

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

Andrew Weitz, PhD

Grace Bendinger, MS, BSN, RN



HÔME
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

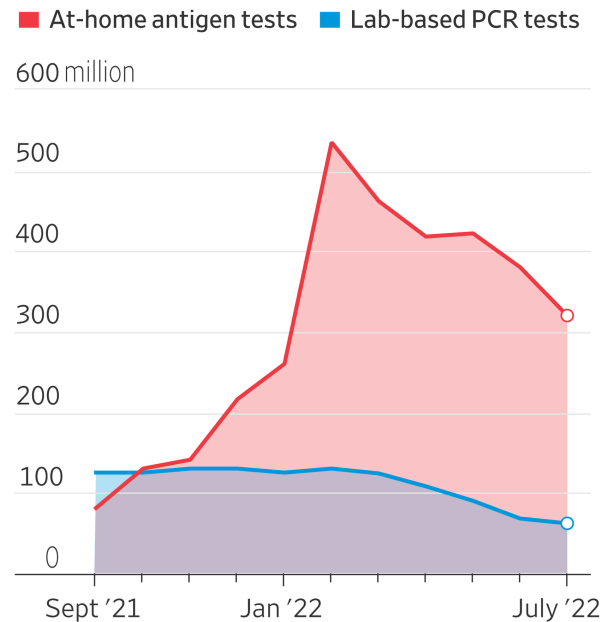


Case reporting impacted by at-home testing shift

Paradigm shift from lab to home

Increasing need to capture unreported test results

Estimated monthly Covid-19 testing capacity



Source: Mara Aspinall, COVID Weekly Testing Newsletter

Bloomberg | Business | Prognosis | [Subscribe](#)

Millions of Rapid Covid-19 Test Results Risk Going Uncounted

Many Virus Cases Go Uncounted. Are There Better Ways to Track the Pandemic?

CNN health | [Live TV](#)

Rise in at-home testing means we could be undercounting Covid-19 cases even more than before

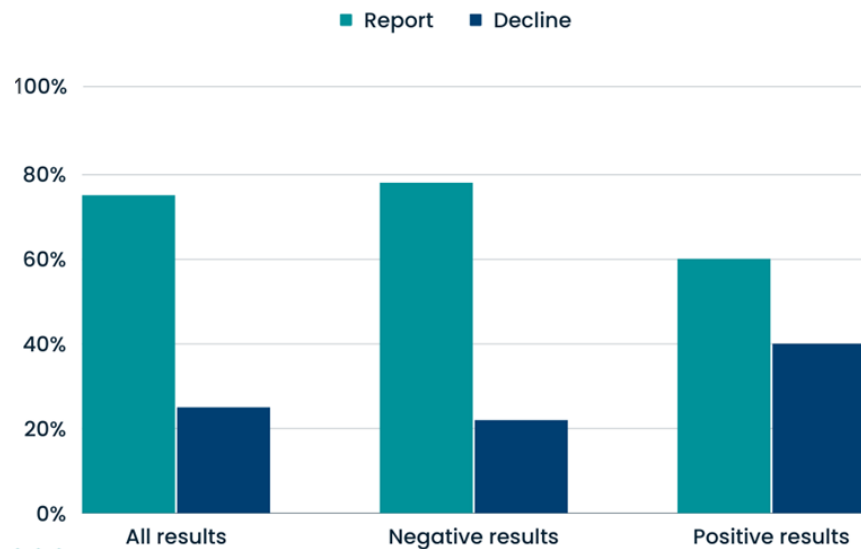
FIERCE Biotech | [Subscribe](#)

MEDTECH

Lack of antigen test reporting leaves country 'blind to the pandemic'

Willingness of individuals to self-report test results

TEST RESULTS REPORTING ON MOBILE APPLICATION: 3/2022



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

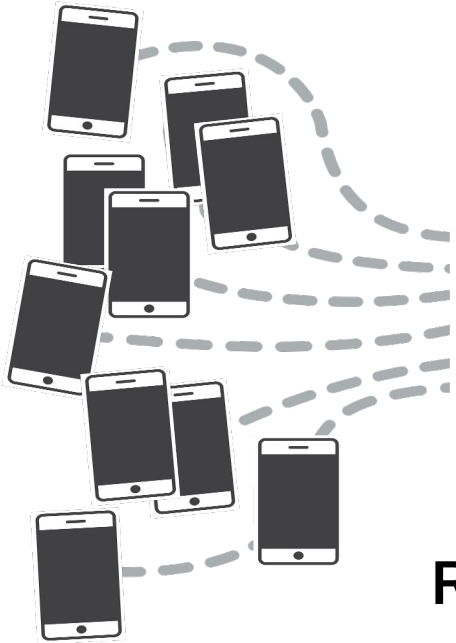
SAY YES!
COVID TEST™
KEEP OUR COMMUNITIES SAFE

care evolution
HEALTHCARE TECHNOLOGY

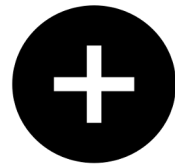
UMass Chan
MEDICAL SCHOOL

System Barriers to Mobile At-Home Reporting

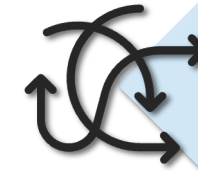
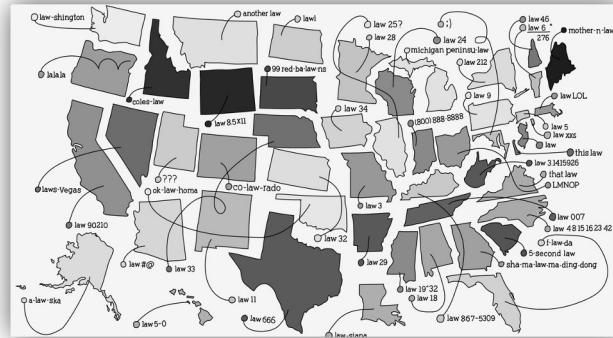
Novel OTC
Testing Apps



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

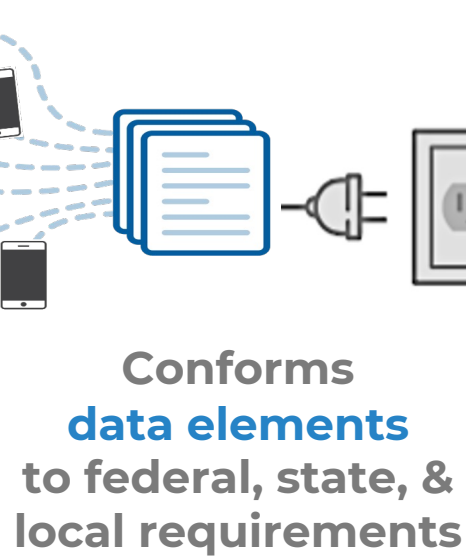
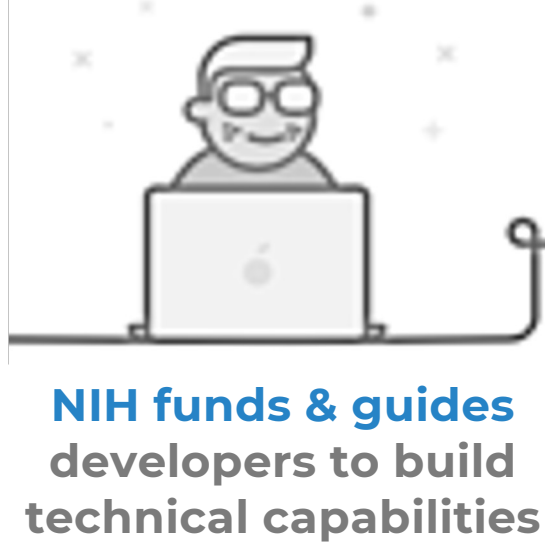


The RADx[®] MARS Solution

RADx[®]
MARS



Mobile At-Home Reporting through Standards



RADx[®] MARS Leverages Industry-Wide Standards

HL7V2 SPECIFICATION

Last Updated 01/09/2023

[Download Current Version](#)

[Version History and Changelog](#)

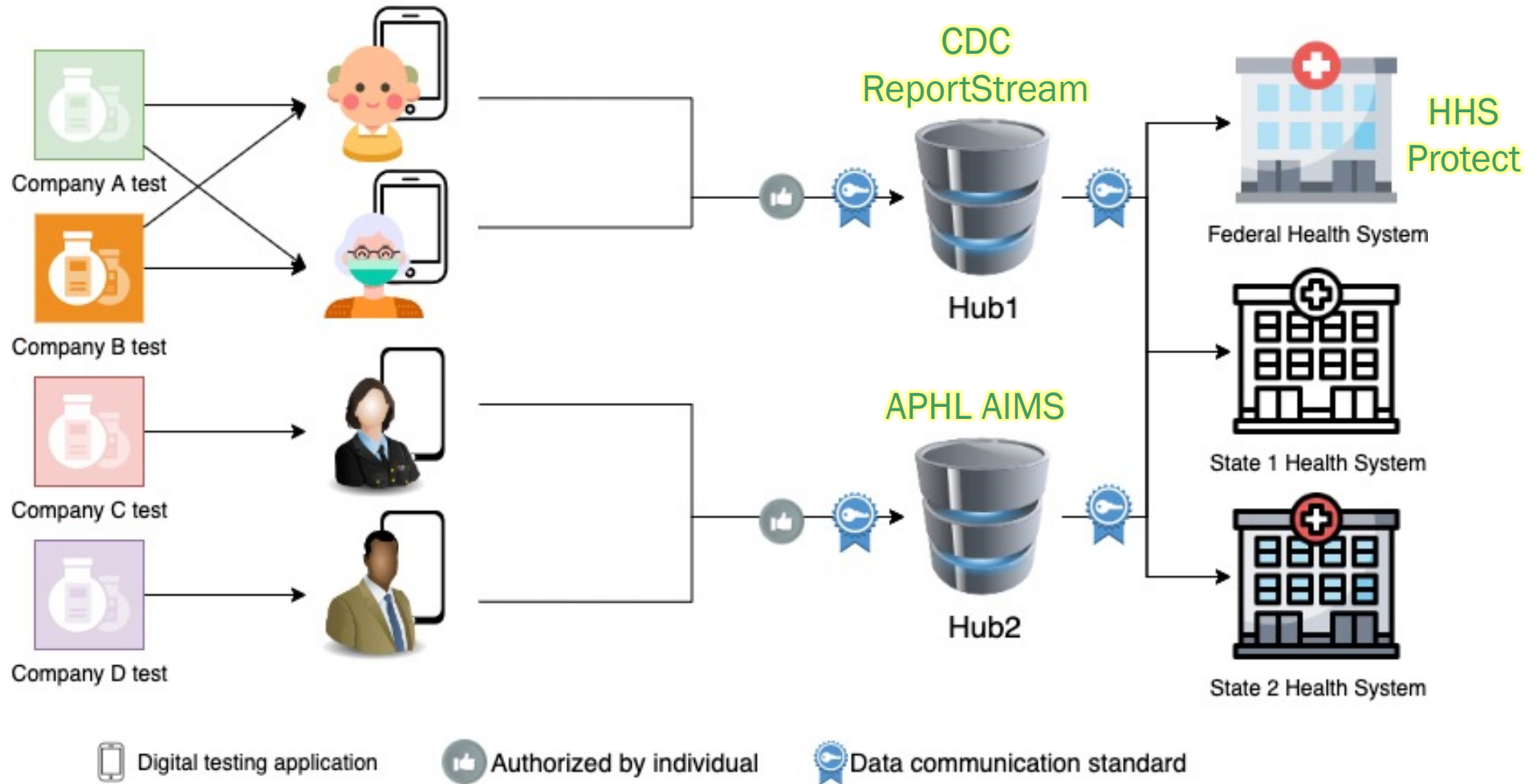
Index	Segment	Set	Component	Title
101	OBX	1	2	Test result form
102	OBX	1	3.1	Test performed c
103	OBX	1	3.2	Test performed c
104	OBX	1	3.3	Test performed c
105	OBX	1	3.7	Test Performed c version
106	OBX	1	5.1	Test result code
107	OBX	1	5.2	Test result descr
108	OBX	1	5.3	Test result code:
109	OBX	1	5.7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

```
MSH|^~\&|DETECT.BACKEND.PROD^2.16.840.1.113883.3.8589.4.2.86.1^ISO|Detect^
00Z0000038^CLIA|AIMS.INTEGRATION.PR^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-
b304-4b8e-a4cb-d40b5d36e703|P|2.5.1|||NE|NE|||PHLabReport-NoAck^ELR251R1
_Rcvr_Prof^2.16.840.1.113883.9.11^ISO
SFT|Detect|1.0.0|DetectBackend|DetectBackend-v1.0.0
PID|1||034370864^^^DETECT.BACKEND.PROD&2.16.840.1.113883.3.8589.4.2.86.1
&ISO^PI^Detect&2.16.840.1.113883.3.8589.4.1.135&ISO||^M||2106-3
^White^HL70005^^^2.5.1|^MD^208|||N^Not Hispanic or Latino^HL70189^^^
2.5.1
ORC|RE|^DETECT.BACKEND.PROD^2.16.840.1.113883.3.8589.4.2.86.1
^ISO|||SA.OTCSelfReport^D|^MD^208
^PRN^PH^
OBR|1|^DETECT.BACKEND.PROD^2.16.840.1.113883.3.8589.4.2.86.1^ISO|94559-2^SARS-
CoV-2 (COVID-19) ORF1ab region [Presence] in Respiratory specimen by NAA with probe
detection^LN^^^2.71||20220621164902+0000|||F
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
||N^Normal (applies to non-numeric results)^HL70078^^^2.71||F||00Z0000042
||Detect Covid-19 Test_Detect, Inc.^EUA^^99ELR^^^Vunknown||20220621164902+0000
||SA.OTCSelfReport^D^^^CLIA&2.16.840.1.113883.3.8589.4.1.152&ISO^XX^^00Z0000042|
OBX|2|NM|35659-2^Age at specimen collection^LN^^^2.71||73|a^year^UCUM^^^2.1
||F||00Z0000042||SA.OTCSelfReport^^^&2.16.840.1.113883.3.8589.4.1.152
&ISO^XX^^00Z0000042||QST
SPM|1|^0396c821-8d5c-4612-be4d-708a195d90ef&DETECT.BACKEND.PROD&
2.16.840.1.113883.3.8589.4.2.86.1&ISO||697989009^Anterior nares swab^SCT^^^20210301
||20220621164902+0000|20220621164902+0000
```

HL7 FHIR SPECIFICATION

The Office of the National Coordinator for Health Information Technology

RADx[®] MARS Streamlines Information Flow



RADx[®] MARS Adopters

Detect

iHealth[®]



QuidelOrtho[™]

Intrivo[™]

eMed[®]



BOSON[™]

care evolution
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

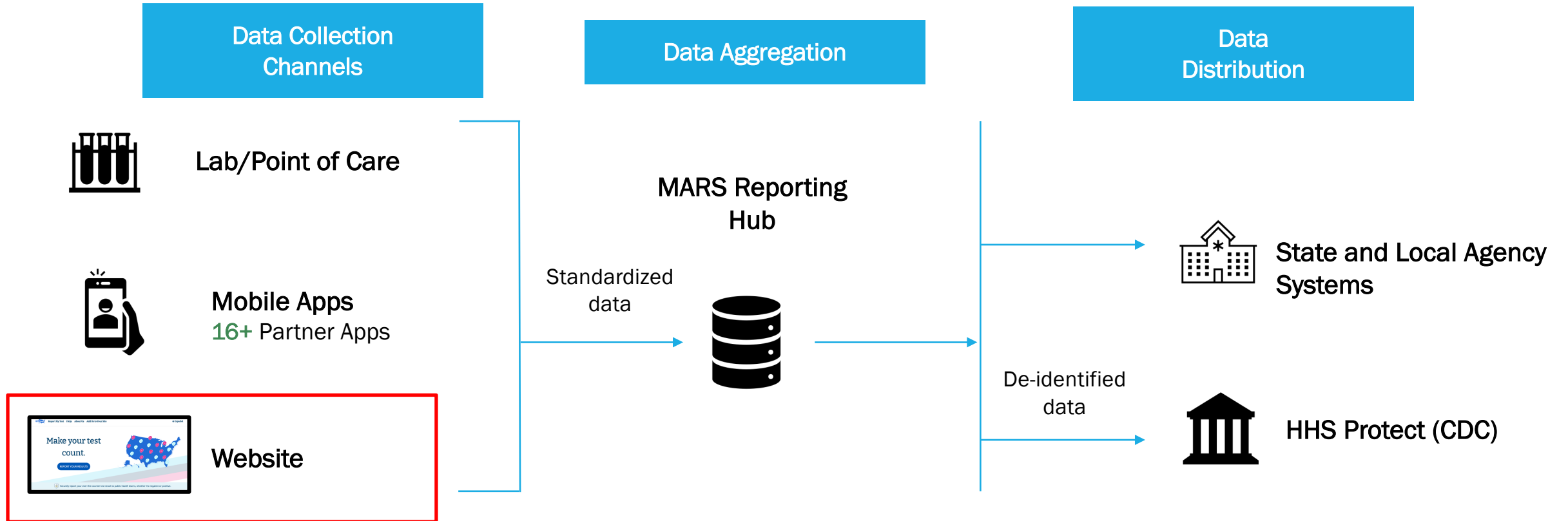
Visit the RADx[®] MARS Website:
<https://www.nibib.nih.gov/covid-19/radx-tech-program/mars>



The screenshot shows the top portion of a website. At the top left is the NIH logo (National Institute of Biomedical Imaging and Bioengineering). To the right of the logo is a search icon and a menu icon. Below the header, the main heading reads "RADx[®] MARS - Mobile At Home Reporting through Standards". Underneath the heading is a "Share:" section with icons for email, Facebook, LinkedIn, Twitter, WhatsApp, and a plus sign for more options. At the bottom of the screenshot, there is a paragraph: "A partnership with the Office of the National Coordinator for Health Information Technology (ONC)".

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

The screenshot shows the MakeMyTestCount.org website interface. At the top, there is a navigation bar with the logo, 'Report My Test', 'FAQs', 'About Us', 'Add Us to Your Site', and a language selector for 'Español'. The main content area features a green banner with the text 'Results submitted' and 'Thank you for submitting your test results.', followed by a blue button labeled 'Report another result'. Below this, there are three sections: 'Next steps' with a warning about negative results and two expandable boxes for 'If you have COVID symptoms' and 'If you've been exposed to someone with COVID'; 'Share' with social media icons for Facebook, Instagram, and Twitter; and 'When To Test' with a sub-header icon and a list of resources for COVID-19 information.

MAKEMYTESTCOUNT

Report My Test FAQs About Us Add Us to Your Site

🌐 Español

Results submitted
Thank you for submitting your test results.

Report another result

Next steps

Negative is not a guarantee. If you just got infected, you may not have enough virus in your body for the test to find it. Plus, no test is perfect - there's a very small chance that your result could simply be an error.

If you have COVID symptoms +

If you've been exposed to someone with COVID +

Testing Journal

Negative 4/6/2023

Share

Share MakeMyTestCount with anyone who wants to make their test count.

Facebook Instagram Twitter

When To Test

Have questions about COVID and how to protect yourself and your loved ones? Visit [WhenToTest.org](https://www.whentotest.org).

- Learn your [personal COVID risk](#).
- Read tips on safely navigating everyday life.
- Get quick answers to frequently asked questions.

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

COVID-19 Rapid Antigen At-Home Test

REF: P0038, P0039, P0040, P0041
 IVD, RE, RUO, RUO, RUO
 Suitable for ages 2+ years
 Must be 14+ to use kit unsupervised

Performing Your Test

1. [Image: Step 1: Prepare the test device and buffer solution vial.]
2. [Image: Step 2: Swab the nostrils. 20 sec timer shown.]
3. [Image: Step 3: Release sample into buffer solution vial.]
4. [Image: Step 4: Cap the vial and expose dropper tip.]
5. [Image: Step 5: Add buffer solution to test device. 3 drops shown.]
6. [Image: Step 6: Let test device sit for 20 minutes. 20 mins timer shown.]
7. [Image: Step 7: Dispose of used test kit materials.]
8. [Image: Step 8: Read the results.]
9. [Image: Step 9: Interpretation of results.]
10. [Image: Step 10: Final disposal instructions.]

Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the test will produce a false negative result.

Do NOT read the results before 20 minutes or if it has been longer than 25 minutes from when the vial solution has been added to the sample well, as the test may have an inaccurate outcome.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

POSITIVE TEST RESULT
 A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your healthcare provider about your test results, and seek immediate medical attention if you have symptoms.

NEGATIVE TEST RESULT
 A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is higher chance of false negative results with antigen tests than with laboratory-based molecular tests such as PCR. This means that there is higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your healthcare provider.

INVALID TEST RESULT
 No red-colored line next to the "C" means the test is invalid. Re-test with a new swab and a new test device.

Take these next steps
 Collect a new nasal swab sample and repeat the test with a new INDIKAID™ COVID-19 Rapid Antigen At-Home Test. If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately.

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

MakeMyTestCount can be promoted by health departments

ALLEGHENY COUNTY | LIVE WORK EXPLORE GOVERNMENT NEWS AND EVENTS ABOUT

CORONAVIRUS

MY ALLEGHENY SAVE PAGE

COVID-19

HOW DO I... SEE MORE

Type what you're looking for

- Contact
- Public Meeting Schedule
- Locations
- Online Plumbing

Health Department > Resources > COVID-19 > COVID-19

COVID-19

Since Allegheny County's first confirmed case of COVID-19 in March of 2020, our lives have been dramatically altered by the global pandemic.

As the pandemic abates and more effective therapies and public health strategies exist to combat the disease that has taken the lives of more than 3,000 county residents, the Health Department encourages all eligible residents to be vaccinated against COVID-19. Residents should test if they believe they have been exposed to the virus, or are exhibiting symptoms.

Stay up to date with the fluctuations in the pandemic by [visiting the ACHD's online dashboards](#) that track infections, hospitalizations, deaths and many other aspects of the pandemic.

Additional resources

- [Report an at-home COVID-19 test result](#)
- [Stay Up to Date with COVID-19 Vaccines including Boosters | CDC](#)
- [Frequently Asked Questions about COVID-19 Vaccination | CDC](#)
- [Isolation and Precautions for People with COVID-19 | CDC](#)
- [What to Do If You Were Exposed to COVID-19 | CDC](#)
- [Long COVID or Post-COVID Conditions | CDC](#)

Allegheny County Health Department

Report COVID at-home test results to help your community.
You can report negative or positive tests for yourself or any member of your family.

What was your at-home test result?

Positive Negative

Your answers are anonymous, secure, and cannot be traced back to you.

Powered By:

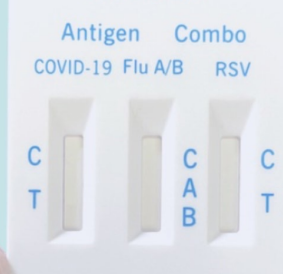
MAKE MY TEST COUNT

MakeMyTestCount Future Directions

Data
Viz



SMART Health Cards

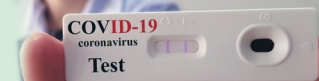


Multiplex Reporting

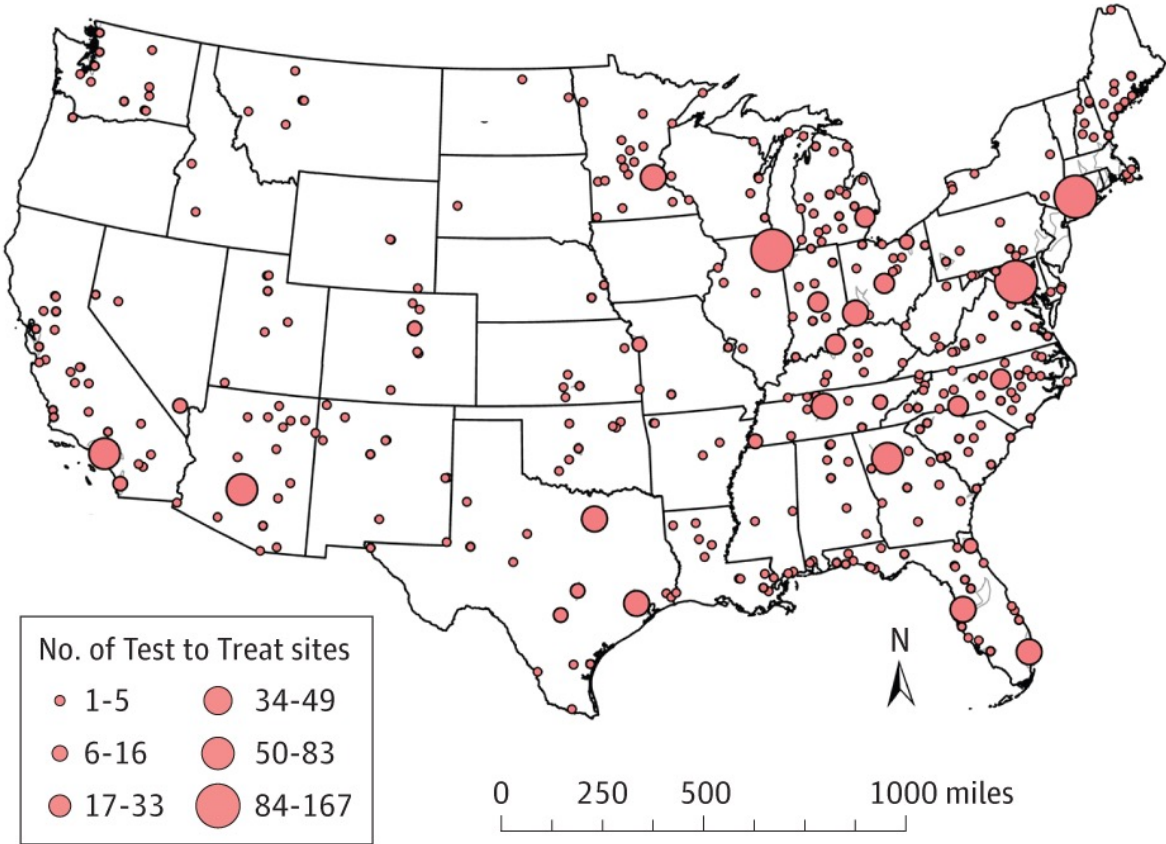
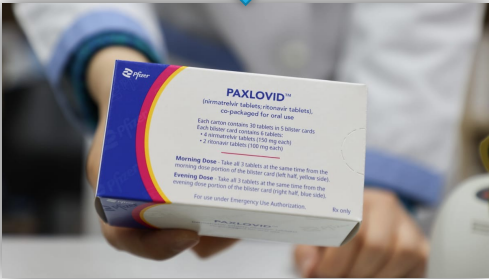
Sharing Results with
Healthcare Providers



Test-to-Treat
Linkages

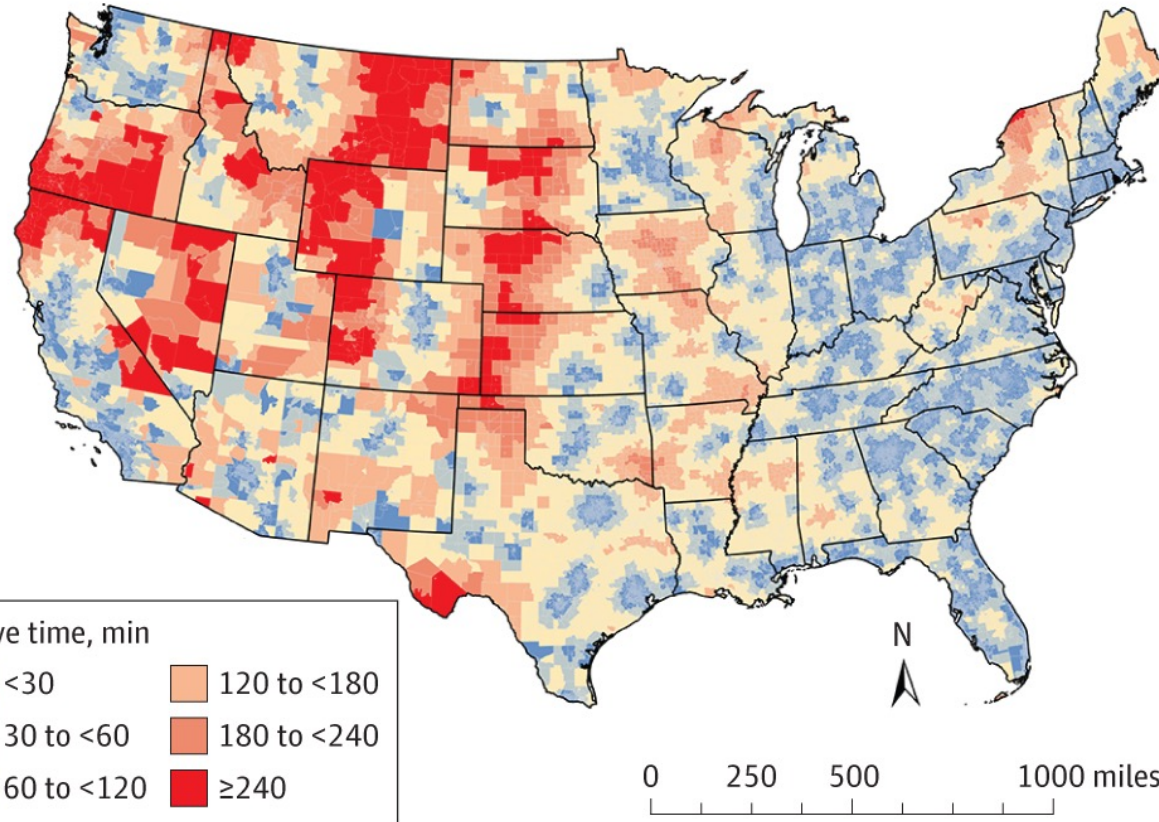
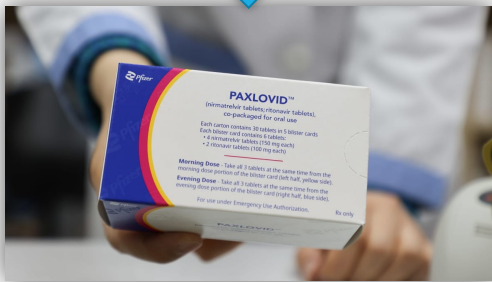


“Test to treat” enables individuals to be tested, see a healthcare provider, receive a prescription for a treatment, and have the prescription filled—all in one location.



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

“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.



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

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

HÖME TEST TO TREAT PROGRAM



SEPTEMBER 08, 2022

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

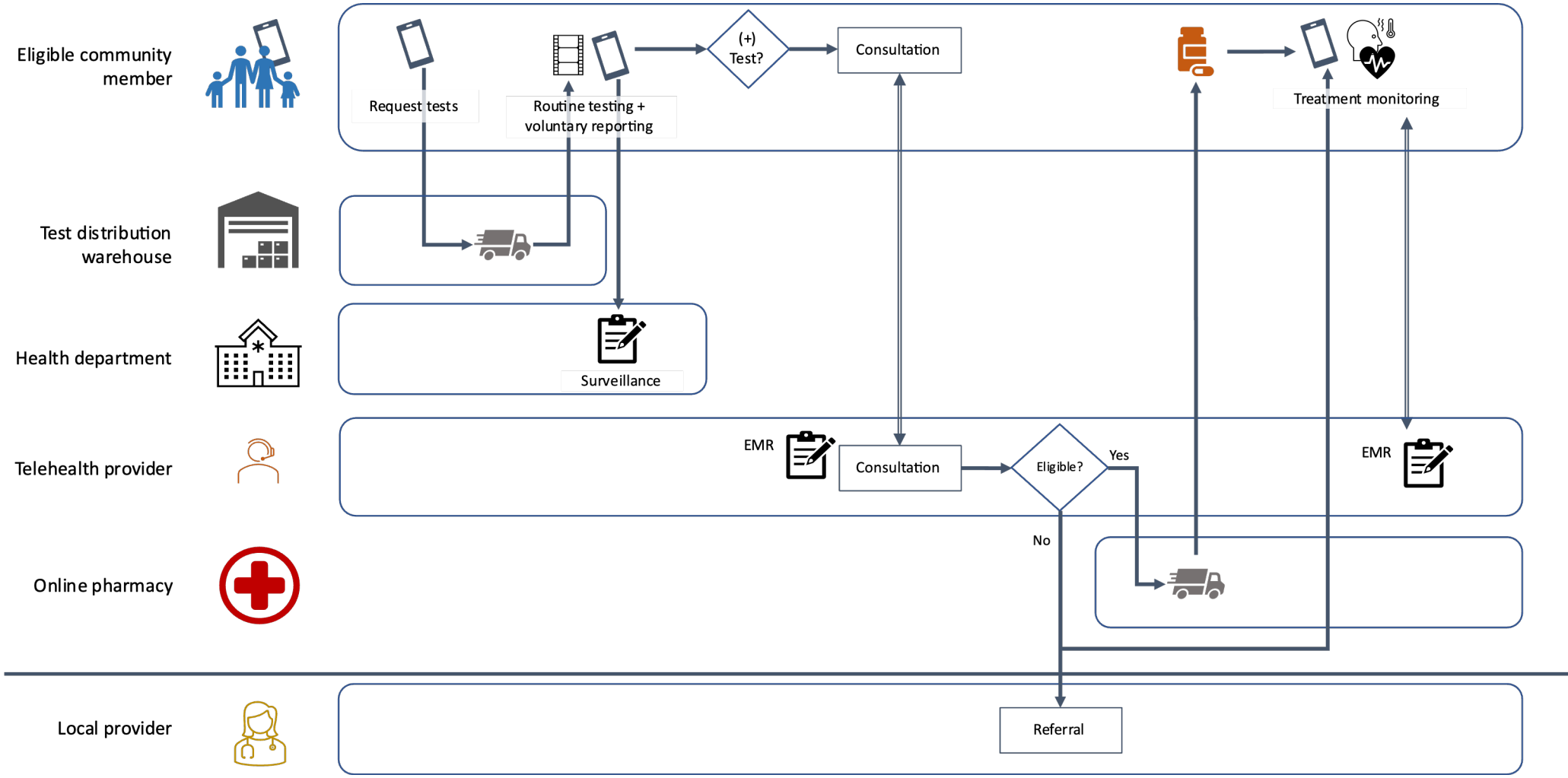
Goals

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



- **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.

HÔME TEST TO TREAT



HÔME TEST TO TREAT

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

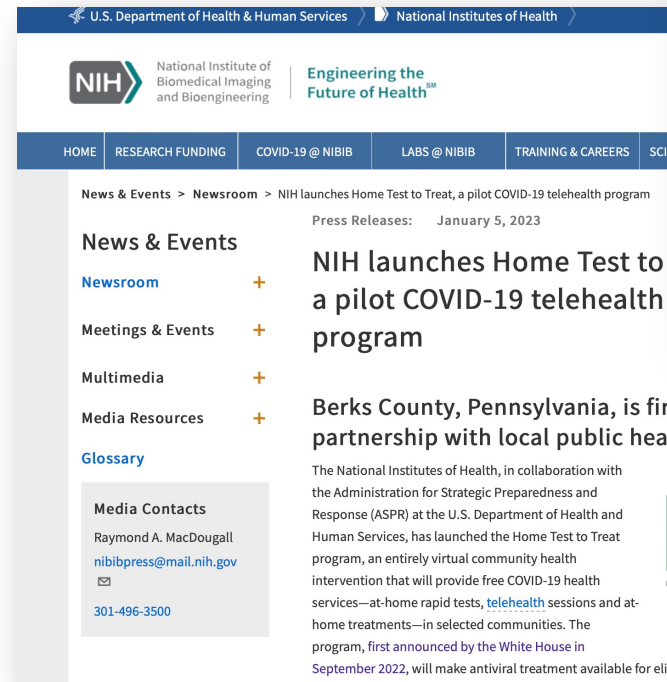
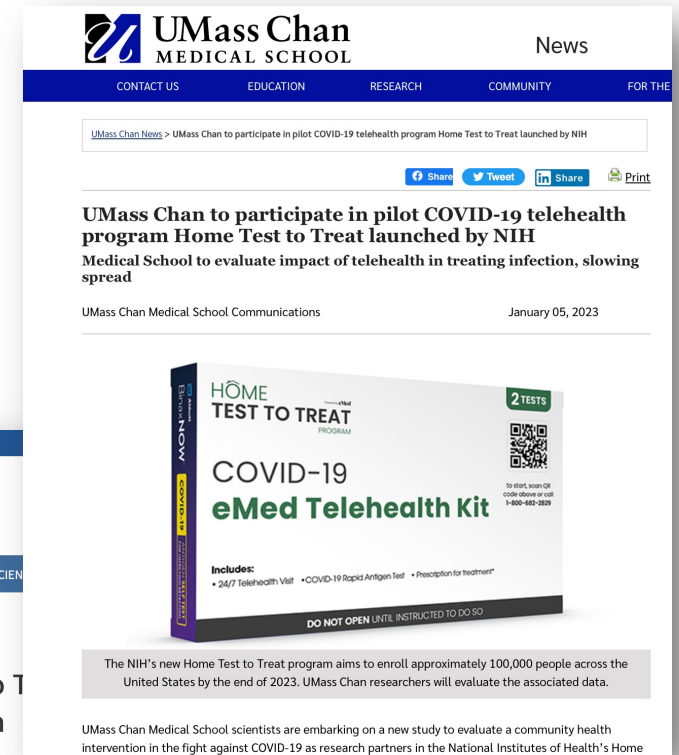
* Targeting 50% enrollment of underserved individuals



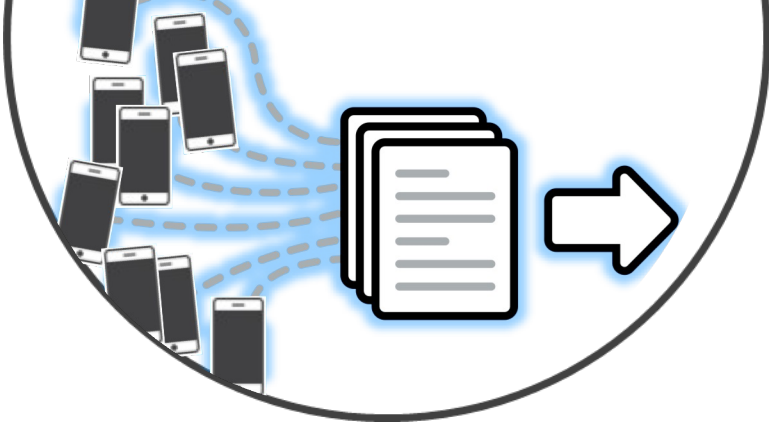
Pilot site launched in January

Berks County, PA

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



HÔME TEST TO TREAT PROGRAM



Home Diagnostic Reporting



Equitable Access



Additional Pathogens



Personal Health Records

Opportunities and Future Directions

Continuity of Care



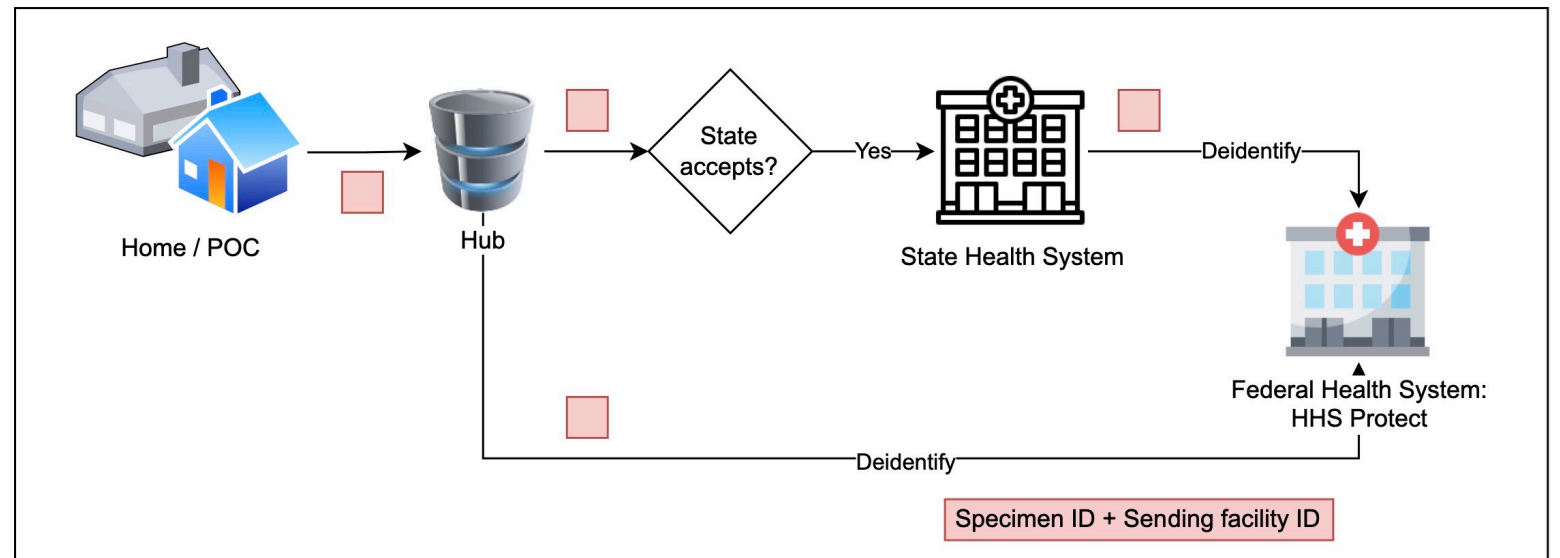
Key insights to building connected diagnostic reporting systems



Adapting to Novel Technologies

Build technical pathways that connect novel technologies to existing reporting systems

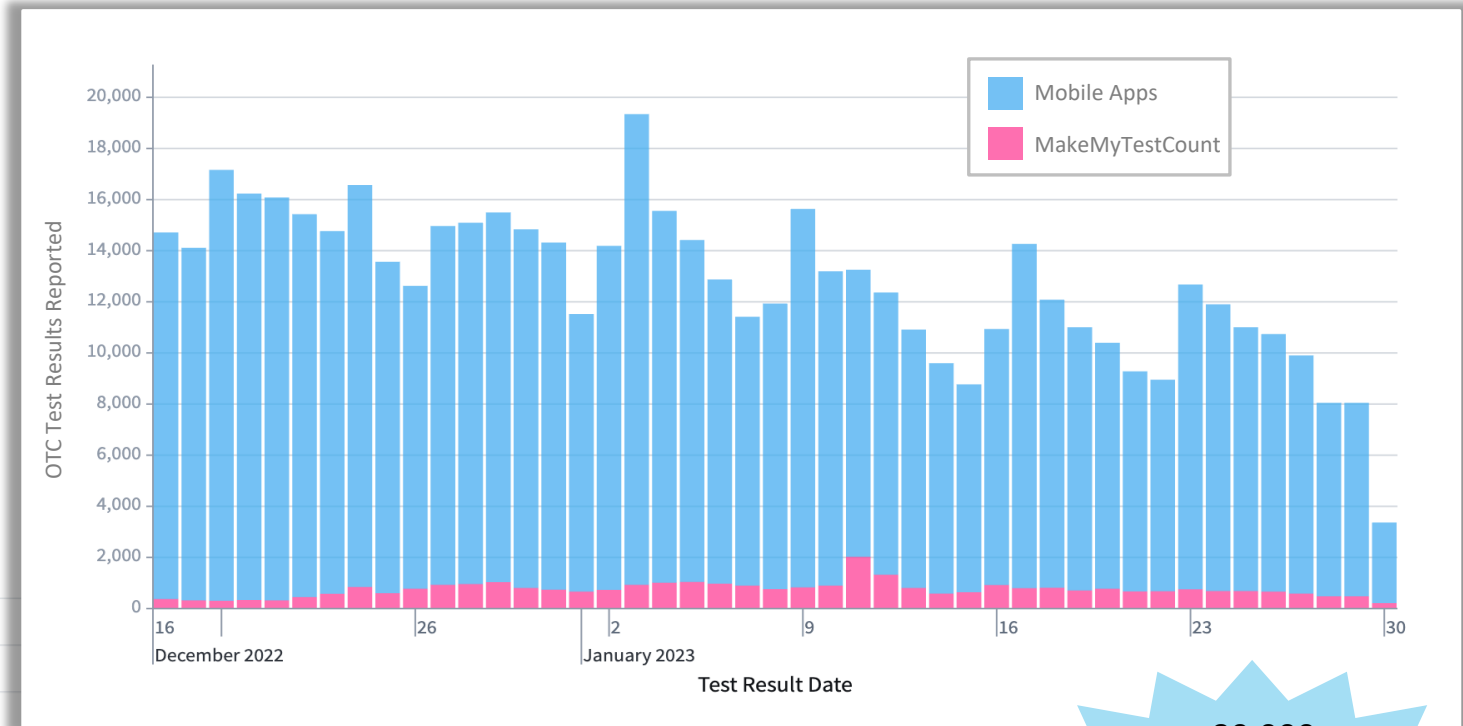
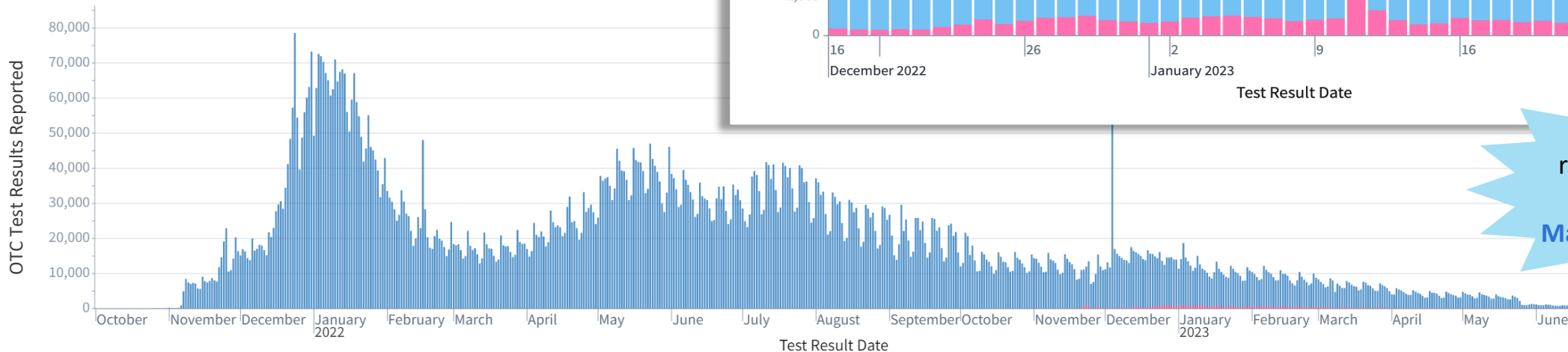
Parallel data streams to state and federal systems represent a paradigm shift



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

U.S. COVID-19 Self-Test Data

Public Health Surveillance

This dataset includes COVID-19 self-test result data voluntarily reported by users of tests through manufacturer websites and mobile companion applications. At this time, the dataset does not include data reported through the MakeMyTestCount website. All fields are self-

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

It will be updated monthly.

What's in this Dataset?

Rows: 527K
Columns: 11

Each row is a

Number of self-tests, aggregated by week, state, age group, race, ethnicity, sex, and test result.

State	Age Group	Race	Ethnicity	Sex	Test Result	Count
22	18-24	Unknown	Hispanic	Female	Positive	1014846
33	CA	Unknown	Hispanic	Female	Negative	8646481
34	PA	Unknown	Hispanic	Female	Negative	1060232
35	VA	Unknown	Hispanic	Female	Negative	1197746
36	TX	Unknown	Hispanic	Female	Negative	1215318
37	IA	Unknown	Hispanic	Female	Negative	1298188
38	CA	Unknown	Hispanic	Male	Negative	1314141
39	IA	Unknown	Hispanic	Male	Negative	1404744
40	FL	18-24	Hispanic	Female	Positive	1414807
41	OR	Unknown	Hispanic	Female	Negative	1538676
42	CA	Unknown	Hispanic	Female	Positive	1674339
43	FL	18-24	Hispanic	Male	Negative	1912889
44	VA	Unknown	Hispanic	Female	Positive	1938975
45	OR	Unknown	Hispanic	Male	Negative	2011168
46	CA	Unknown	Hispanic	Female	Positive	2046238
47	FL	Unknown	Hispanic	Female	Negative	2088866
48	FL	Unknown	Hispanic	Female	Positive	2197729
49	CO	Unknown	Hispanic	Female	Negative	2199862
50	IA	Unknown	Hispanic	Male	Negative	2197729
51	IA	Unknown	Hispanic	Female	Negative	2197729
52	FL	Unknown	Hispanic	Female	Negative	2197729

Data available to public online:

<https://data.cdc.gov/Public-Health-Surveillance/U-S-COVID-19-Self-Test-Data/275g-9x8h>

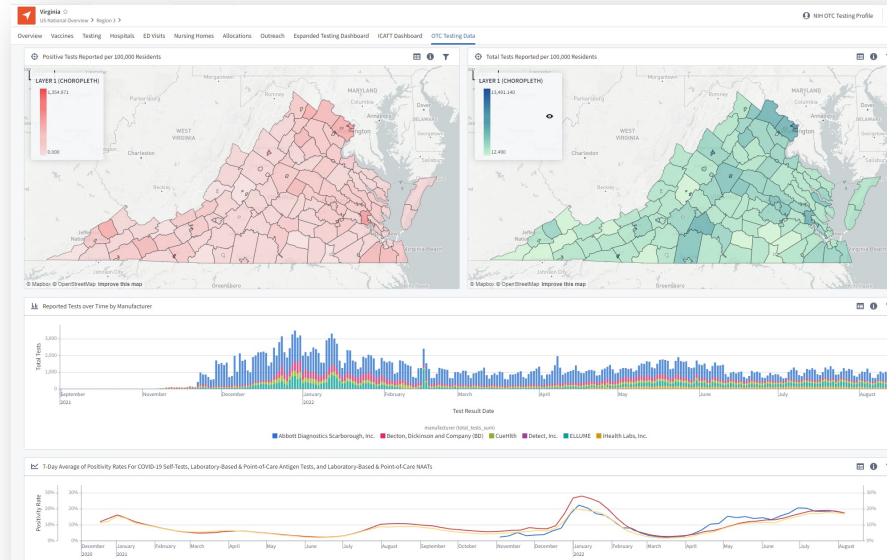
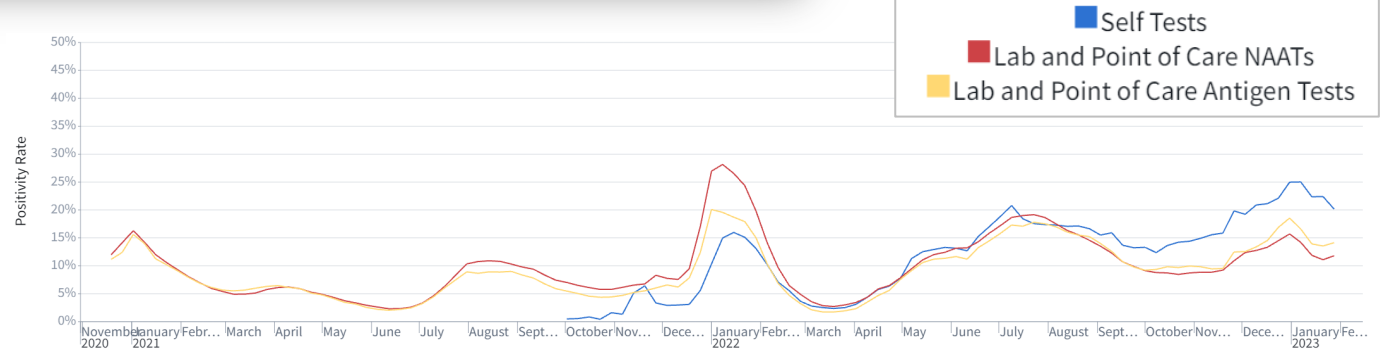
Enhancing Public Health Response

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

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

Matthew D. Richey^{1,2}; Hannah G. Rosenblum^{1,3}; Kim Del Guercio⁴; Matthew Humbard⁵; Steven Santos⁵; Jason Hall⁴; Jasmine Chaitram⁶; Reynolds M. Salerno⁶

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

info@makemytestcount.org

