At-Home Testing: Advancing Data Connectivity, Timely Reporting, and Access to Treatment

Andrew Weitz, PhD

Grace Bendinger, MS, BSN, RN

MAKE MY TEST COUNT

HOME TEST TO TREAT PROGRAM

Overview

1. The role of RADx Tech
   - Paradigm shift in diagnostics
2. RADx MARS
   - Developing technical pathways for reporting test results
3. MakeMyTestCount
   - Empowering individuals to manage their health through self-testing and reporting
4. Home Test to Treat
   - Expanding equitable access to at-home diagnostic tests and treatment
5. Looking Ahead
   - Continued work and commitment to overcome diagnostics reporting barriers

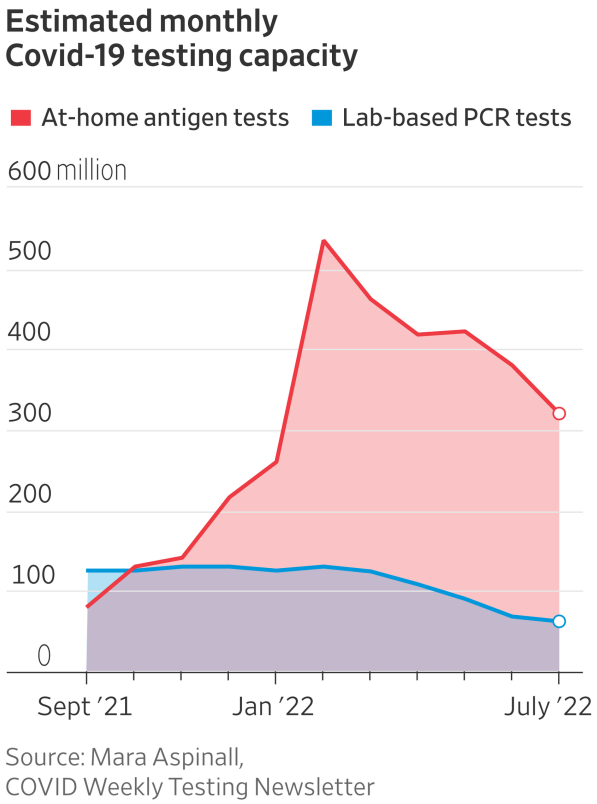
NIH's Rapid Acceleration of Diagnostics (RADx®) Tech

Goal: Speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing

- Over 7 Billion tests/products
- 52 FDA authorized tests
- >100 organizations supported
- 1st Over-the-Counter test for use at home

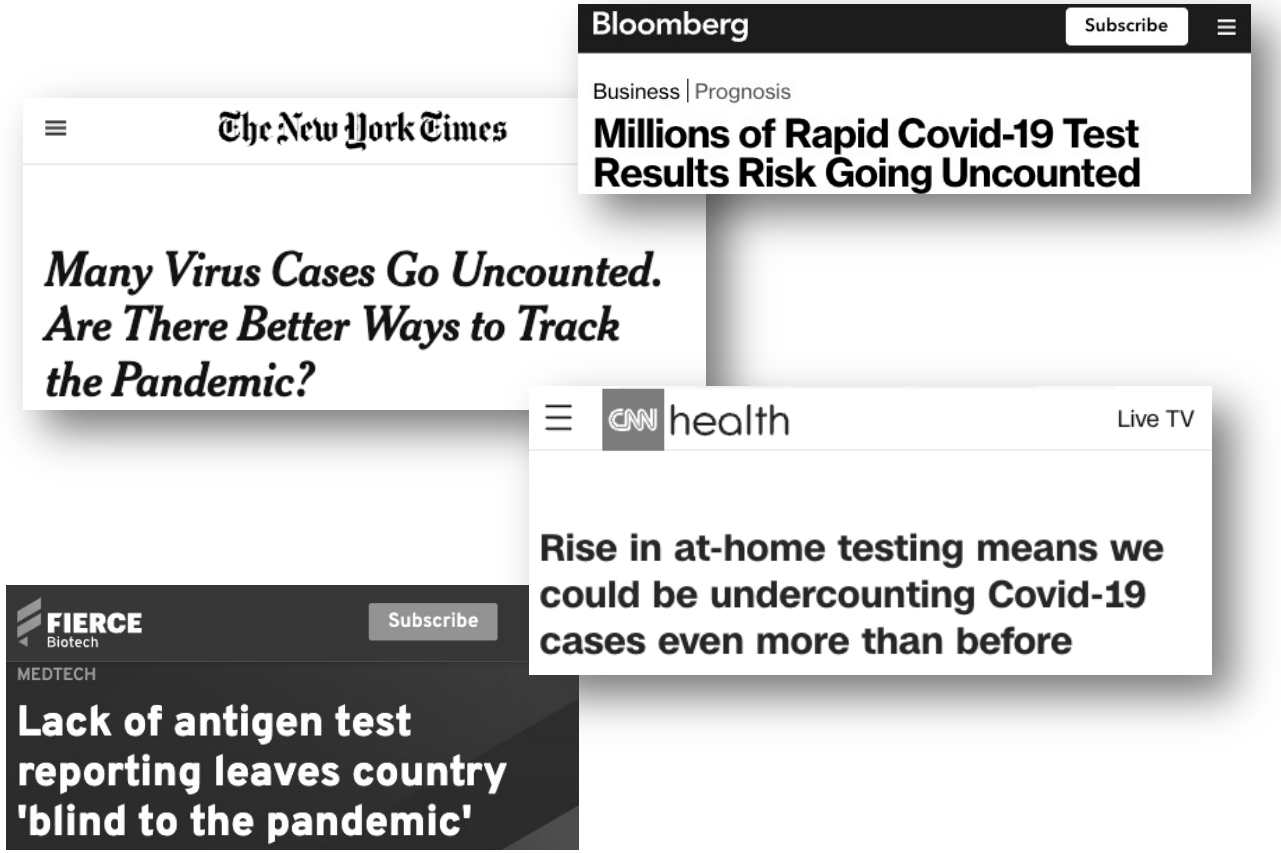
Case reporting impacted by at-home testing shift

Paradigm shift from lab to home

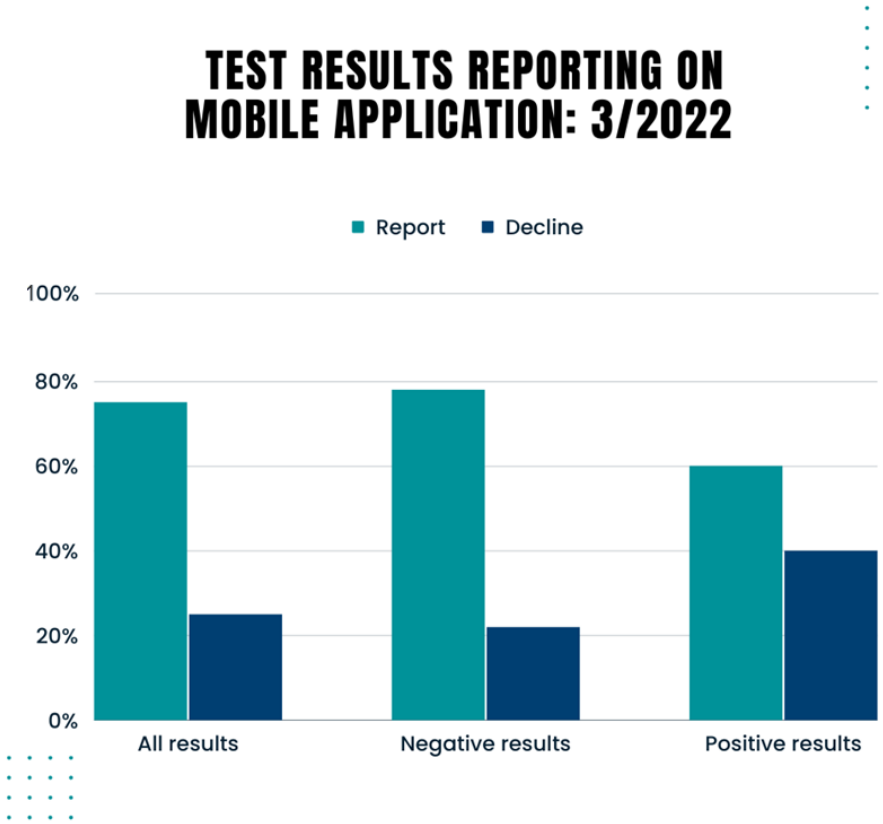


Source: Mara Aspinall,
COVID Weekly Testing Newsletter

Increasing need to capture unreported test results



Willingness of individuals to self-report test results



~3 in 4 individuals agreed to report at-home test results when invited to do so through a mobile app

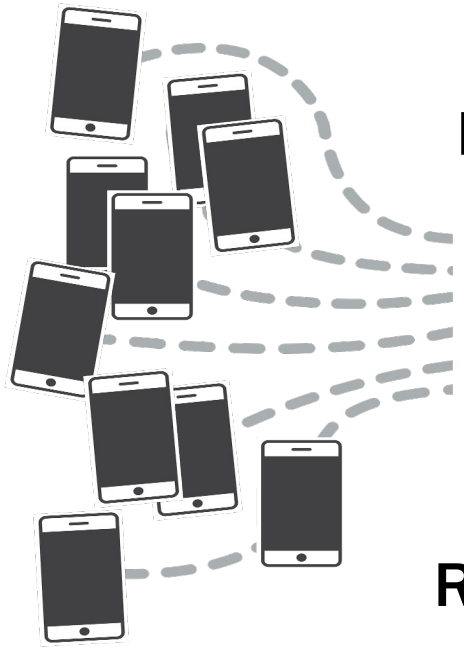
SAY YES! COVID TEST™ KEEP OUR COMMUNITIES SAFE

careevolution HEALTHCARE TECHNOLOGY

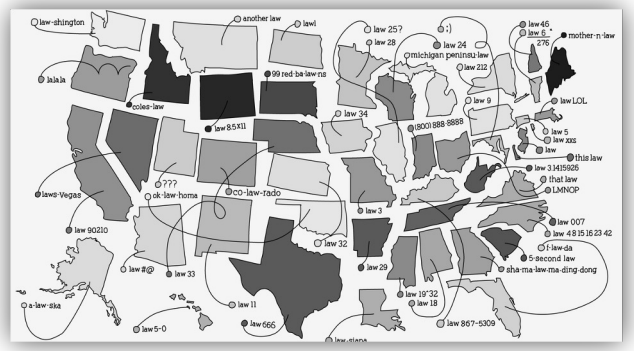
UMass Chan MEDICAL SCHOOL

System Barriers to Mobile At-Home Reporting

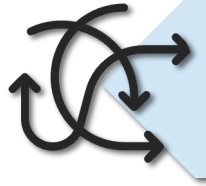
Novel OTC Testing Apps



State Requirements



Federal Requirements



Inconsistent guidance of data elements to capture

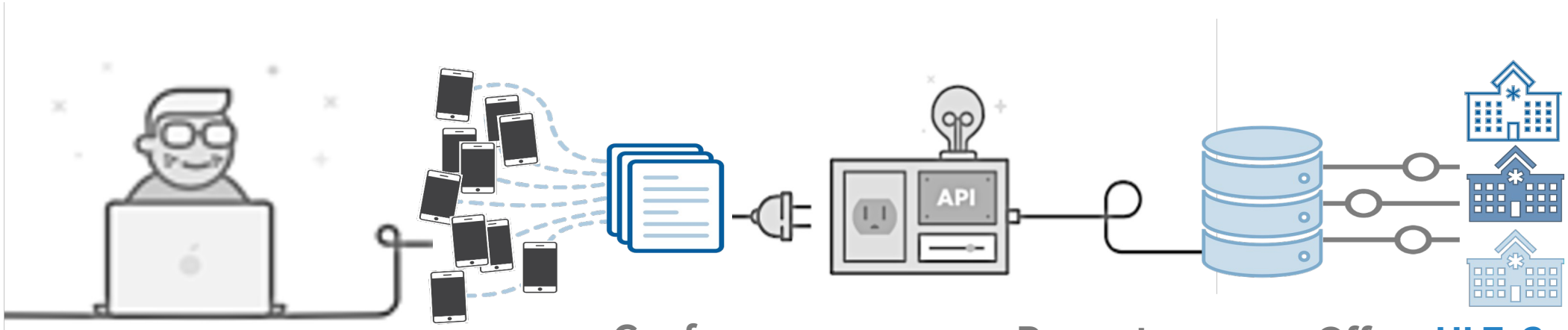
No standards for representing and transmitting OTC test results

High cost for novel software solutions

The RADx® MARS Solution

RADx® MARS

Mobile **A**t-Home **R**eporting through **S**tandards



NIH funds & guides developers to build technical capabilities

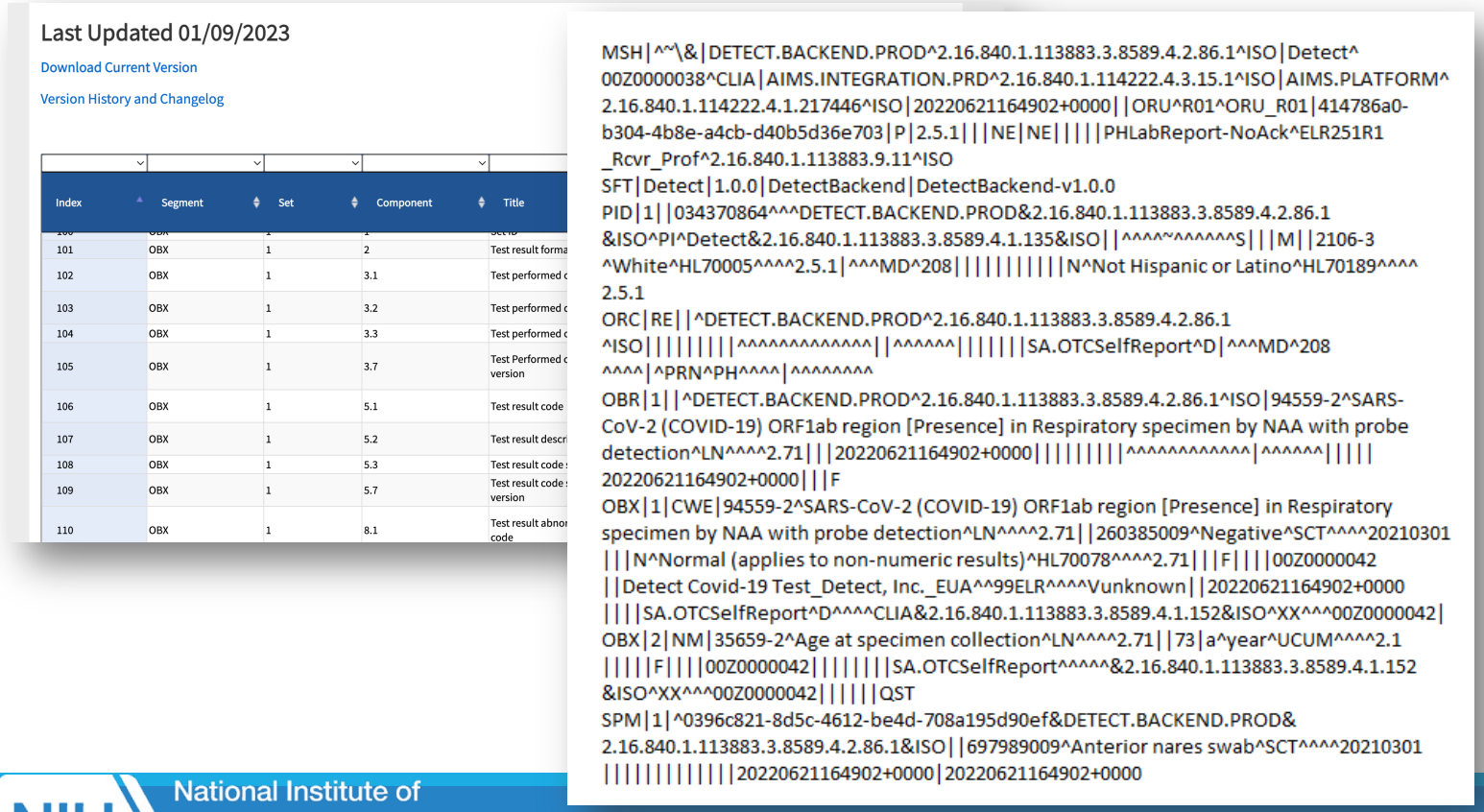
Conforms **data elements** to federal, state, & local requirements

Promotes **data hubs** to decrease complexity

Offers **HL7v2 native compatibility** to state & local health systems

RADx® MARS Leverages Industry-Wide Standards

HL7V2 SPECIFICATION



Last Updated 01/09/2023

Download Current Version

Version History and Changelog

Index	Segment	Set	Component	Title
101	OBX	1	2	Test result forma
102	OBX	1	3.1	Test performed c
103	OBX	1	3.2	Test performed c
104	OBX	1	3.3	Test performed c
105	OBX	1	3.7	Test Performed c version
106	OBX	1	5.1	Test result code
107	OBX	1	5.2	Test result descr
108	OBX	1	5.3	Test result code s
109	OBX	1	5.7	Test result code s version
110	OBX	1	8.1	Test result abnor code

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00Z0000038^CLIA|AIMS.INTEGRATION.PRD^2.16.840.1.114222.4.3.15.1^ISO|AIMS.PLATFORM^
2.16.840.1.114222.4.1.217446^ISO|20220621164902+0000||ORU^R01^ORU_R01|414786a0-
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^^^^|^PRN^PH^^^^|^^^^^^^^
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CoV-2 (COVID-19) ORF1ab region [Presence] in Respiratory specimen by NAA with probe
detection^LN^^^^2.71|||20220621164902+0000|||||||||^^^^^^^^^^^^^|^^^^^^|||||
20220621164902+0000|||F
OBX|1|CWE|94559-2^SARS-CoV-2 (COVID-19) ORF1ab region [Presence] in Respiratory
specimen by NAA with probe detection^LN^^^^2.71||260385009^Negative^SCT^^^^20210301
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OBX|2|NM|35659-2^Age at specimen collection^LN^^^^2.71||73|a^year^UCUM^^^^2.1
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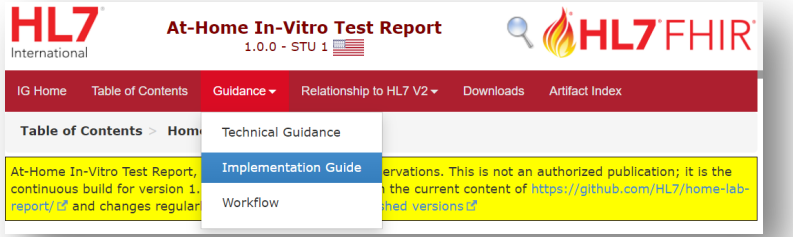
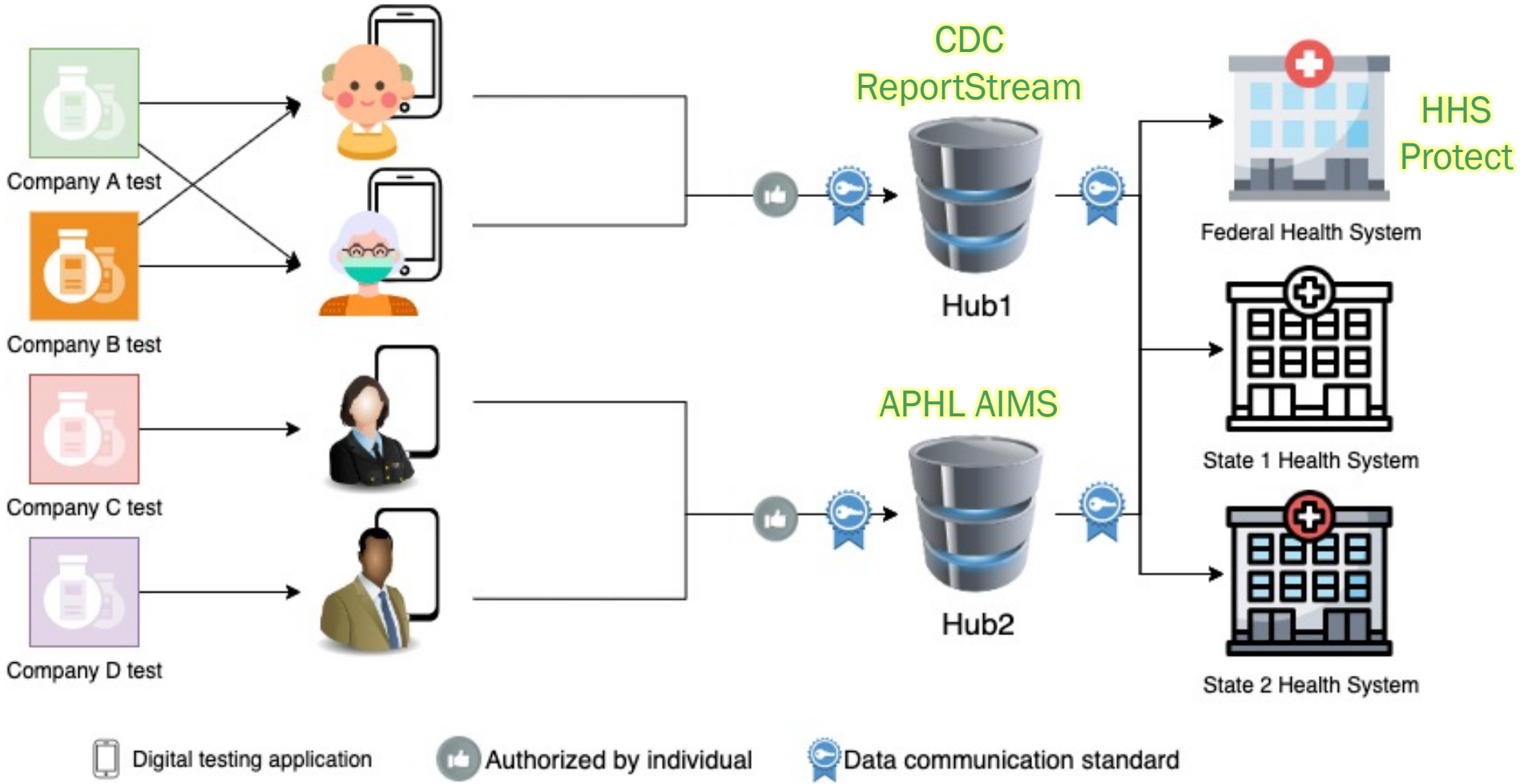
HL7 FHIR SPECIFICATION



The Office of the National Coordinator for Health Information Technology

RADx® MARS Streamlines Information Flow



RADx® MARS Adopters

Detect

iHealth

Roche

QuidelOrtho™

Intrivo™

eMed®

BD

BOSON™

careevolution HEALTHCARE TECHNOLOGY

ACON

Scanwell

RECURO HEALTH

MAKE MY TEST COUNT

IMAGEMOVER

primary

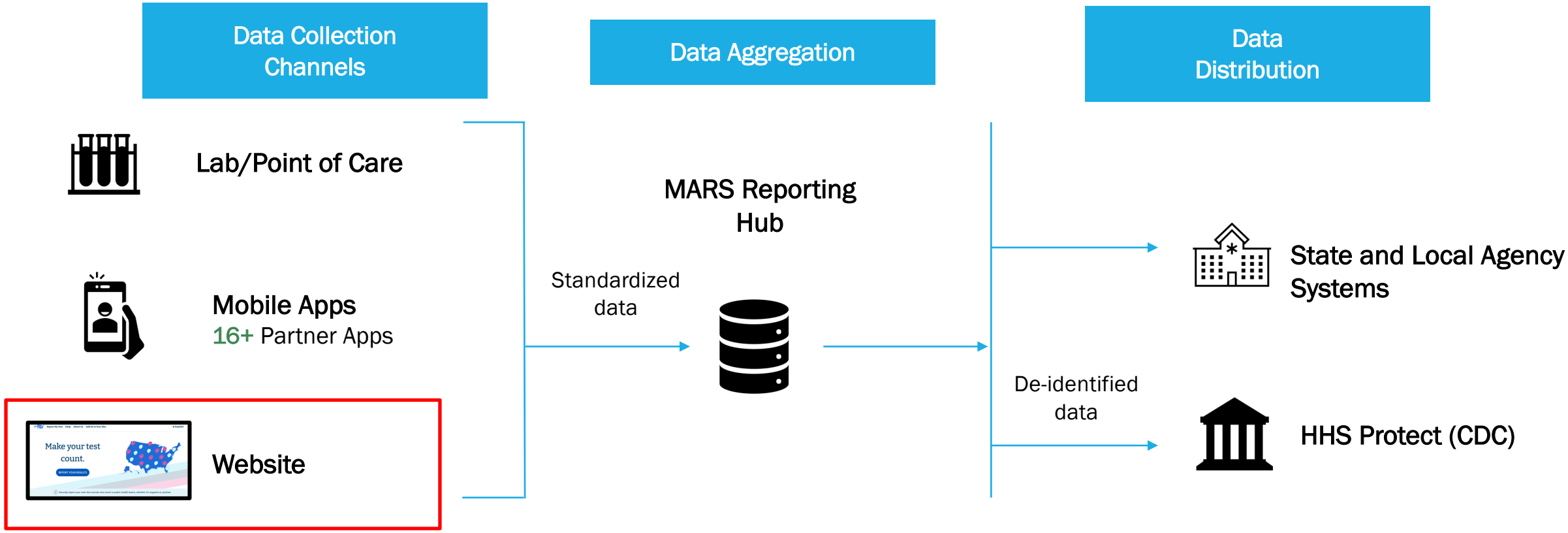
CLXHEALTH

Impact of RADx® MARS

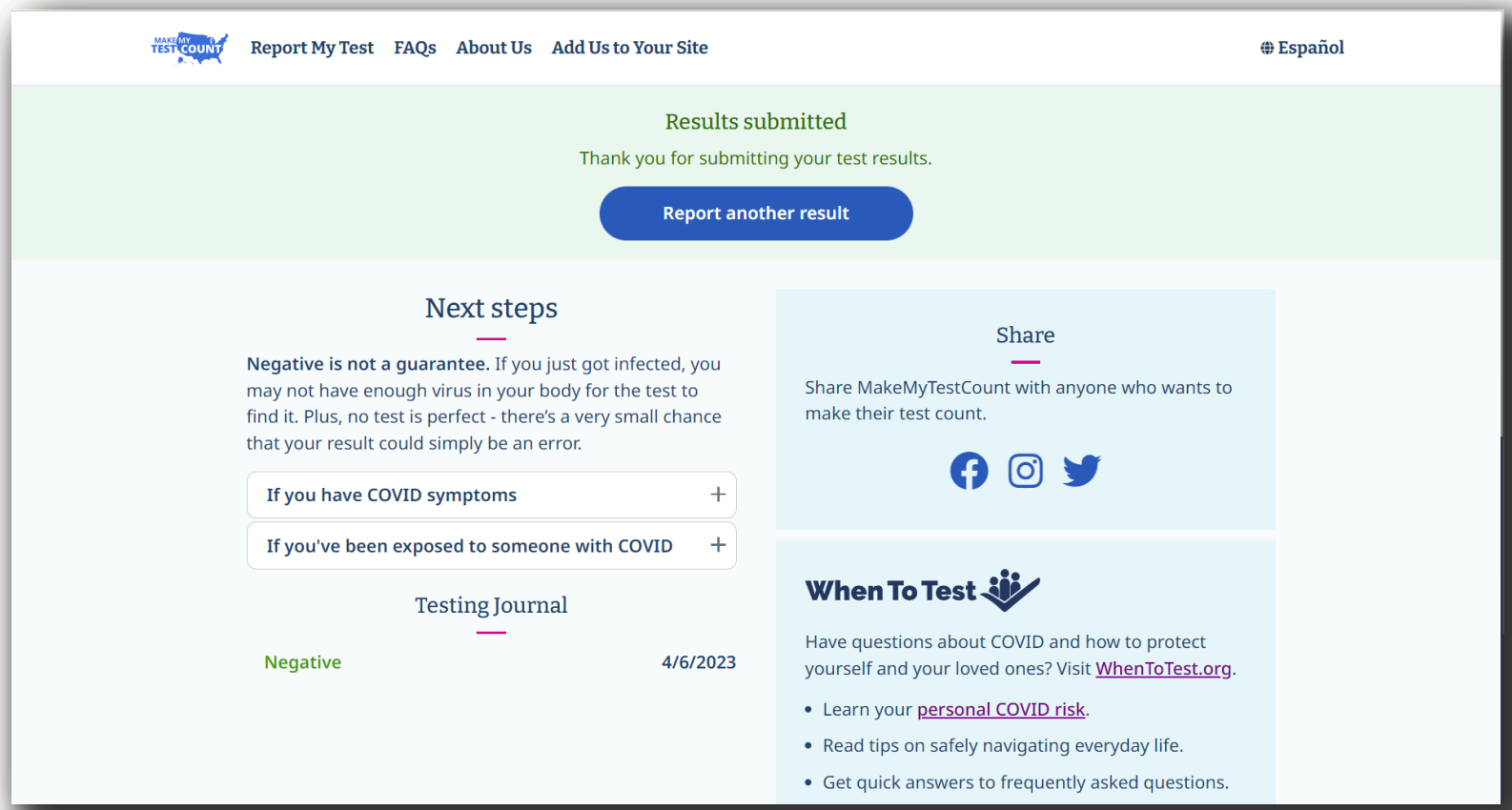
- Established a consistent reporting system
- Expanded pathways for seamless data integration
- Facilitated standardized data access for public health teams

Visit the RADx® MARS Website: https://www.nibib.nih.gov/covid-19/radx-tech-program/mars

It is estimated that fewer than 1% of at-home test results are reported.
Additional channels are needed to reduce barriers to reporting.



MakeMyTestCount.org offers a convenient reporting solution



Designed for the Public

- **Convenient** – few questions, mobile optimized, with 80%+ completion rates
- **Safe and secure** – site compliant with FISMA requirements
- **Scalable** – built to handle millions of concurrent submissions
- **Educational** – provides clear answers on what to do if test is negative or positive

Partner With MakeMyTestCount

Use this platform for all your at-home OTC test-reporting needs.
There's no cost to you, whichever option you choose.

Partnering Options

It doesn't have to be complicated. If your tech is limited, simply add a link to MakeMyTestCount.org on your website.
Want more? It's all free.

Stand-Alone Site

Let us create a MakeMyTestCount reporting page with your organization's logo and a custom URL. There's no cost to you.

Modal Pop-Up

Embed a MakeMyTestCount plug-in on your website with your logo. There's no cost to you.

Stay in the Know

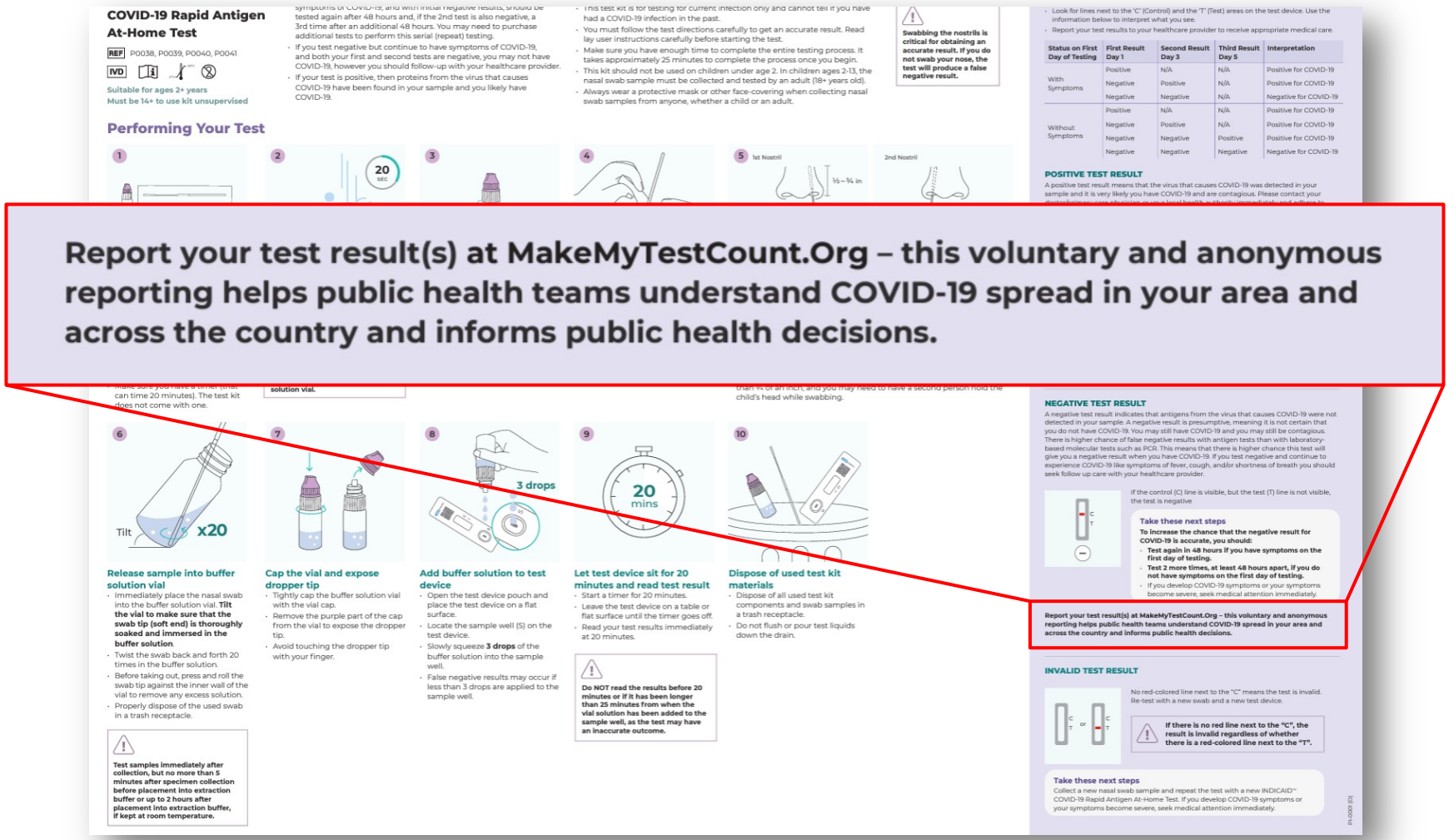
Get updates when new features go live.

Talk with us

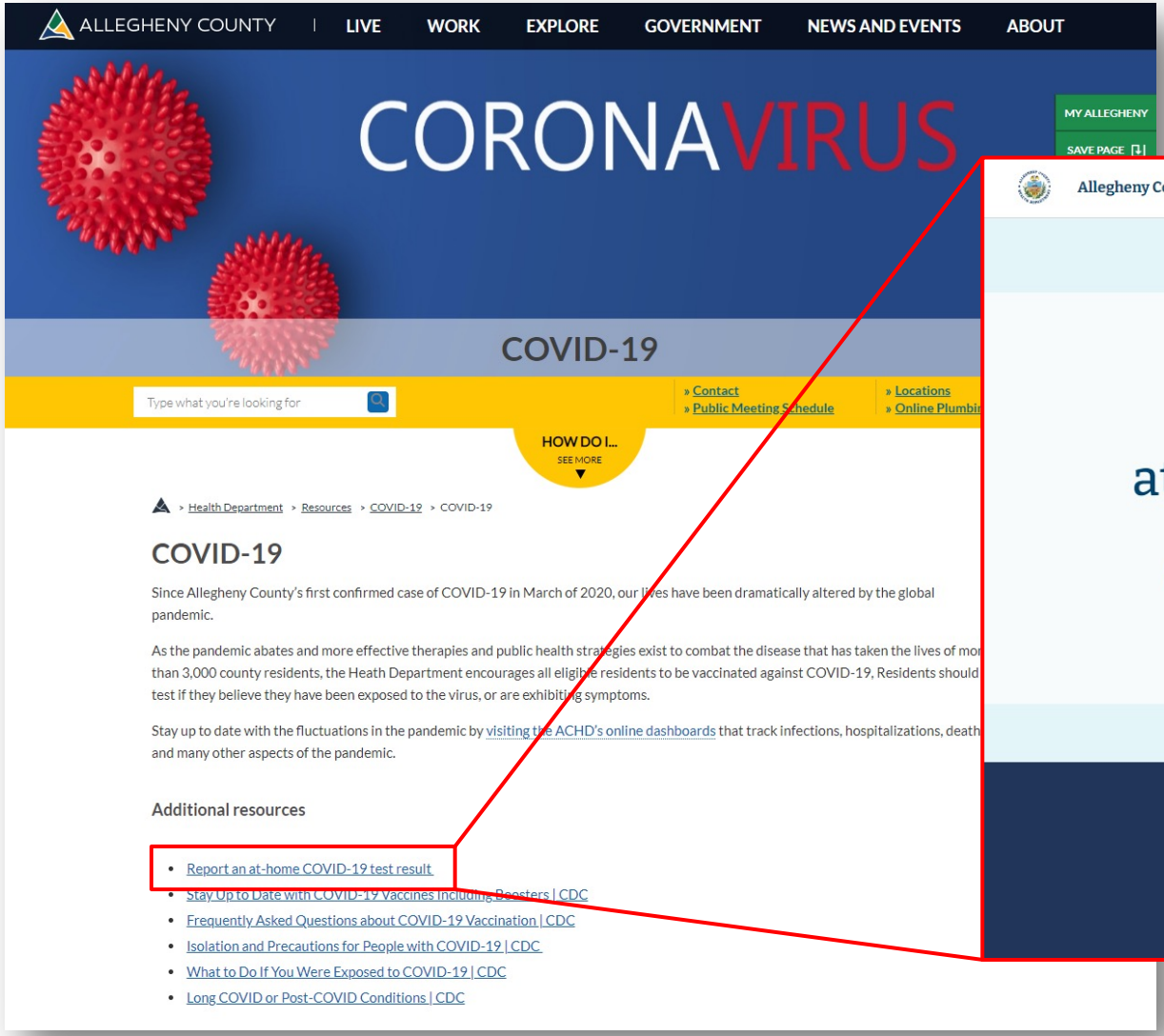
Find out more about how you can install and use this free resource.

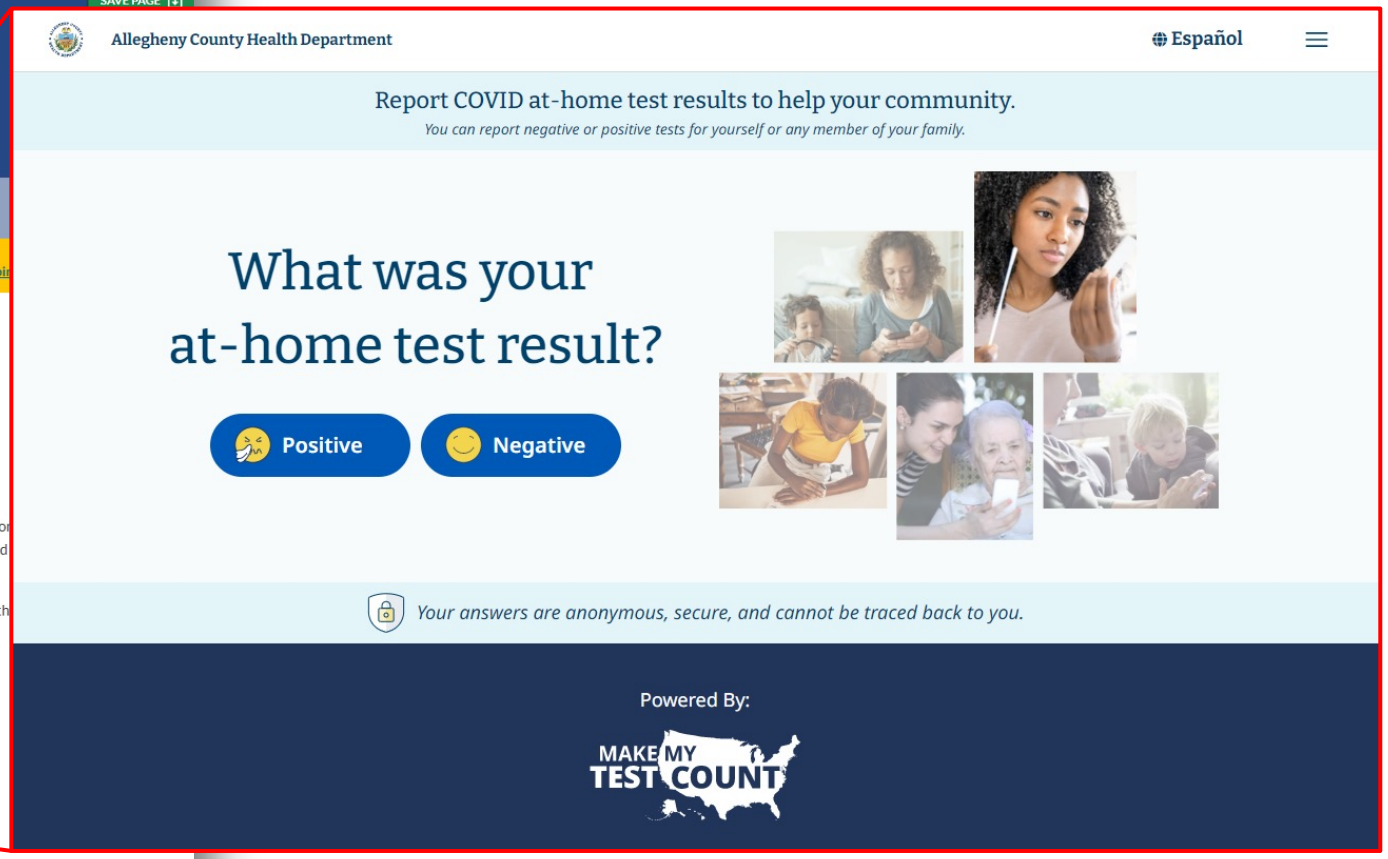
https://learn.makemytestcount.org/for-partners

MakeMyTestCount can be promoted by test manufacturers



MakeMyTestCount can be promoted by health departments



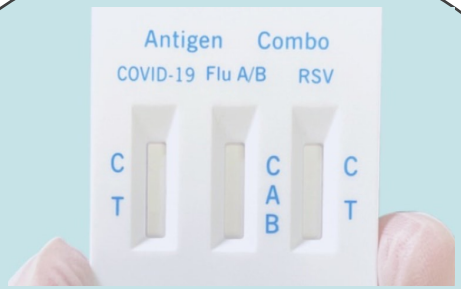


MakeMyTestCount Future Directions

Data Viz

SMART Health Cards

SMART®

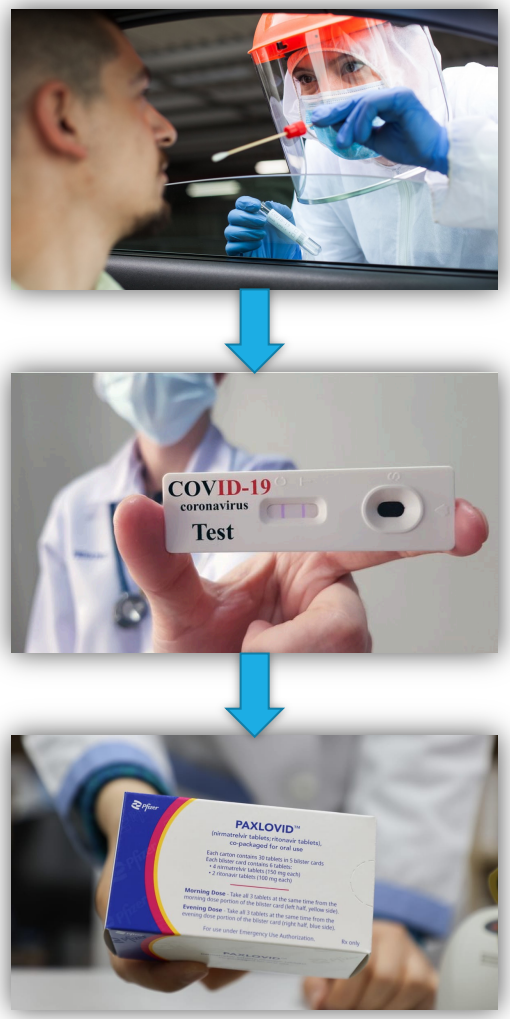


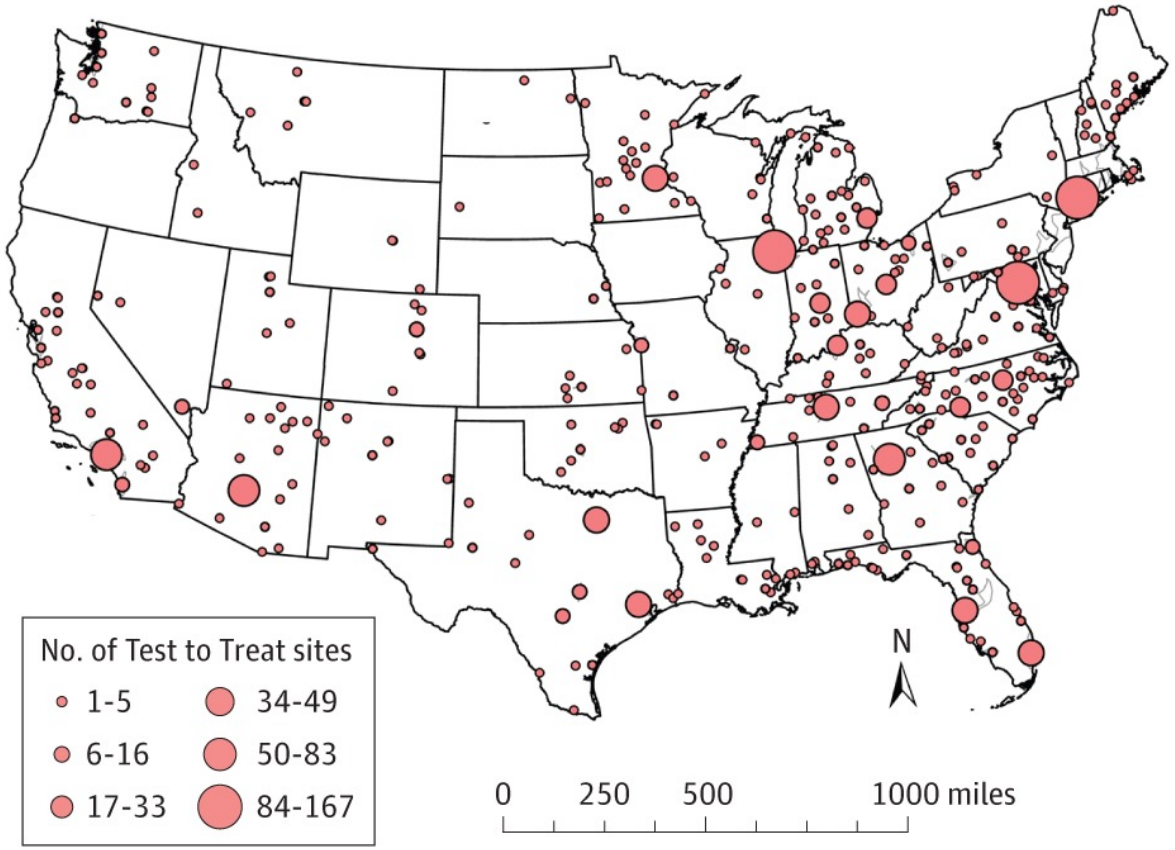
Multiplex Reporting

Sharing Results with Healthcare Providers

Test-to-Treat Linkages

"Test to treat" enables individuals to be tested, see a healthcare provider, receive a prescription for a treatment, and have the prescription filled—all in one location.





JAMA Netw Open. 2022;5(11):e2241144.
doi:10.1001/jamanetworkopen.2022.41144

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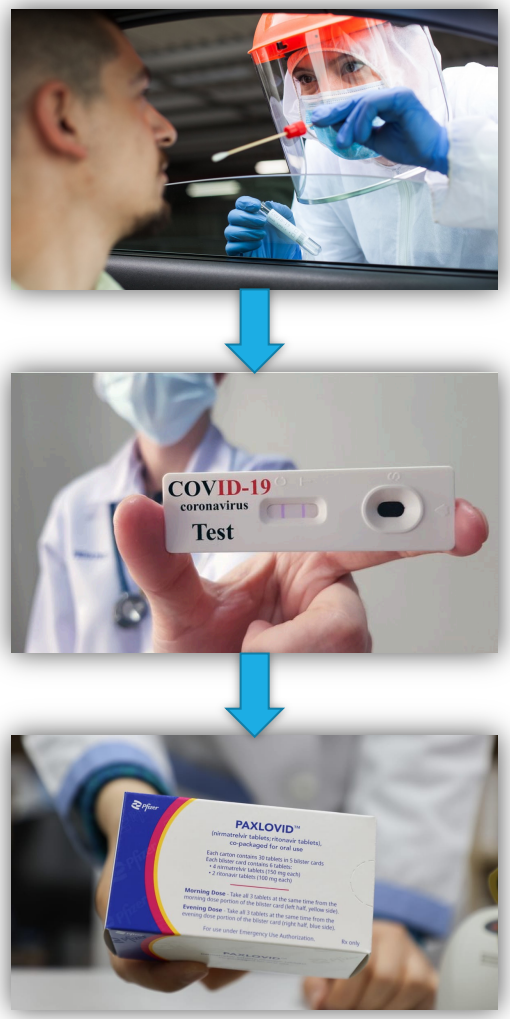
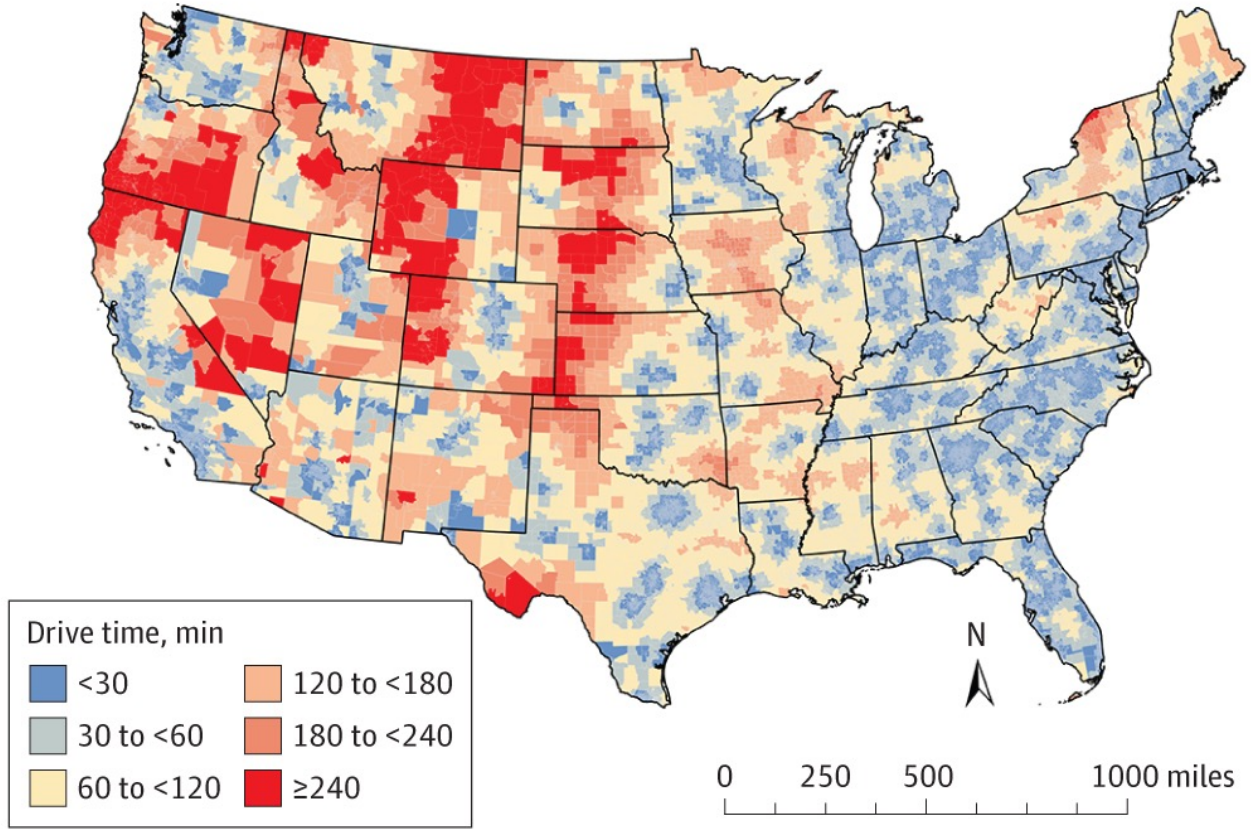




JAMA Netw Open. 2022;5(11):e2241144.
doi:10.1001/jamanetworkopen.2022.41144

Access

Large areas of country without nearby facilities

Safety

Risk to sick person who must leave home

Risk to public who interacts with someone who may be infectious

HOME TEST TO TREAT PROGRAM

Goals

1. Equity in vulnerable populations
2. Effectiveness of home test-to-treat
3. Electronic healthcare records management

NIH National Institute of Biomedical Imaging and Bioengineering

ASPR Administration for Strategic Preparedness & Response

CDC Centers for Disease Control and Prevention

eMed®

UMass Chan Medical School

SEPTEMBER 08, 2022

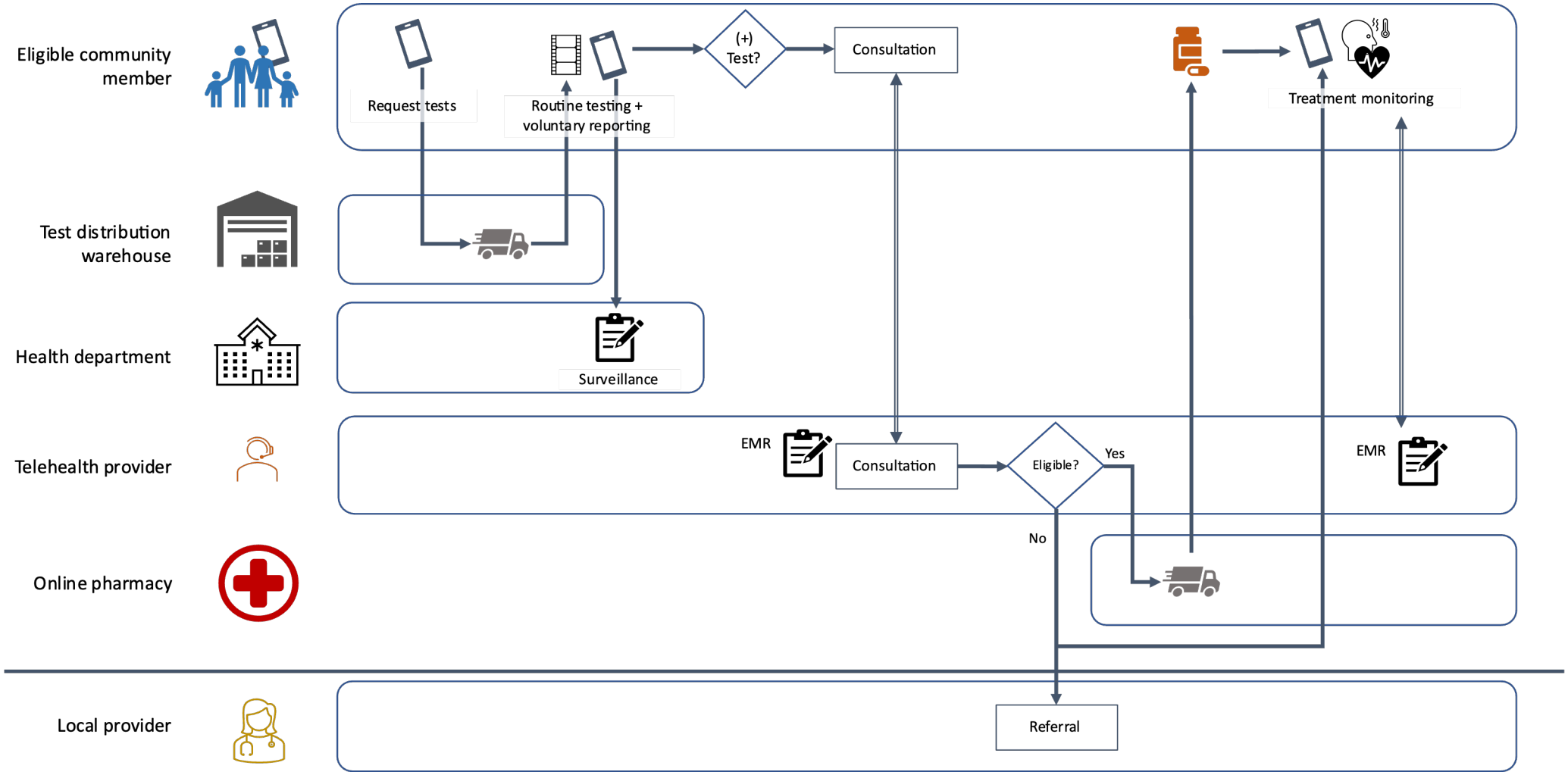
FACT SHEET: Biden Administration Outlines Plan to Get Americans an Updated COVID-19 Vaccine Shot and Manage COVID-19 this Fall

- **Advancing equitable access to COVID-19 treatments, including through additional Test to Treat sites:** The Administration will work to expand the Test to Treat footprint beyond the 2,800 current Test to Treat sites, including more mobile and telehealth-based models that will meet people where they are and reduce barriers to access for highest-risk individuals. As part of this effort, the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx®) Tech program and ASPR are launching a new telehealth Test to Treat pilot program that will partner with state, local, Tribal, and/or territorial health departments to serve as many as 15 rural and high-risk communities. This pilot will allow individuals in vulnerable communities to receive home-delivery of at-home tests, use telehealth to consult a clinician without having to leave home, receive a prescription for COVID-19 treatment when appropriate, and have the medications delivered to their home, all at no cost to the individual.

HOME

TEST TO TREAT

https://test2treat.org



HOME TEST TO TREAT

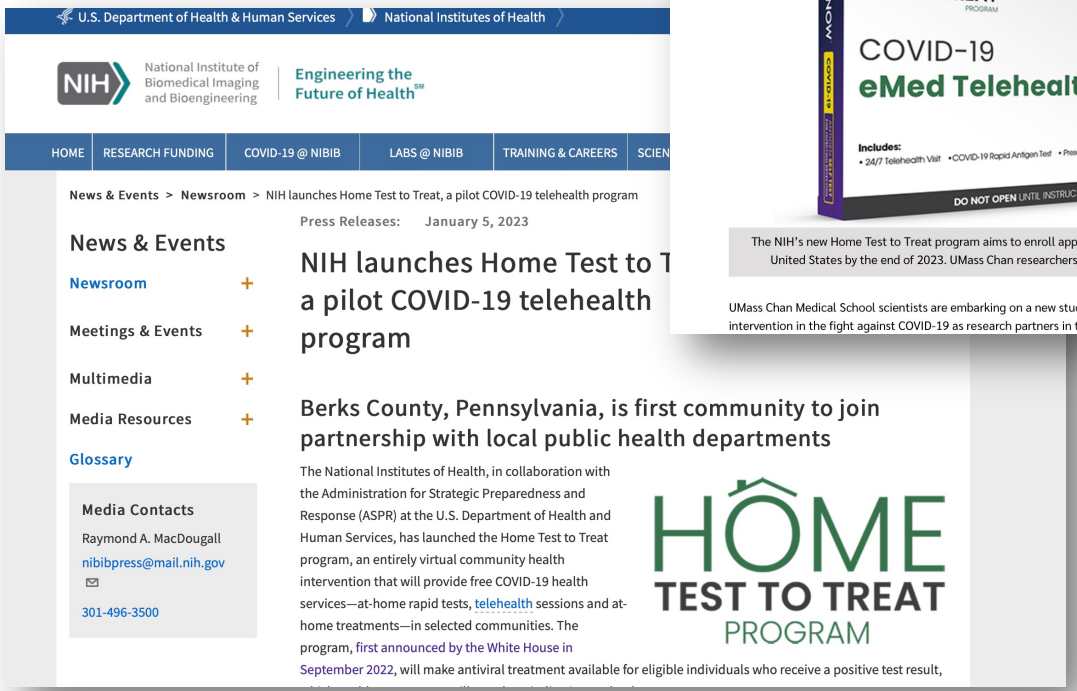
Target population size	Expected telehealth visits	Expected antiviral shipments
80,000*	8,200	6,200

* Targeting 50% enrollment of underserved individuals

Pilot site launched in January

Berks County, PA

Two additional sites planned for July, with a national expansion coming this fall


U.S. Department of Health & Human Services › National Institutes of Health

NIH National Institute of Biomedical Imaging and Bioengineering | Engineering the Future of Health℠

HOME | RESEARCH FUNDING | COVID-19 @ NIBIB | LABS @ NIBIB | TRAINING & CAREERS | SCIEN

News & Events > Newsroom > NIH launches Home Test to Treat, a pilot COVID-19 telehealth program

Press Releases: January 5, 2023

News & Events

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Meetings & Events +

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Media Resources +

Glossary

Media Contacts

Raymond A. MacDougall

nibibpress@mail.nih.gov

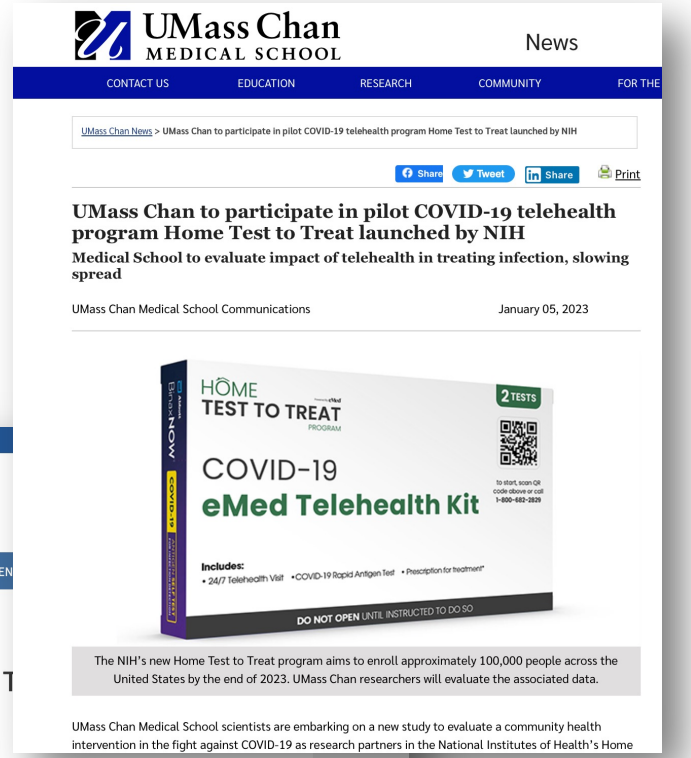
301-496-3500

NIH launches Home Test to T… a pilot COVID-19 telehealth program

Berks County, Pennsylvania, is first community to join partnership with local public health departments

The National Institutes of Health, in collaboration with the Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services, has launched the Home Test to Treat program, an entirely virtual community health intervention that will provide free COVID-19 health services—at-home rapid tests, telehealth sessions and at-home treatments—in selected communities. The program, first announced by the White House in September 2022, will make antiviral treatment available for eligible individuals who receive a positive test result,

HOME TEST TO TREAT PROGRAM


UMass Chan MEDICAL SCHOOL News

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UMass Chan News > UMass Chan to participate in pilot COVID-19 telehealth program Home Test to Treat launched by NIH

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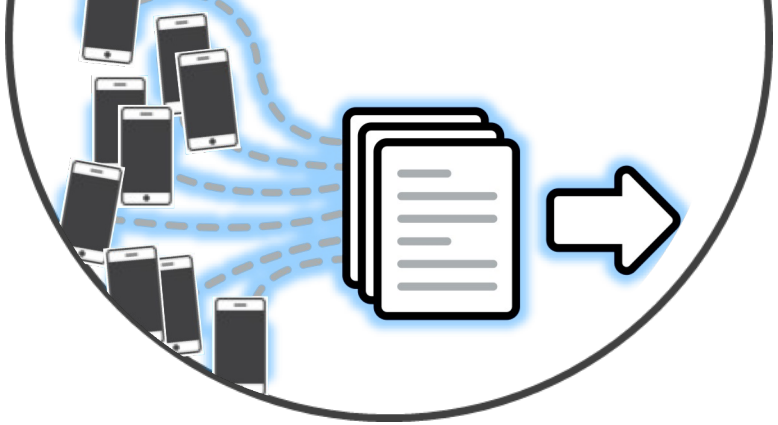
UMass Chan to participate in pilot COVID-19 telehealth program Home Test to Treat launched by NIH

Medical School to evaluate impact of telehealth in treating infection, slowing spread

UMass Chan Medical School Communications January 05, 2023

The NIH's new Home Test to Treat program aims to enroll approximately 100,000 people across the United States by the end of 2023. UMass Chan researchers will evaluate the associated data.

UMass Chan Medical School scientists are embarking on a new study to evaluate a community health intervention in the fight against COVID-19 as research partners in the National Institutes of Health's Home



Home Diagnostic Reporting

Equitable Access

Additional Pathogens

Personal Health Records

Opportunities and Future Directions

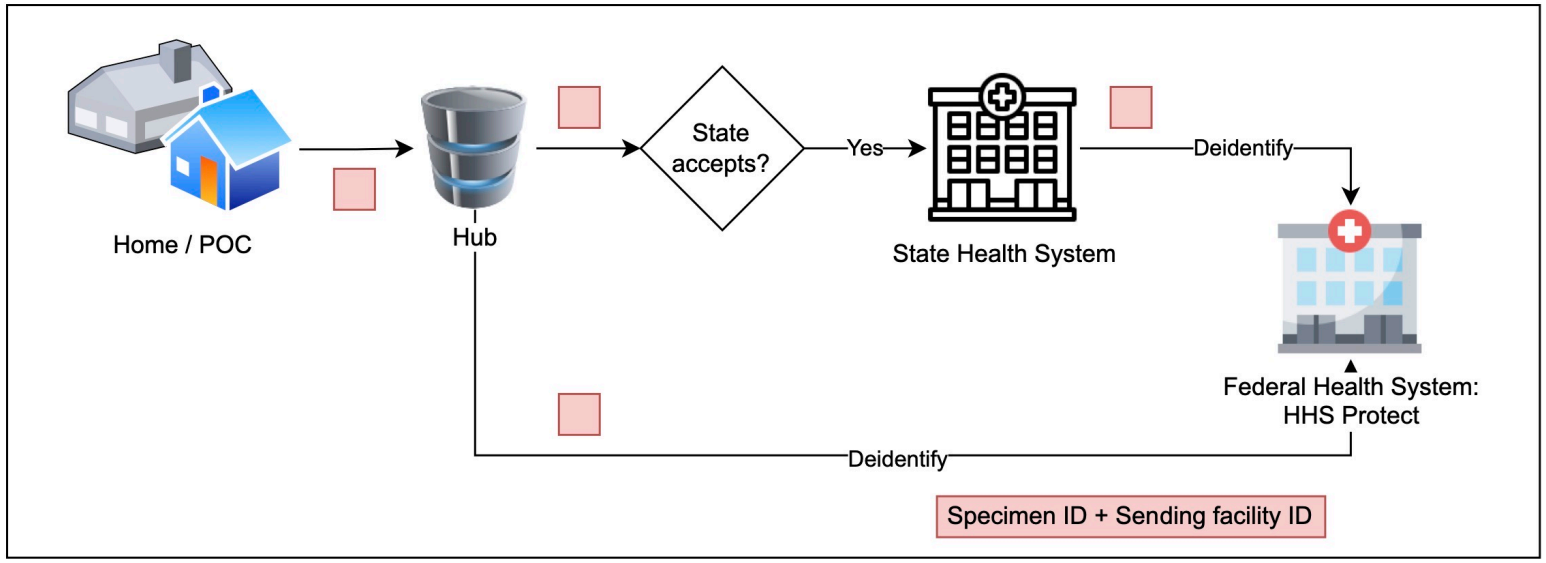
Continuity of Care

Key insights to building connected diagnostic reporting systems

Adapting to Novel Technologies

Build technical pathways that connect novel technologies to existing reporting systems

Parallel data streams to state and federal systems represent a paradigm shift

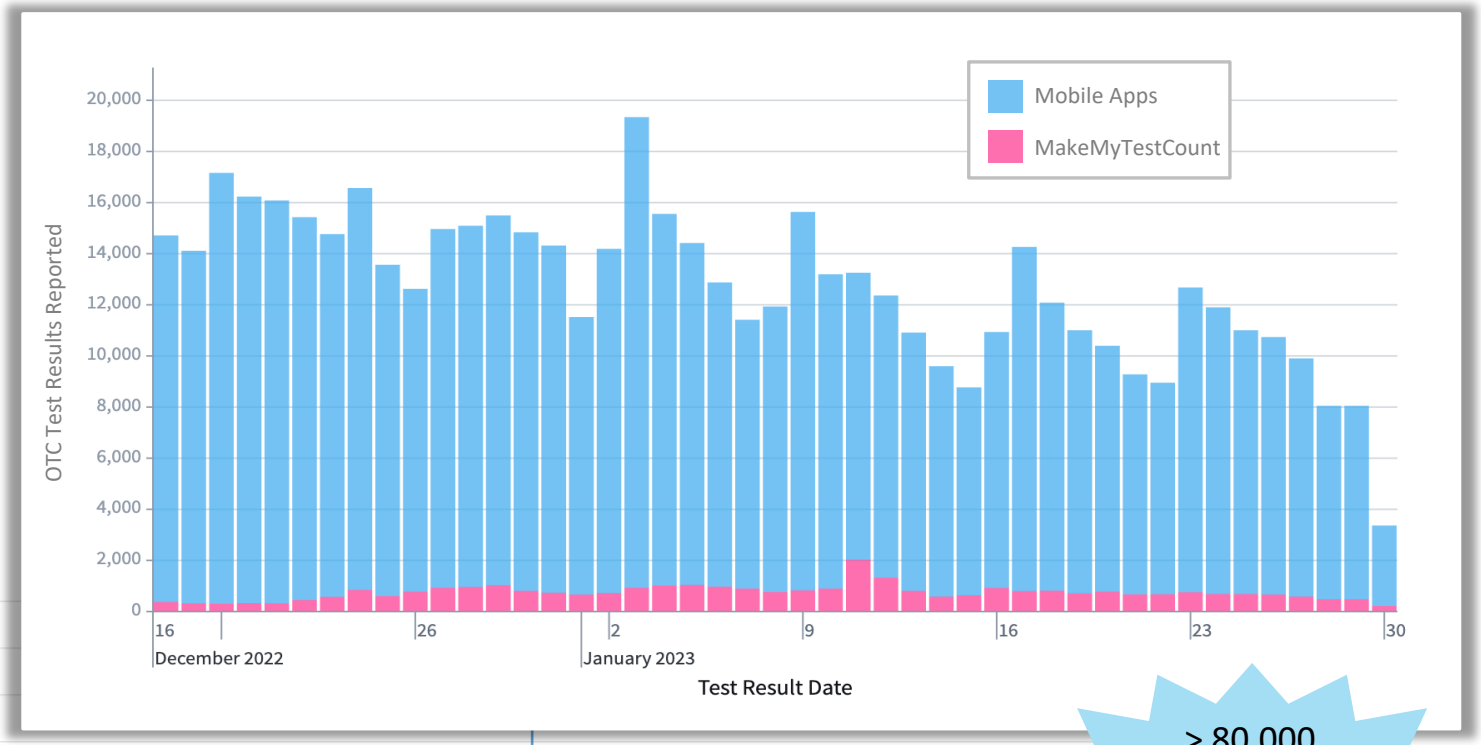


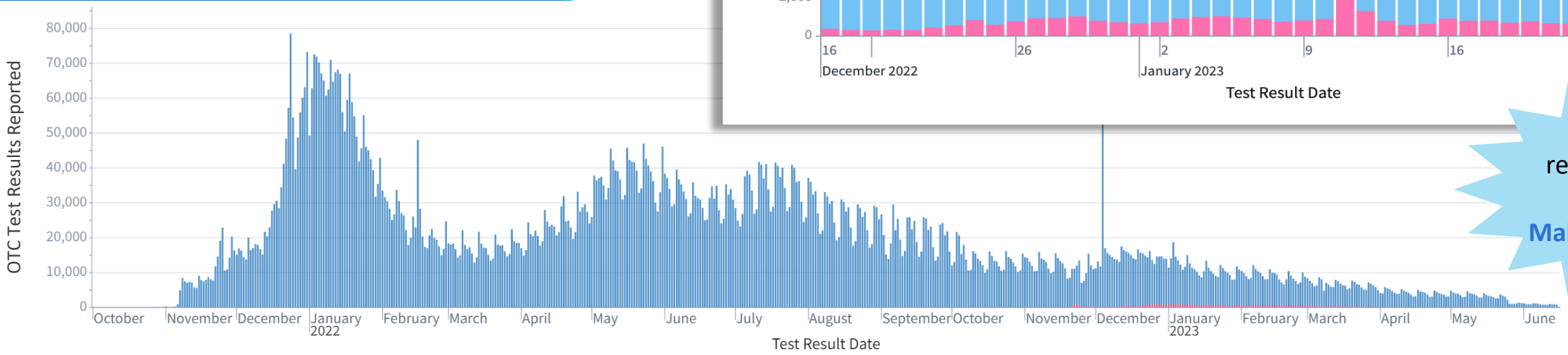
HL7® V2®

Empowering Individuals

Individuals who desire to contribute to public health can continue to do so by reporting at-home test results

12M OTC test results have been reported since Fall 2021

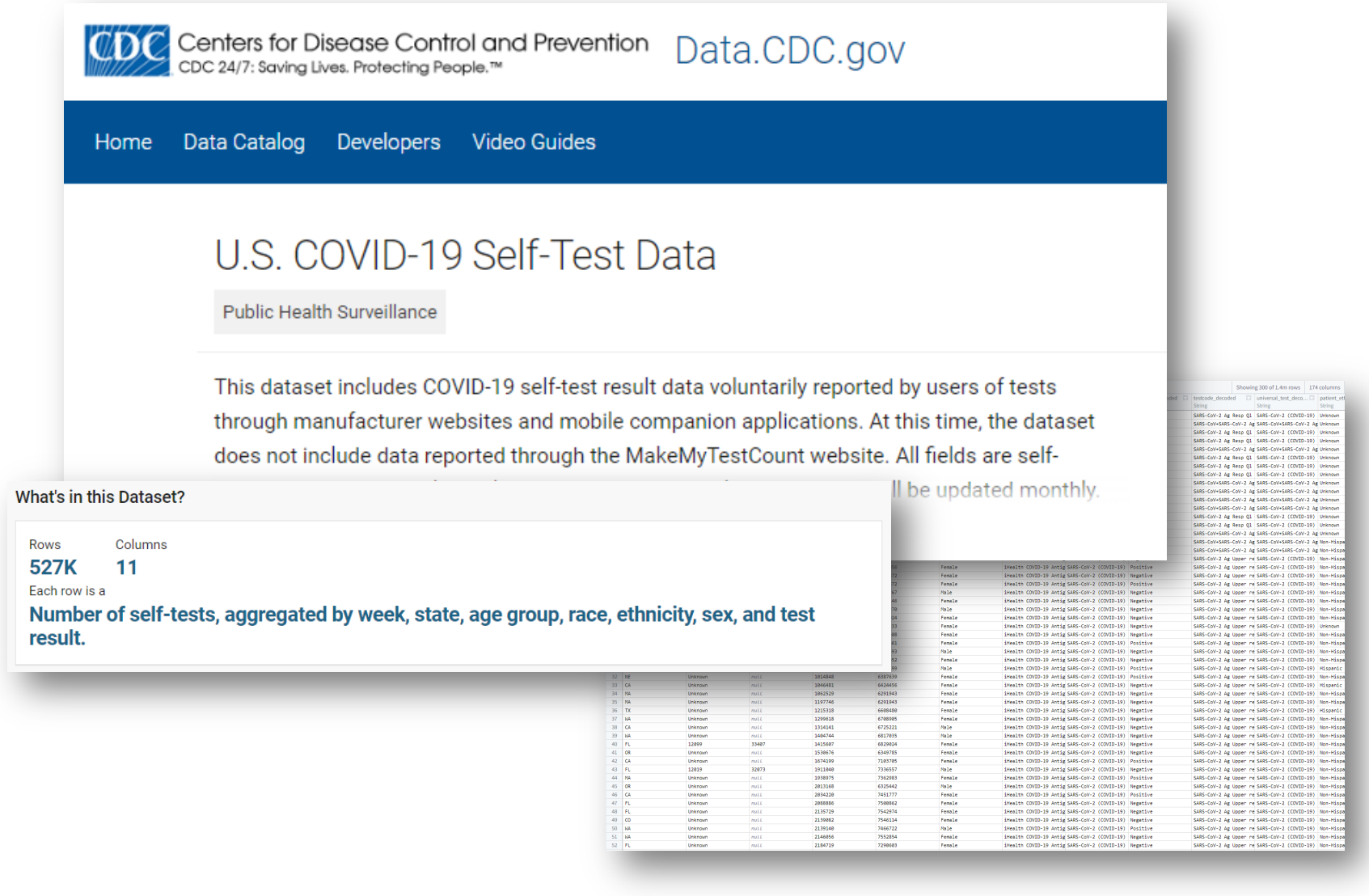




> 80,000 results reported through **MakeMyTestCount**

Improving Data Quality & Validity

Common language, structure, and data types pave the way for more efficient data analysis



Data available to public online: https://data.cdc.gov/Public-Health-Surveillance/U-S-COVID-19-Self-Test-Data/275g-9x8h

Enhancing Public Health Response

Providing insights into the data reduces strain to public health teams and makes the data more accessible

Centers for Disease Control and Prevention

MMWR

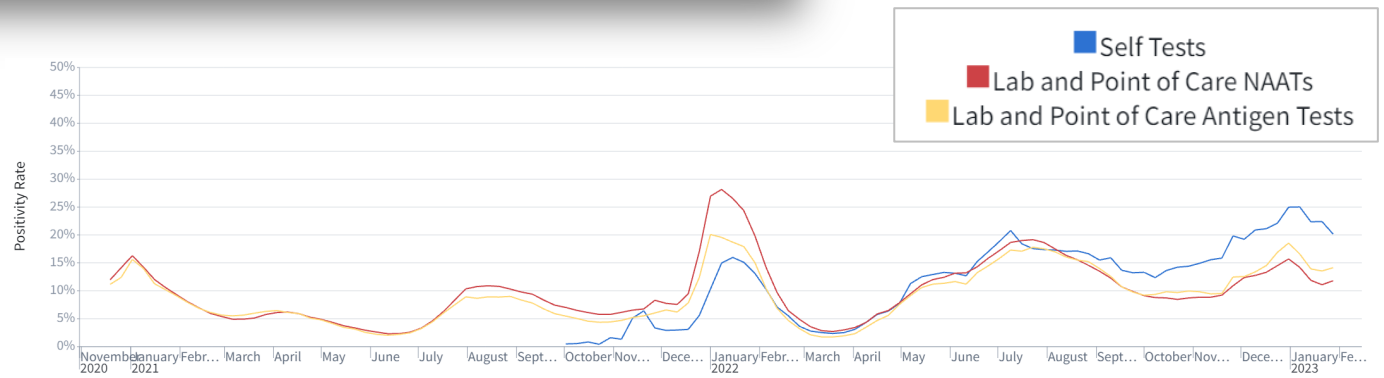
Morbidity and Mortality Weekly Report

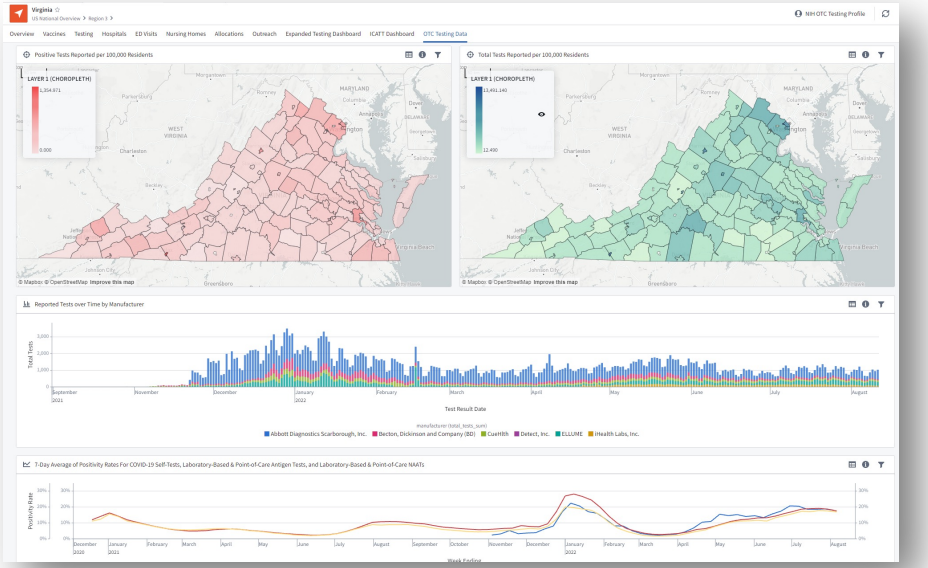
Weekly / Vol. 71 / No. 32 August 12, 2022

COVID-19 Self-Test Data: Challenges and Opportunities — United States, October 31, 2021–June 11, 2022

Matthew D. Ritchey[1,2]; Hannah G. Rosenblum[1,3]; Kim Del Guercio[4]; Matthew Humbard[5]; Steven Santos[5]; Jason Hall[4]; Jasmine Chaitram[6]; Reynolds M. Salerno[6]

Positivity rates for OTC tests follow similar trends to those of lab and POC tests





How can you help / call to action

- **Public health agencies** can access the data and promote reporting through MakeMyTestCount
- **Test manufacturers** can promote reporting through MakeMyTestCount and MARS
- **Researchers** can explore the value of the data
- **People** can continue reporting their results

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