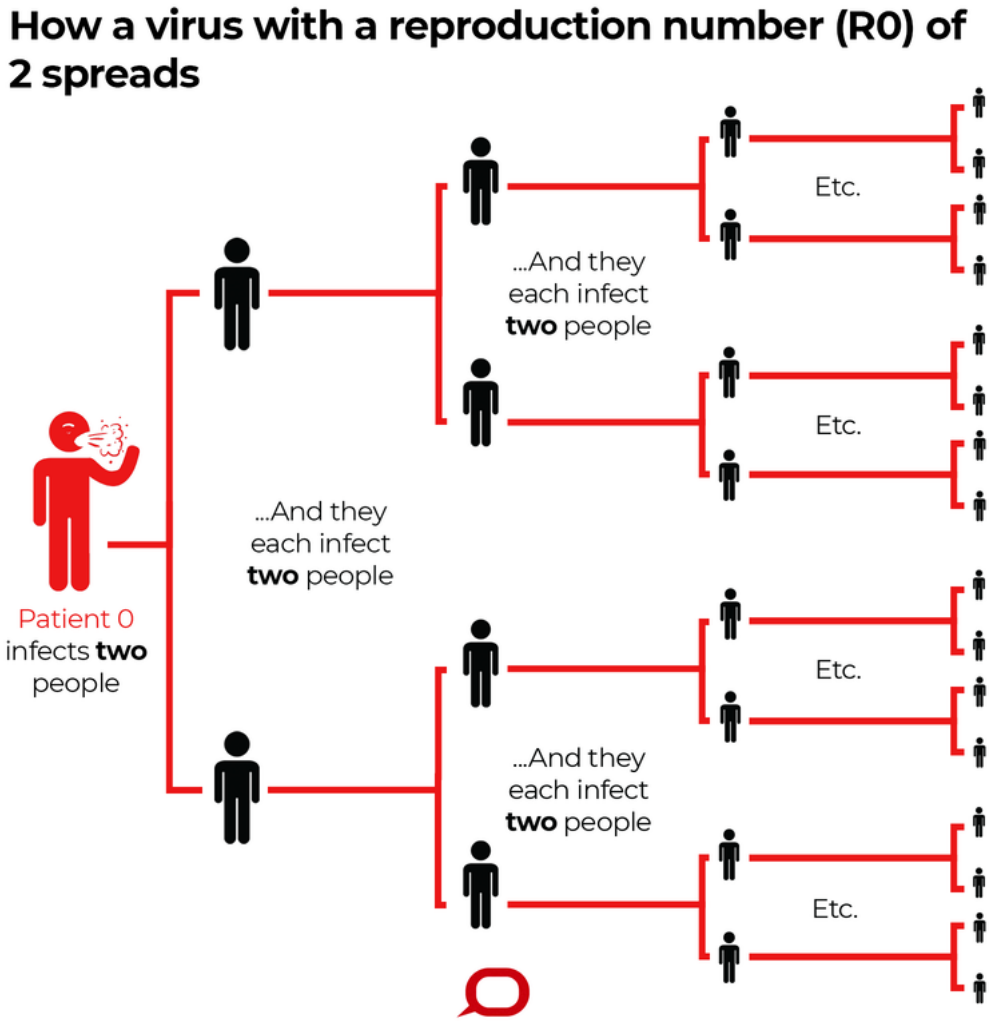
- The R0 of SARS-CoV-2 is 2.87, even higher than this graphic. The R0 of Delta is between 6-8.

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



Source: The Conversation, Jan. 28, 2020

IMPORTANCE OF FREQUENT TESTING

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Testing **everyone** is critical because ~75% of spread by the Delta variant is done by asymptomatic or pre-symptomatic individuals.

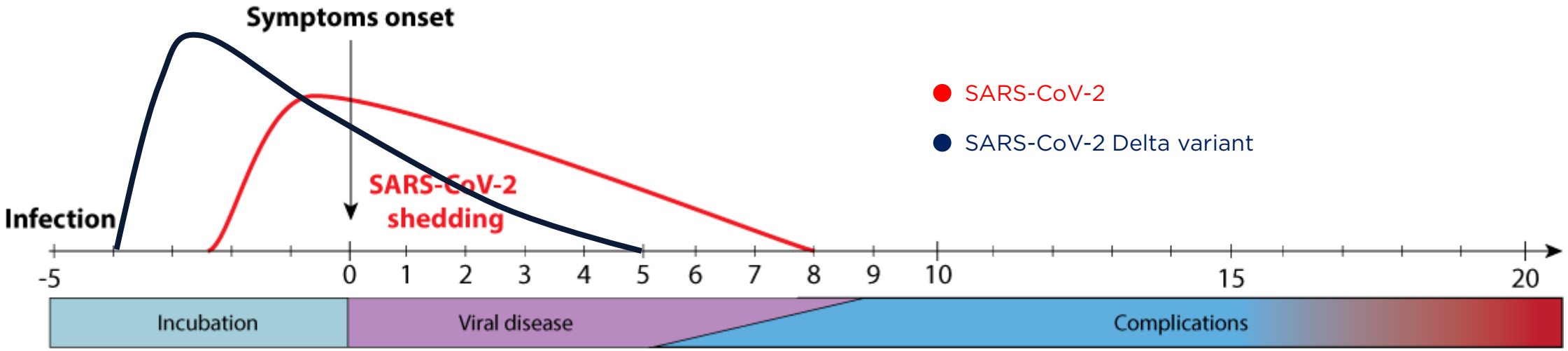

Figure from https://viralzone.expasy.org/9116

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

SALIVA TESTS

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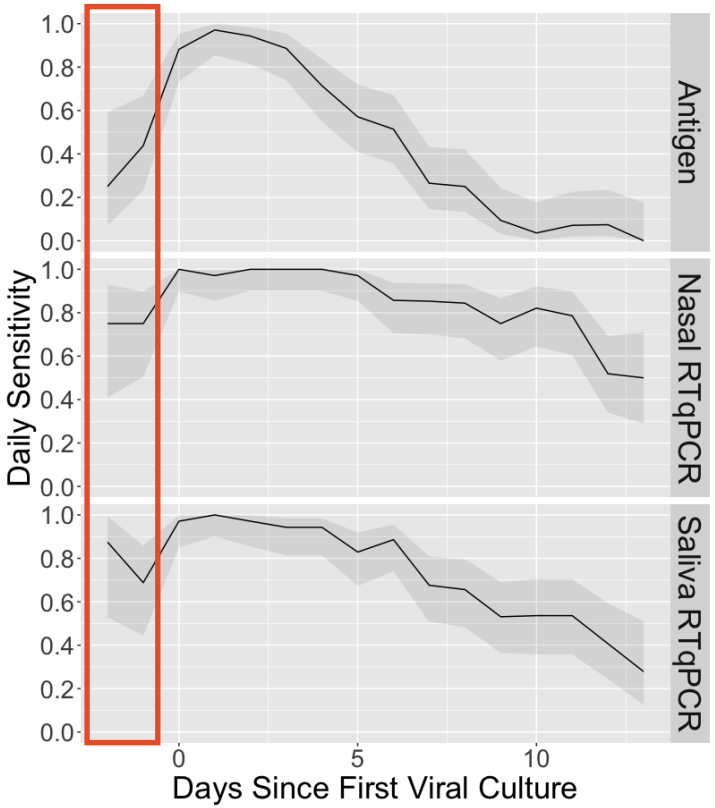
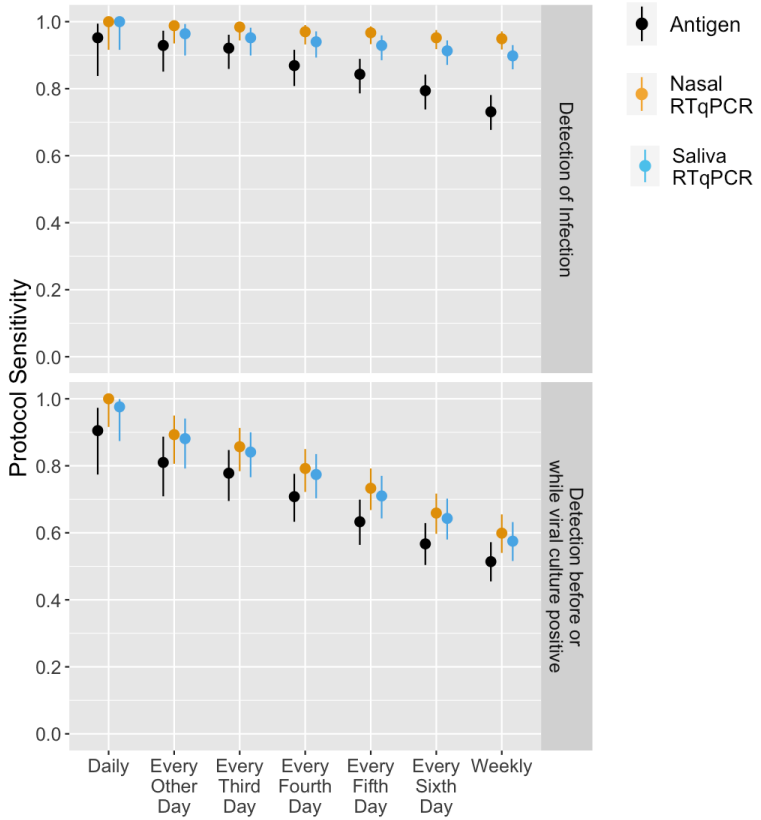
Saliva PCR tests can find positives earlier than other tests, even 1-2 days before the infectious phase



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

METHODS OF COLLECTION

VS.

Sample Collection

Saliva or nasal?

- Saliva is noninvasive and captures more copies of virus DNA than nasopharyngeal swabs.
- Saliva tests have shown to detect the virus sooner than nasal swab tests.
- Saliva doesn't require medically trained collection staff.
- Saliva tests don't detect dead virus like nasal swabs do.

On a positive test, individuals typically become infectious before symptoms are present

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Infection Timeline

Day 1-2: Infection

You have been infected and virus is replicating

Day 2: Positive

You can now begin to test positive

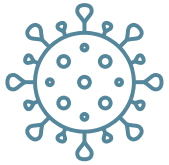
Day 2-4: Infectious

You are likely now infectious

Day 4-9: Symptoms

Typical Covid-19 symptoms begin to show

Key Takeaways



When you test positive, **there is genetic material from the virus** in your saliva

You were infected at some point in time that was **at least two days ago**

IMPORTANCE OF FREQUENT TESTING

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- The program tests everyone, not just symptomatic individuals. Many infected individuals report no symptoms; however, they may still be transmitting the virus.

- Testing frequently can identify the virus before shedding begins. This enables quicker isolation of infected individuals, which reduces community spread.

COLLECTION PROCESS

SHIELD Illinois' collection process is quick, self-administered and non-invasive.

COLLECTION SITE EXAMPLE

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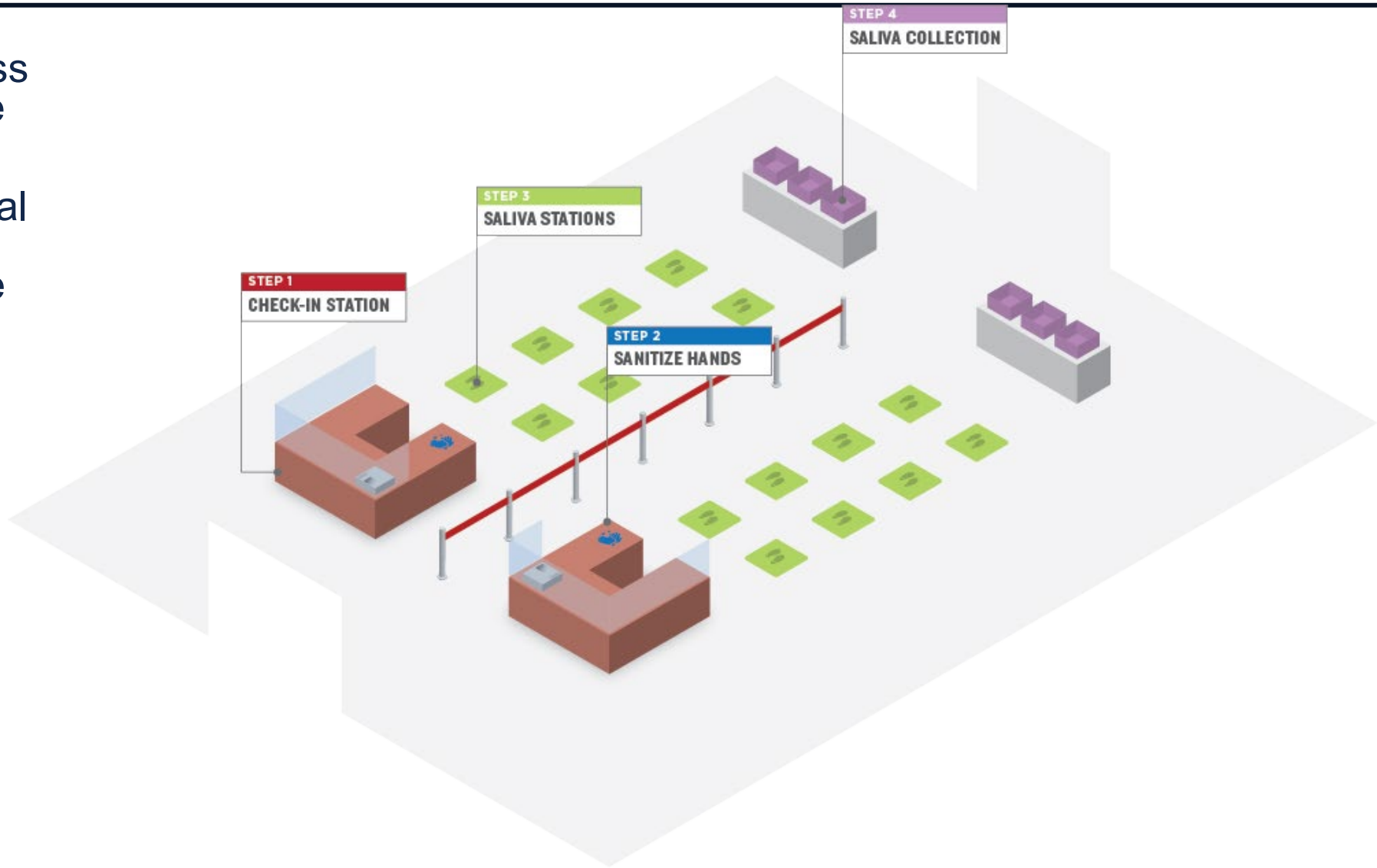
- A collection lane can process approximately 40-60 people per hour.
- It typically takes an individual 3-5 minutes to provide a saliva sample and complete the process.
- Patients must refrain from eating, drinking, or putting anything in their mouth for 1 hour prior to providing a sample.



COLLECTION EXAMPLES

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SAMPLE COLLECTION PROCESS

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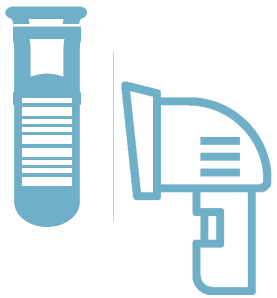
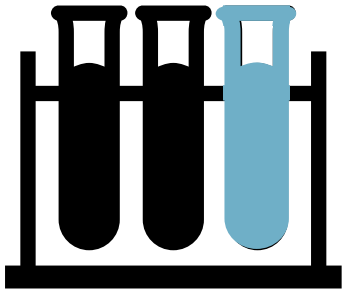


A patient checks in by confirming their identity, then a barcoded label is associated with their sample vial

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 the lab.

- Patients must refrain from eating, drinking, or putting anything in their mouth for 1 hour prior to providing a sample.

REPORTING DASHBOARD: Point and Click

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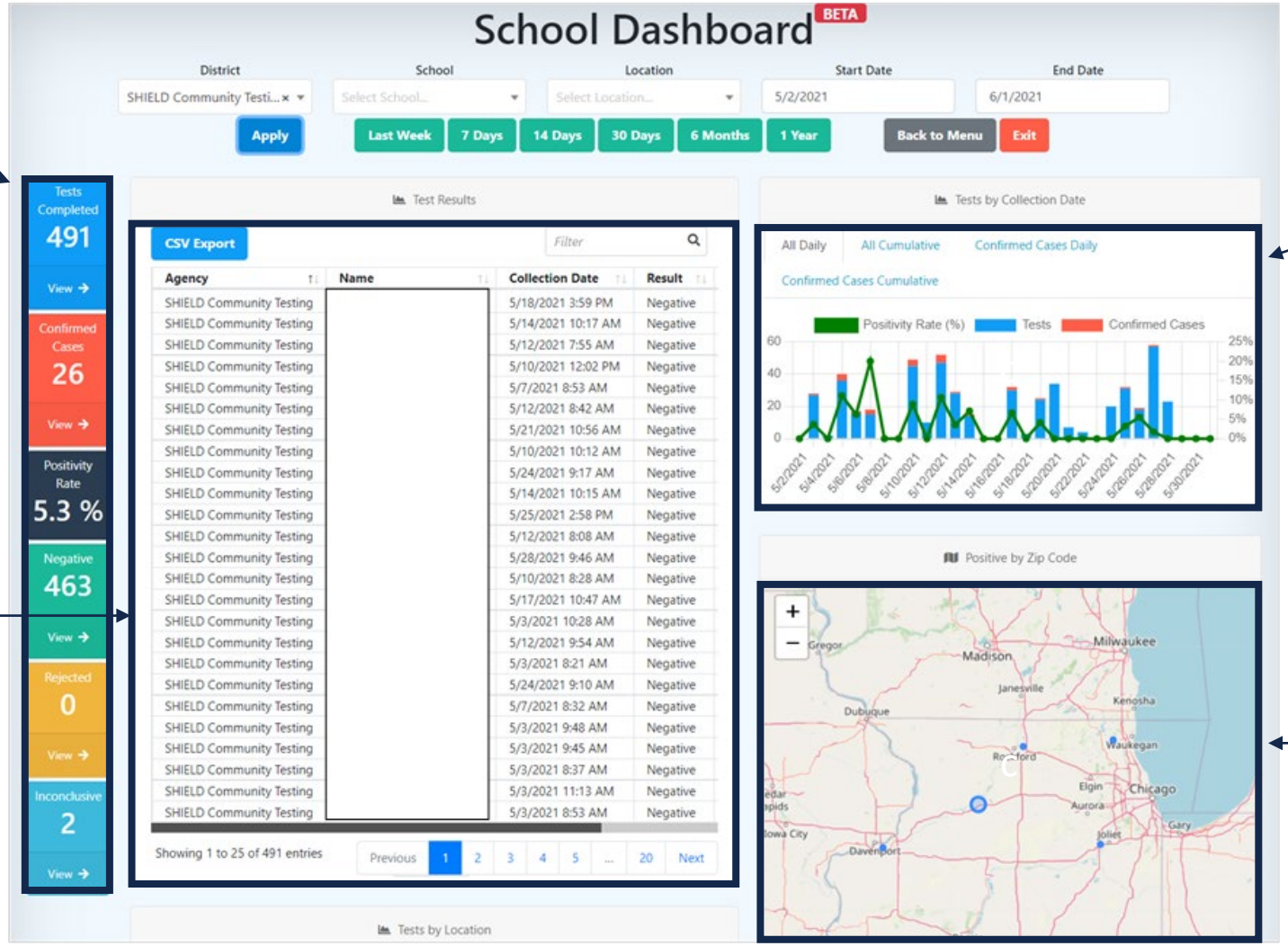
Overall Testing Statistics

Results By Individual

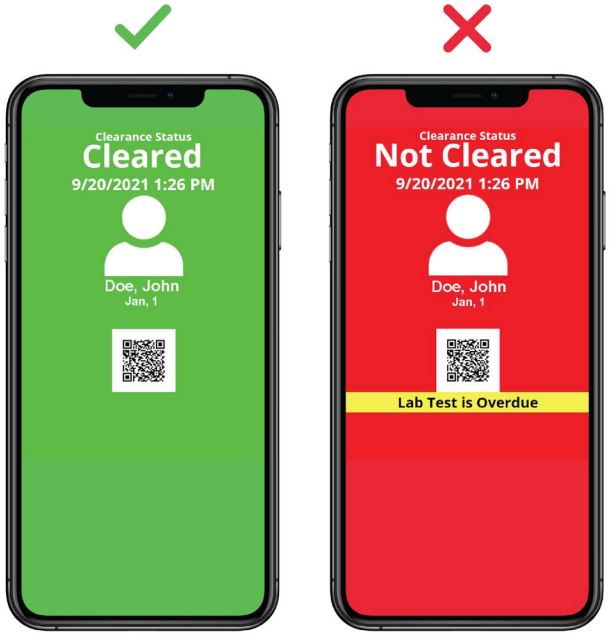
Daily Testing Trends

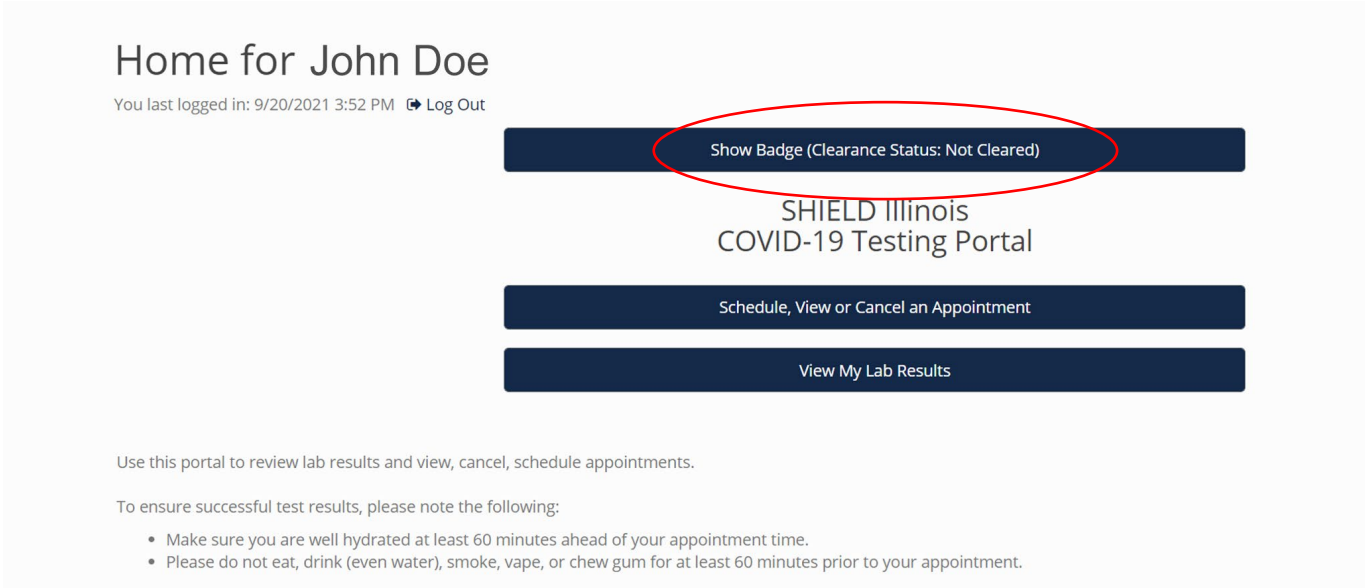
Positives Mapped By Zip Code



Data available at a collection site level and aggregate level

SHIELD PASSPORT





With SHIELD Badges, one can easily identify and confirm testing compliance before returning to work or school.

SHIELD Badges are viewable at https://shieldilportal.pointnclick.com/

BREAKDOWN OF RESPONSIBILITIES

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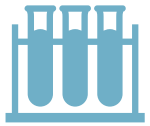
SHIELD Illinois provides

Training for non-medical staff

A proven strategy for sample collection



Equipment and an initial supply of consumables for collections

A technology and reporting platform to provide secure results

The partner provides

Operational plan (including test frequency and schedule) and staffing

Collection location

Individuals to be tested

Transporting samples to SHIELD Illinois lab

Equipment, PPE and consumable items for sample collection

Patient consent forms

Roster with contact information to upload to testing system

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Key Terms

GLOSSARY

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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

GLOSSARY

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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

MORE INFORMATION

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ullinois.edu/shield

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