

# Clinical Laboratory COVID-19 Response Call

Monday, June 28, 2021, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Public Health Laboratory Support of Point-of-Care Testing Sites**
  - Sanjib Bhattacharyya, City of Milwaukee Health Department
- **Over-the-Counter Tests and CLIA**
  - Amy Zale, Centers for Medicare & Medicaid Services (CMS)

# New Online Biological Risk Assessment Resource for Point-of-Care Testing Sites

<https://www.cdc.gov/csels/dls/point-of-care-testing.html>

- Audience is point-of-care testing site managers and staff
- Find CDC's general guidance on risk management, risk assessment, and more
- Download a job hazard analysis template to use onsite

The screenshot shows a webpage with a left sidebar and a main content area. The sidebar contains a 'DLS Home' link and several expandable menu items: 'About Us', 'LIVD Mapping Tool for SARS-CoV-2 Tests', 'Strengthening Clinical Laboratories', 'CDC's Laboratory Outreach Communication System (LOCS)', 'Laboratory Communicators' Network', 'Free Educational Materials for Public Health and Clinical Laboratories', 'Competency Guidelines for Laboratory Professionals', 'CDC Biorepository', 'Biological Risk Assessment: General Considerations for Laboratories', and 'Lab Week'. At the bottom of the sidebar is a 'Get Email Updates' button. The main content area has a title 'Biological Risk Management for Point-of-Care Testing Sites' and a sub-header 'Point-of-Care Testing Staff Support Health and Reduce Risk'. Below this is a paragraph explaining the role of POC testing and the risks involved. A second sub-header reads 'Perform Risk Management Using these Five Steps', followed by a paragraph defining risk management. A circular diagram illustrates the five steps: Step 1: Identify hazards and risks; Step 2: Assess the risks; Step 3: Choose controls that reduce the risks; Step 4: Put the controls into practice; Step 5: Evaluate whether the controls are effective.

🏠 DLS Home

About Us +

LIVD Mapping Tool for SARS-CoV-2 Tests

Strengthening Clinical Laboratories

CDC's Laboratory Outreach Communication System (LOCS) +

Laboratory Communicators' Network +

Free Educational Materials for Public Health and Clinical Laboratories

Competency Guidelines for Laboratory Professionals

CDC Biorepository

Biological Risk Assessment: General Considerations for Laboratories

Lab Week +

✉ Get Email Updates

## Biological Risk Management for Point-of-Care Testing Sites

### Point-of-Care Testing Staff Support Health and Reduce Risk

As someone who delivers point-of-care (POC) testing, you help people understand their health status. You collect specimens that contain biological material, such as blood or saliva, from people to test and determine what is making them sick. The results from these tests can help the people you serve make informed decisions about what to do next.

From the time you start each testing process until you finish, there are risks involved. Use this guidance to help make sure you reduce those risks as much as possible to keep you and your coworkers, patients, customers, family, and community safe and healthy while you perform POC tests. Learn how to evaluate and reduce risks using the information below; learn why risk assessment is important in your role [here](#).

### Perform Risk Management Using these Five Steps

Risk management is a five-step process of identifying and analyzing risks and taking steps to reduce or eliminate them.

**Step 1:** Identify hazards and risks

**Step 2:** Assess the risks

**Step 3:** Choose controls that reduce the risks

**Step 4:** Put the controls into practice

**Step 5:** Evaluate whether the controls are effective

# Packing and Shipping Job Aid

[https://www.cdc.gov/labtraining/docs/job\\_aids/covid\\_19/COVID-19-Pack-and-Ship-Job-Aid-508.pptx](https://www.cdc.gov/labtraining/docs/job_aids/covid_19/COVID-19-Pack-and-Ship-Job-Aid-508.pptx)

A quick reference guide for personnel trained to pack and ship suspected or confirmed SARS-CoV-2 specimens as UN 3373 Biological Substance, Category B

## SARS-CoV-2 Specimens: Packing and Shipping

Personnel must be trained to pack and ship suspected or confirmed SARS-CoV-2 specimens according to the regulations and in a manner that corresponds to their function-specific responsibilities. This job aid is not a substitute for the required training to pack and ship infectious substances, but instead serves as a quick reference guide adapted from the CDC Laboratory Training course [Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know](#).

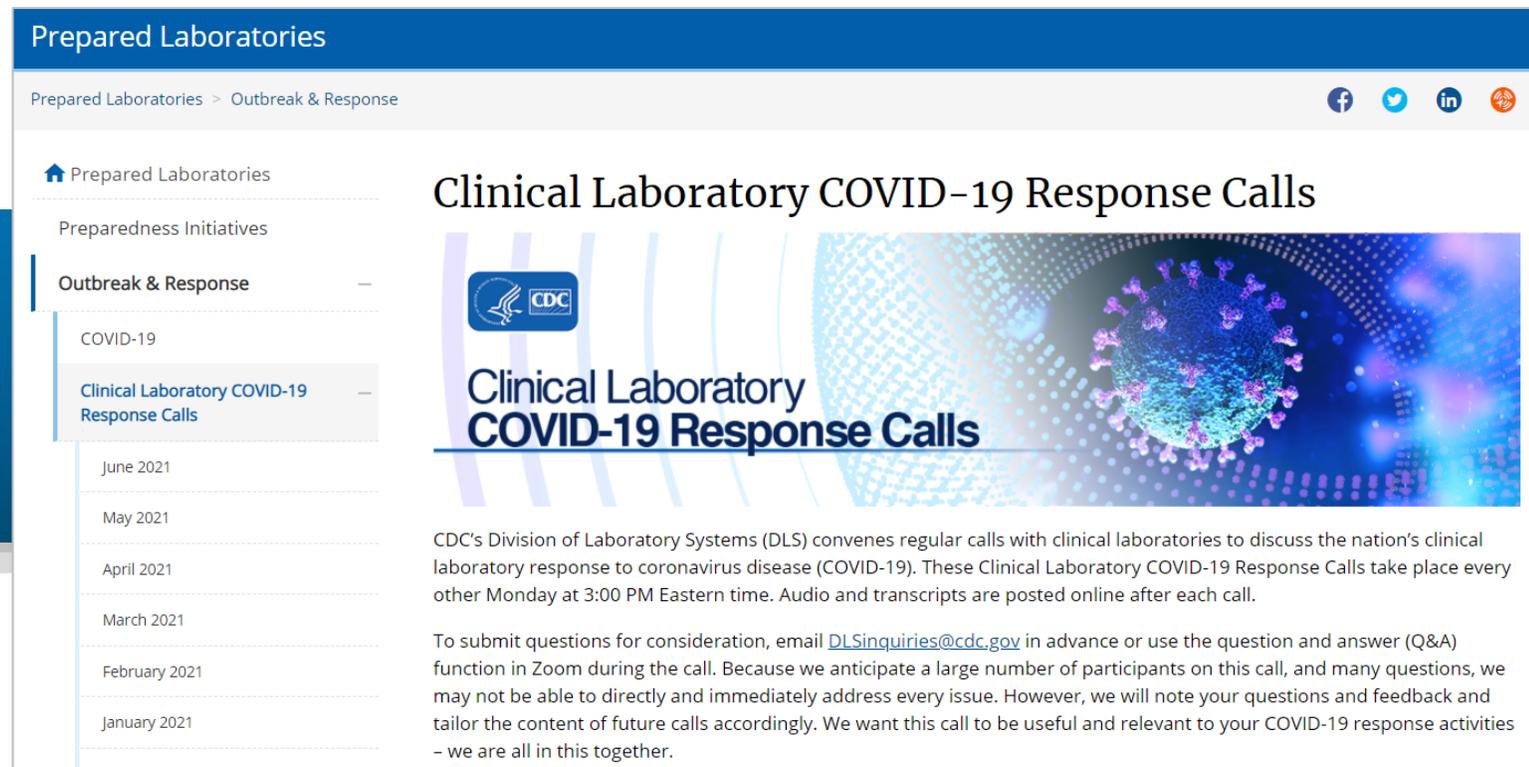


[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

# CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>

Find CLCR call information,  
transcripts, and audio recordings  
on the CDC Preparedness Portal



The screenshot displays the CDC Preparedness Portal interface. The main heading is "Prepared Laboratories" with a sub-path "Prepared Laboratories > Outbreak & Response". A sidebar on the left lists navigation options: "Preparedness Initiatives", "Outbreak & Response" (selected), "COVID-19", and "Clinical Laboratory COVID-19 Response Calls" (highlighted). Below this, a list of months from June 2021 to January 2021 is visible. The main content area features a banner for "Clinical Laboratory COVID-19 Response Calls" with the CDC logo and a background image of a virus particle. The text below the banner states: "CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM Eastern time. Audio and transcripts are posted online after each call." It also provides instructions for submitting questions via email ([DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov)) or using a Q&A function in Zoom.

# Schedule for Clinical Laboratory COVID-19 Response Calls

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The next call will be on **Monday, July 12** from  
**3:00 PM to 4:00 PM EDT**

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# We Want to Hear from You!

## Training and Workforce Development

Questions about education and training?

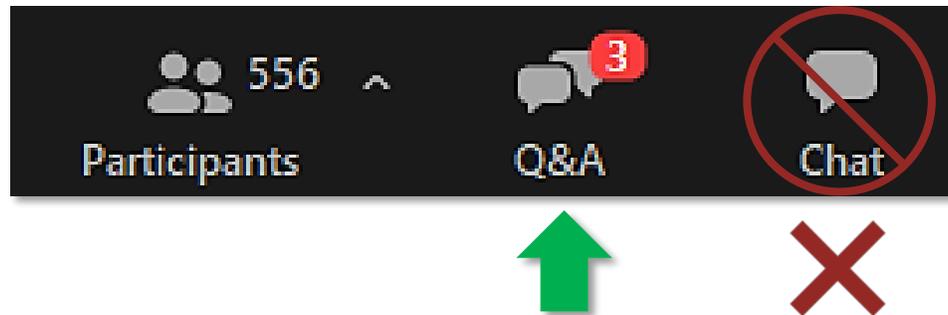
Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)



# How to Ask a Question

- **Using the Zoom Webinar System**

- Click the **Q&A** button in the Zoom webinar system
- Type your question in the **Q&A** box and submit it
- **Please do not submit a question using the chat button**



- For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider



*Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.*

# Public Health Laboratory Support of Point-of-Care Testing Sites

**Sanjib Bhattacharyya**

City of Milwaukee Health Department



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# COVID-19 POC TESTING FOR PUBLIC HEALTH IN NON-TRADITIONAL TESTING SITES

BEST PRACTICES AND REGULATORY CONSIDERATIONS

**SANJIB BHATTACHARYYA, PH.D.**

HE/HIM/HIS

**LABORATORY DIRECTOR**

SPECIAL DEPUTY HEALTH COMMISSIONER  
**CITY OF MILWAUKEE HEALTH DEPARTMENT**

ADJUNCT FACULTY, JOSEPH J. ZILBER SCHOOL OF PUBLIC HEALTH  
CLINICAL ASSOCIATE PROFESSOR, COLLEGE OF HEALTH SCIENCES  
UNIVERSITY OF WISCONSIN-MILWAUKEE



@MKEhealth

CDC DIVISION OF LABORATORY SYSTEMS CLINICAL LABORATORY COVID-19 RESPONSE CALL  
JUNE 28, 2021



# MHD's MISSION & APPROACH

*ADVANCE THE HEALTH AND EQUITY OF MILWAUKEEANS THROUGH SCIENCE, INNOVATION, AND LEADERSHIP*

## **Innovation**

- Technology, data and partnering
  - Identify non-traditional community sites for analyzer deployment
  - Sites that support high risk and/or underserved populations to advance the health and equity of Milwaukeeans

## **Science**

- Provide training, supplies and resources

## **Leadership**

- Educate on best practices, work flows and reporting
- Monitor site testing patterns and demands

## **Quality**

- Continuously improve and adapt to create sustainable and positive health outcomes



# MILWAUKEE HEALTH LABORATORY

## SCIENCE & HEALTH EQUITY CENTRIC PRACTICE IN A LOCAL PUBLIC HEALTH LABORATORY



- **Since 1874**
- Totally rebuilt 1957 → 2000
- One of the 2 BSL-3 Labs in WI
  - TB and high priority pathogens rule out
  - Renovated 2003
- Keenan Health Center
  - TB control, HIV and STI clinic
  - Family planning testing
  - Expanding STI services

- Clinical Laboratory Improvement Amendment (CLIA)- CMS
- Wisconsin Department of Agriculture, Trade & Consumer Protection (DATCP)
- Wisconsin Department of Natural Resources (DNR)
- American Industrial Hygiene Association (AIHA)
- Centers for Disease Control and Prevention (CDC)
- Federal Select Agent Program
- World Health Organization (WHO)



Nation's Healthiest Laboratory  
Award- APHL (2017)



# QUALITY CONTROL AND WORKFORCE

1. Adhere to **Quality Control Practices** (ISO, CLIA, LEAN)
2. Workforce development- students, interns and faculty development
3. Partnership with clinical, academic, corporate- exploring non-traditional system partners
4. Explore sustained funding



Students & Workforce Development



Collaborations for Applied Research



# COVID-19 RESPONSE

The image features a solid green background. At the bottom, there is a stylized rainbow graphic composed of several overlapping, semi-transparent, curved bands in various shades of green, creating a layered, arch-like effect.

PRESS RELEASE

## First Coronavirus (COVID-19) Case Confirmed in the City of Milwaukee

By [City of Milwaukee Health Department](#) - Mar 13<sup>th</sup>, 2020 07:23 pm

**MILWAUKEE-** The City of [Milwaukee Health Department](#) (MHD) has confirmed Milwaukee's first presumptive case of novel coronavirus, COVID-19, health officials announced today. The [State of Wisconsin Department of Health Services](#) (DHS) has issued [guidelines for ending isolation and quarantine for patients.](#)

**MHD has been preparing for this through our Democratic National Convention (DNC) preparations and experience managing other outbreaks ranging from H1N1 influenza in 2009-2010 and vaccine preventable disease.**

“Now is the time to remember that we all have the ability to help slow the spread of the illness and protect our fellow Milwaukeeans.

# MULTI-STAKEHOLDER RESPONSE TO COVID-19

## RELATIONSHIPS BETWEEN ENTITIES TO ADDRESSING SYSTEMIC REGIONAL CHALLENGES

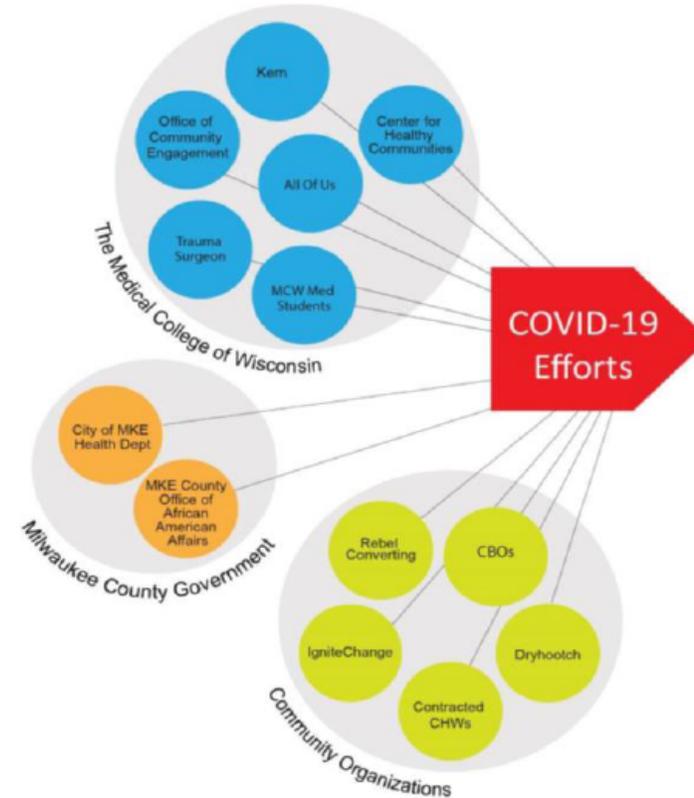
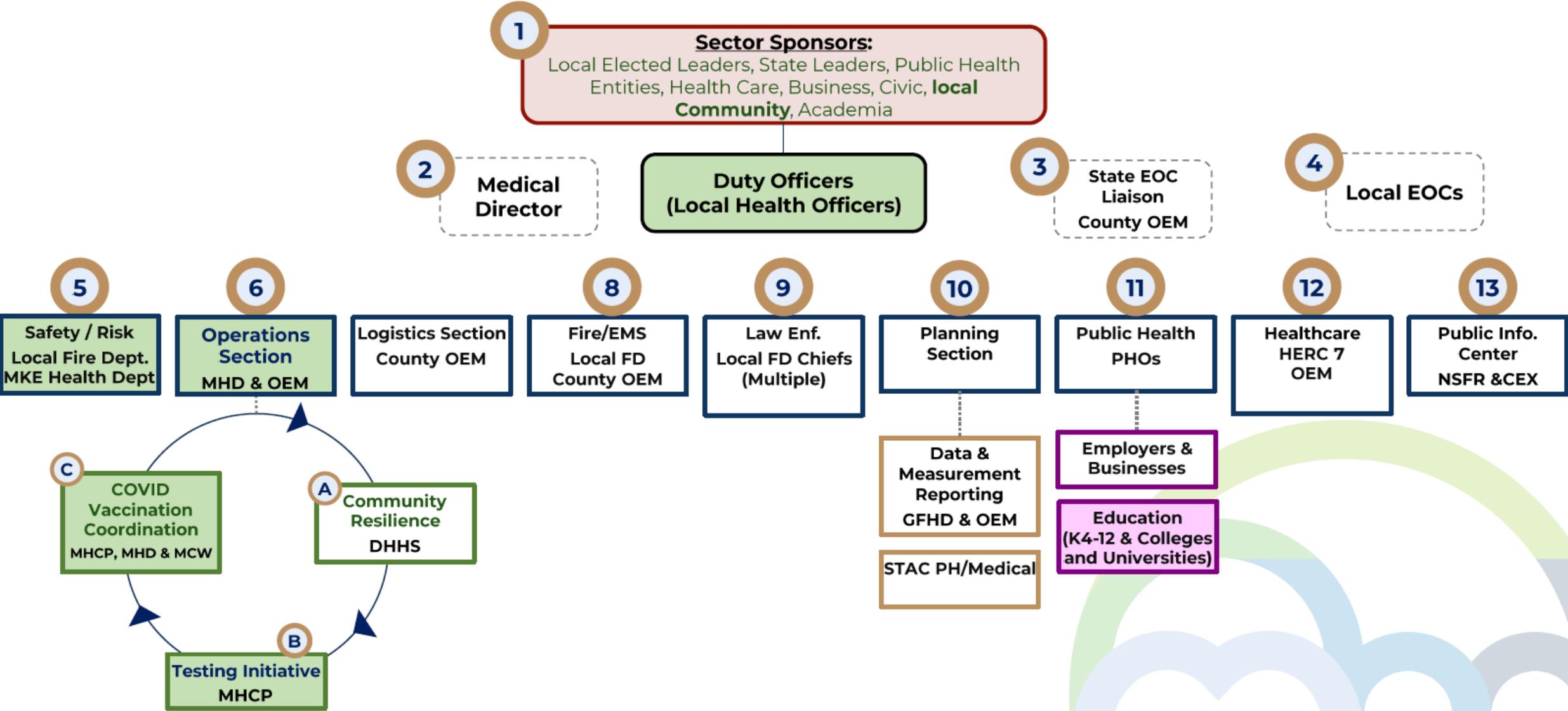


Figure courtesy: Erika Petterson



<https://chealthc.info/art-gallery/>

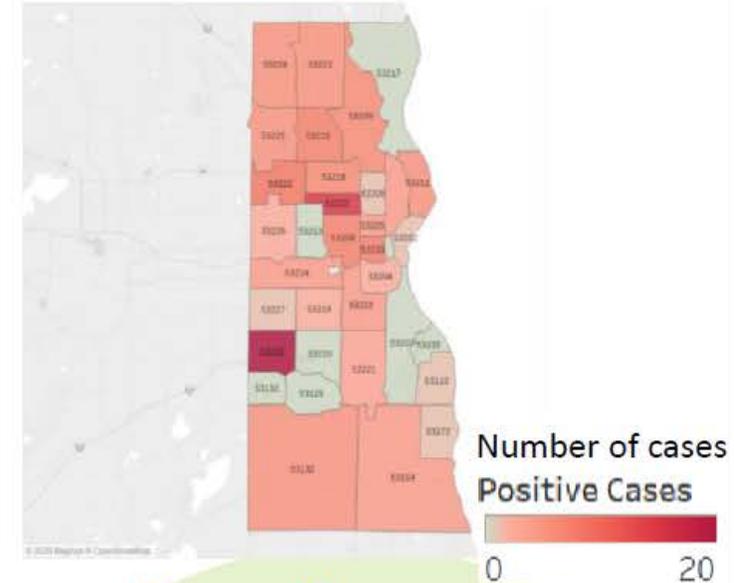
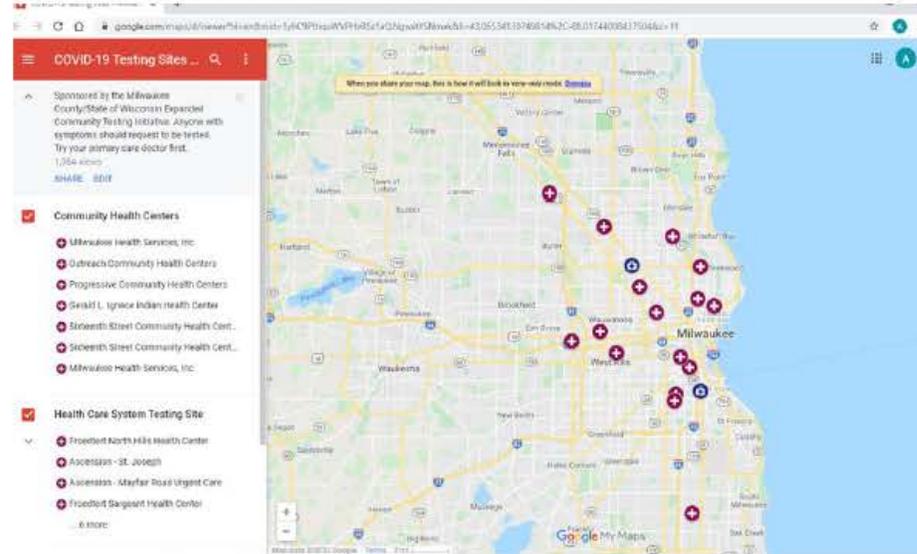
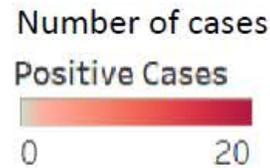
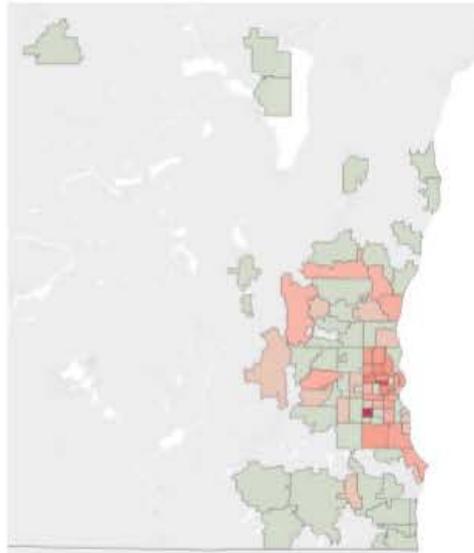
# MKE U.E.O.C PUBLIC HEALTH COLLABORATIVE | STRUCTURE



# GEOGRAPHIC SERVICE DISTRIBUTION

## PHL TESTING GROUP STRATEGIES

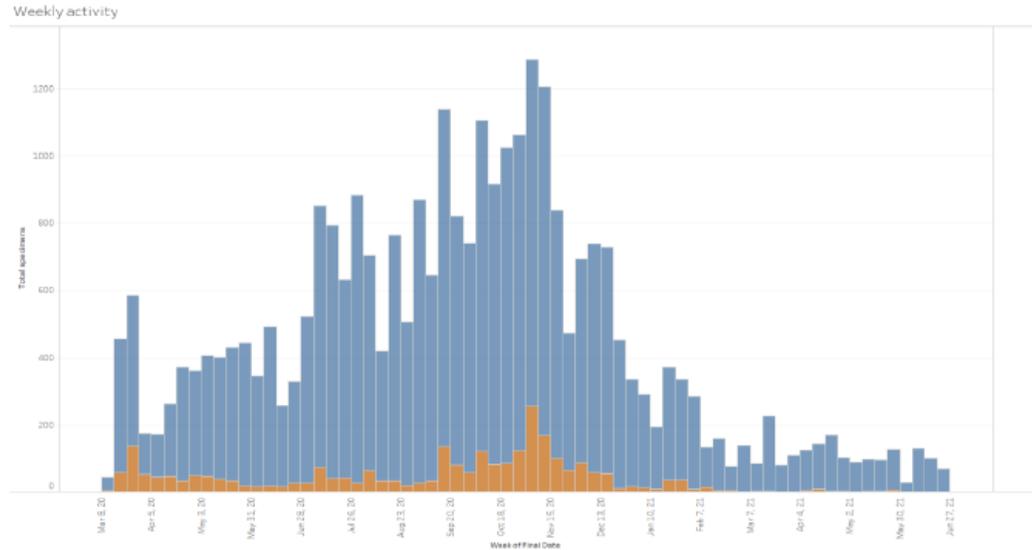
### COMMUNITY HEALTH CENTERS & HEALTH SYSTEMS



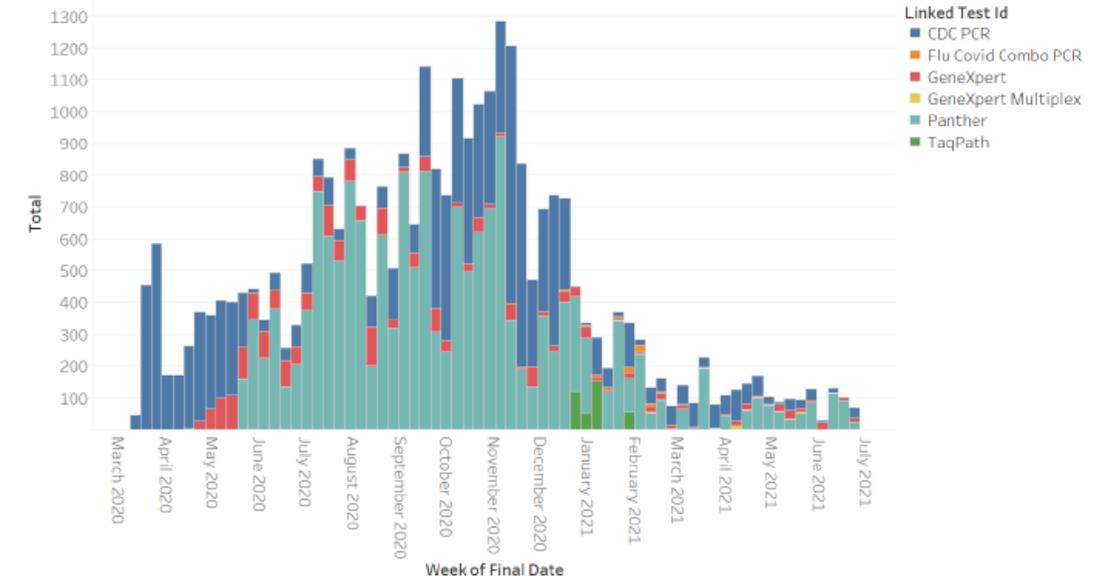
1. Place-Based Testing- Clinical, Reference, Surveillance and Responding to Outbreaks
2. Expand Health Care Provider Testing
3. Community Outreach and Education
4. Measurement and Reporting

# SARS-COV-2 TEST UTILIZATION

## TESTING AND TECHNOLOGY DIVERSITY

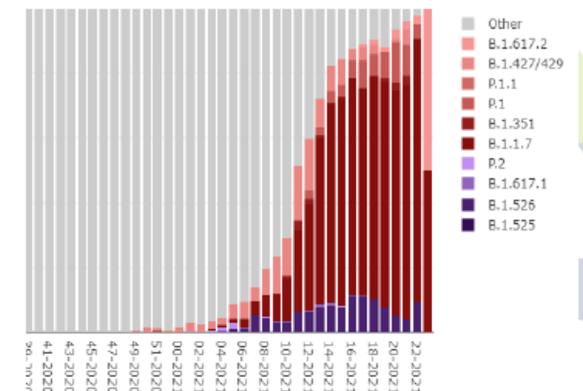
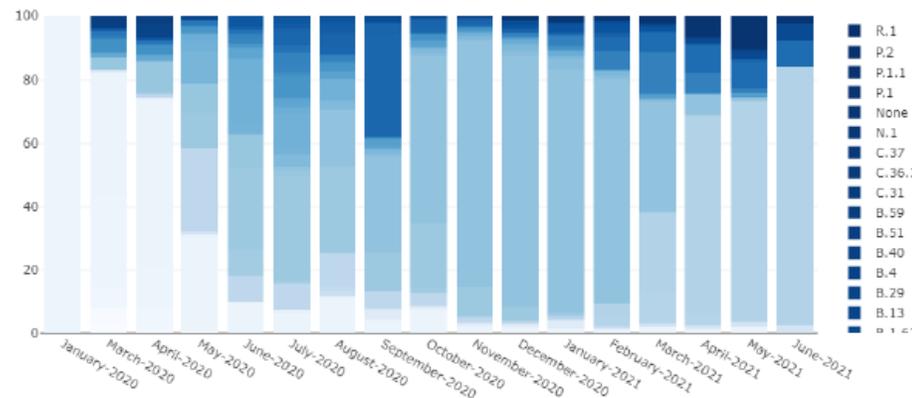


Daily test volume updated 6/25/2021 9:03:52 AM



### Community, Academic & PHL Partnerships

- MHDL (in-house PCR, sequencing)  
UW-Madison, WSLH, CDC
- Corporate partnering  
(Bioinformatics- data analysis consult)
- Epidemiologist's contribution to identify hot spots



# WHAT IS POC?

TESTING THAT IS PERFORMED OUTSIDE OF A LABORATORY SETTING

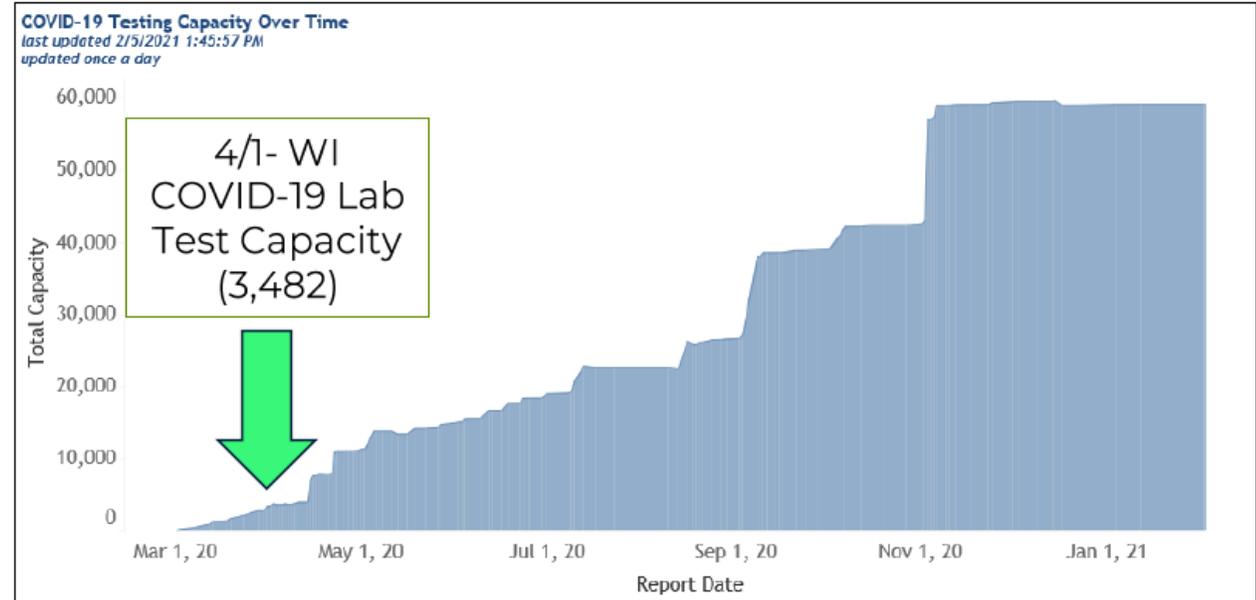


# BACKGROUND

- March 2020
  - Abbott receives EUA for the fastest available molecular point-of-care (POC) test for detection of COVID-19
- April 2020
  - HHS provides Abbott ID Now instruments to public health jurisdictions to best meet testing priorities
  - Milwaukee makes national news as COVID cases & deaths rise disproportionately in minority populations
  - WI DHS, WSLH & MHDL strategize utilization of ID Now POC units within Milwaukee communities

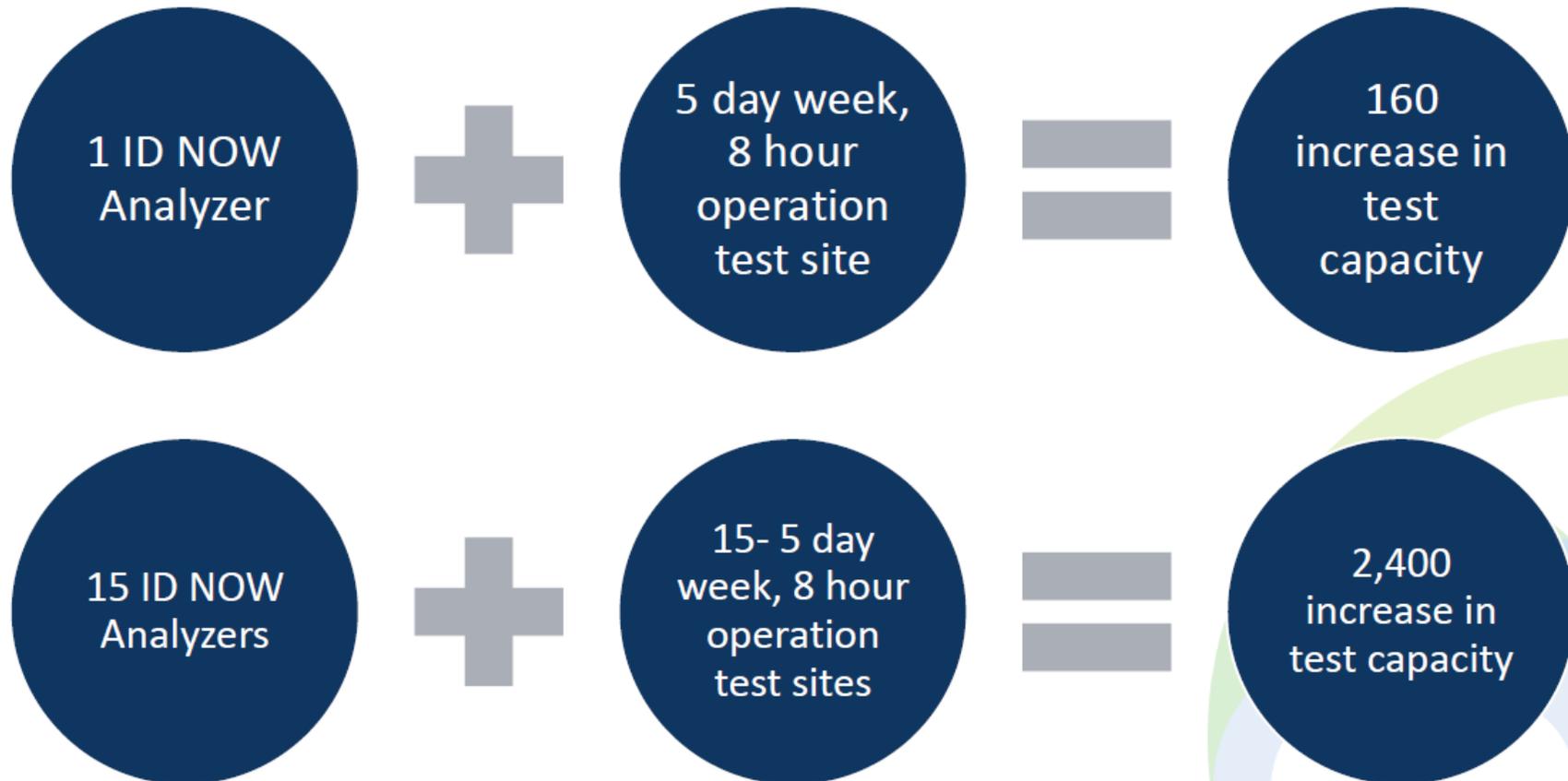
Wisconsin COVID-19 Molecular Testing Capacity

Laboratories actively testing	Laboratories planning to test	Current state capacity (tests/day) <small>Last Updated: 2/5/2021 1:46:00 PM</small>
137	16	59,273



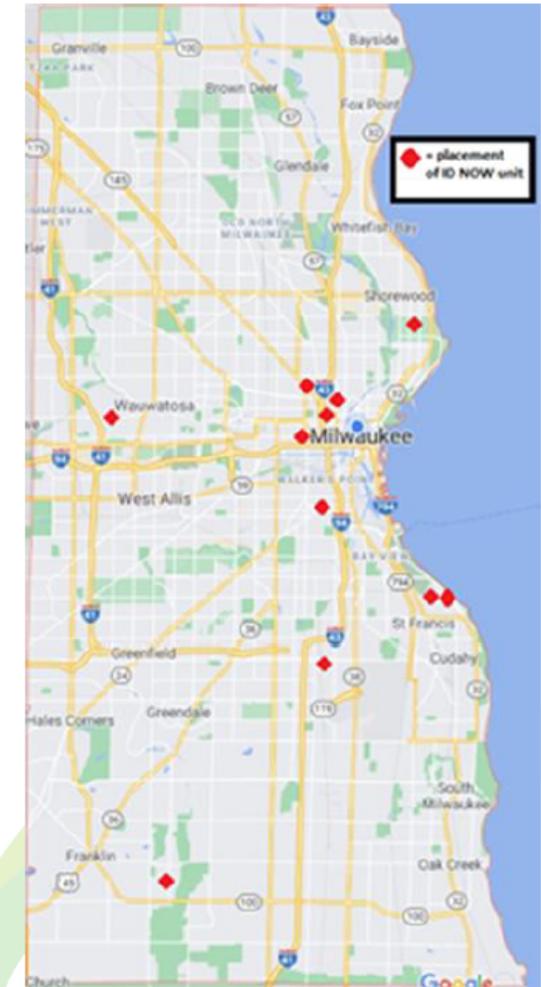
Data collected by voluntary reporting from public, private, and commercial laboratories in Wisconsin. All data are estimates and do not reflect actual number of tests performed in the state. Capacity is dependent on availability of test supplies and adequate staffing

# INCREASING CAPACITY FOR PUBLIC HEALTH



# RAPID POC ID DEPLOYMENT SITES

Location Type	# of locations	Population Served	Benefits	Challenges
Homeless Shelter/ Isolation Facility	2	Residents and staff at shelters	Allow for housing placement	Qualified staff to perform testing Appropriate physical space
Student Health Center	2	College students including those in dorm setting	Mitigate spread in dormitory and non-compliant population	Streamlining reporting requirements
Correctional Facility	2	Inmates and staff	Able to place inmates sooner and limit need for isolation	Establishing dedicated super users to ensure regulatory & reporting requirements met
Fire Department/ EMS	1	Emergency personnel	Mitigate spread and determine quarantine needs rapidly to prevent spread to other EMS personnel; support other agencies	Creating employee/workplace testing policy/procedures
Clinical Service Provider	4	Un- & Underinsured, employees caring for vulnerable populations	Provide access to underserved populations	On-going manual data submission



# Planning

## Team Selection

- Administration (Clinical Services Deputy Commissioner, Laboratory Director)
- Preparedness/Testing Coordinator
- Laboratory Operations Manager
- Technical Staff/Laboratory Scientists

## Training

- Identified **who** would train, **what** content would be, **where** & **when, how** the forma be
- Attended Abbott Virtual ID Now Training Session
- Reviewed Manuals, Instructions for Use, EUA and package inserts
- Reviewed CLIA Waived Testing Guidance documents

## Tools

- Developed standard training guide
- Modified/created user friendly quality logs (temperature, QC) per CLIA requirements
- Created competency assessment documentation and FAQ for non-traditional settings
- Developed a standard site survey for use in assessing physical space and site capability

## Outreach

- Reached out to other state PHL's to learn about their deployment approach
- Pre-screen calls with partners to gauge interest and applicability to their setting
- Focus on local partners to increase access to diverse, high risk, underserved populations
- Upon survey complete, setup visits to confirm site appropriateness and address issues

# SITE ASSESSMENT TOOL

## 1. Certification, Oversight, and Educational Considerations

Does the site have a CLIA license?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, what is their CLIA certificate #?		
Is there medical oversight?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, name and credentials?		
What is the educational/training background for "super-user"?		

## 2. Operational Location Considerations

Does the facility have a designated work space that is clean, flat, level and stable within reach of 120V electrical outlet?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Can the work space accommodate ID Now unit and safety hood?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the workspace out of direct sunlight?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the workspace have a temperature range within 50° - 86°F, and room relative humidity 10-80%, non-condensing?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Can the unit remain in the same location for an extended period of time? (QC must be done every time unit is moved.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will the unit be secluded and away from high traffic areas?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Initial site identified....



Site identified at same building after quality/safety and test training visit...



# SITE ASSESSMENT CONTINUES.....

## 3. Safety Considerations

Does the facility have appropriate PPE for the operators collecting specimens and performing the test? (e.g. gloves, disposable coats, masks, protective eye wear, etc.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the facility have the ability to dispose of biohazardous waste?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## 4. Reporting

Does the facility have the ability to fax or email daily count of tests performed including positive/negative/invalid patient results?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the facility have access or a mechanism in place for reportable result reporting to MHD/DHS/WEDSS? <i>Testing facilities <b>are required</b> to report all positive and negative results to the appropriate health authorities.</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No



# PARTNERS UNDERSTANDING ON SITE SPECS

## 5. Partner Acknowledgement

Partner acknowledges that all requirements above have been, or will be, implemented prior to system installation and training.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Partner acknowledges that all testing will follow manufacturer's guidelines for performing COVID-19 testing on the Abbott ID NOW instrument.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Partner acknowledges that testing is intended only for persons that may have been exposed to the virus based on signs and symptoms, and/or because an individual: <ul style="list-style-type: none"><li>• has lived in or has recently traveled to a high prevalence COVID-19 location</li><li>• has been in close contact with a suspected or confirmed case of COVID-19</li></ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Partner acknowledges that <b><i>a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions</i></b> , especially if the patient's medical, travel, or contact history suggests a strong likelihood of infection. Negative results must be combined with clinical observations, patient history, and epidemiological information.	<input type="checkbox"/> Yes <input type="checkbox"/> No



If any of the previous questions are answered "no", review will be performed to determine what measure(s) may be taken to qualify a site for placement. A "no" response does not automatically disqualify the facility from receiving a unit.

# TRAINING



## PROVIDED ON-SITE TRAINING UTILIZING STANDARD TRAINING GUIDE

- During training, completed initial competency documentation
- Issued a binder with instrument manual and printed resources including CLIA & Waived Testing Booklet, Abbott training links

## COORDINATED WITH WI STATE LAB TO ESTABLISH WEB-BASED LABORATORY REPORTING AND TRAINING

**READY?  
SET?  
TEST!**

**PATIENT TESTING  
IS IMPORTANT.**

Get the right results.

<http://www.cdc.gov/clia/Resources/WaivedTests/>

Center for Infection Control and Laboratory Safety  
A Division of the CDC

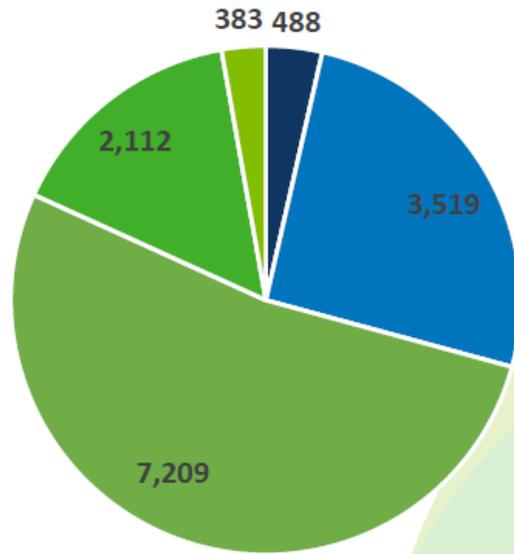


<https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf>

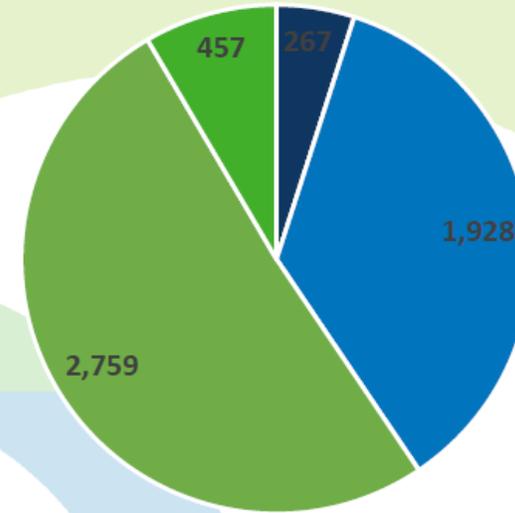
# WORKLOAD

## COMMUNITY SITE DISTRIBUTIONS

2020 - Number of Tests Performed



2021 - Number of Tests Performed



- Homeless Shelter
- Correctional Facilities
- Clinical Service Providers
- Student Health Centers
- Fire Dept./Clare Hall

- Homeless Shelter
- Correctional Facilities
- Clinical Service Providers
- Student Health Centers
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# CONTINUOUS QUALITY IMPROVEMENT

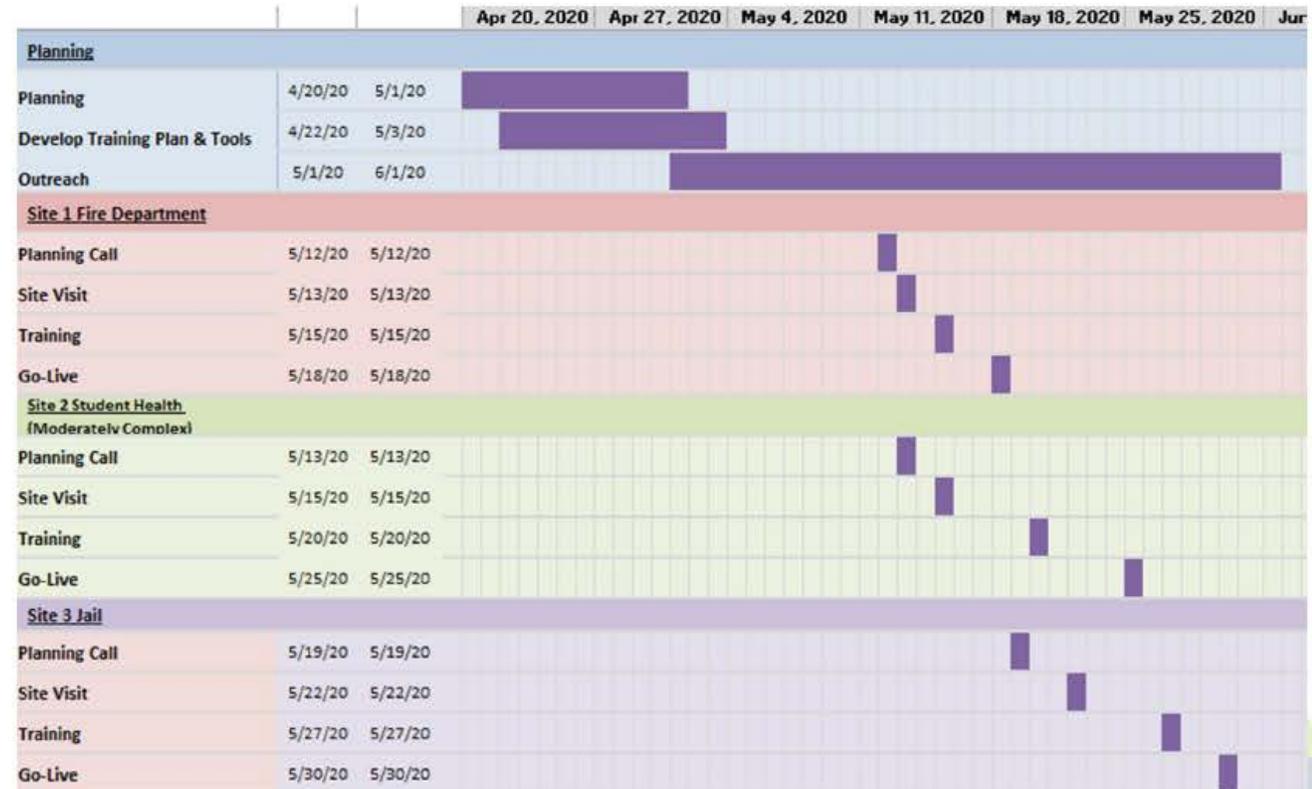


Week	Pos	Neg	Inval
8	1	308	25
9	2	201	38
10	1	307	42
11	3	290	17
12	2	256	5



# COST & TIME CONSIDERATIONS

- Equipment, hardware & software
- Service plan
- Electronic reporting mechanism
- Supplies (for start-up, training and competency)- ongoing costs
- Staff resources
- Provide training/setup before go live
- Be flexible
- Plan for continuous improvement; it's ok if the plan is not perfect!
- Provide information in advance; but plan to emphasize in trainings and follow up communications



# LESSONS LEARNED

- 1** Important to establish that the site is considered a LAB- especially important for state reporting obligations (especially for sites accustomed to CLIA Certificate of Waiver)
- 2** Routine Communication and on-site training are key to compliance success
- 3** Ideal to have a dedicated POC Coordinator with the Health Department Lab to manage the process
- 4** Everything works best if there is a site owner at the non-traditional testing site!!!
- 5** Important to not only consider cost to implement POC, but what is the cost if it isn't



LIVING  
YOUR  
BEST  
LIFE.



LIVING YOUR  
BEST  
LIFE.



LIVING YOUR  
BEST LIFE.



# Over-the-Counter Tests and CLIA

**Amy Zale**

Centers for Medicare & Medicaid Services (CMS)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**

<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>

- **FAQs Only**

<https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>



# CDC Social Media

<https://www.facebook.com/CDC>



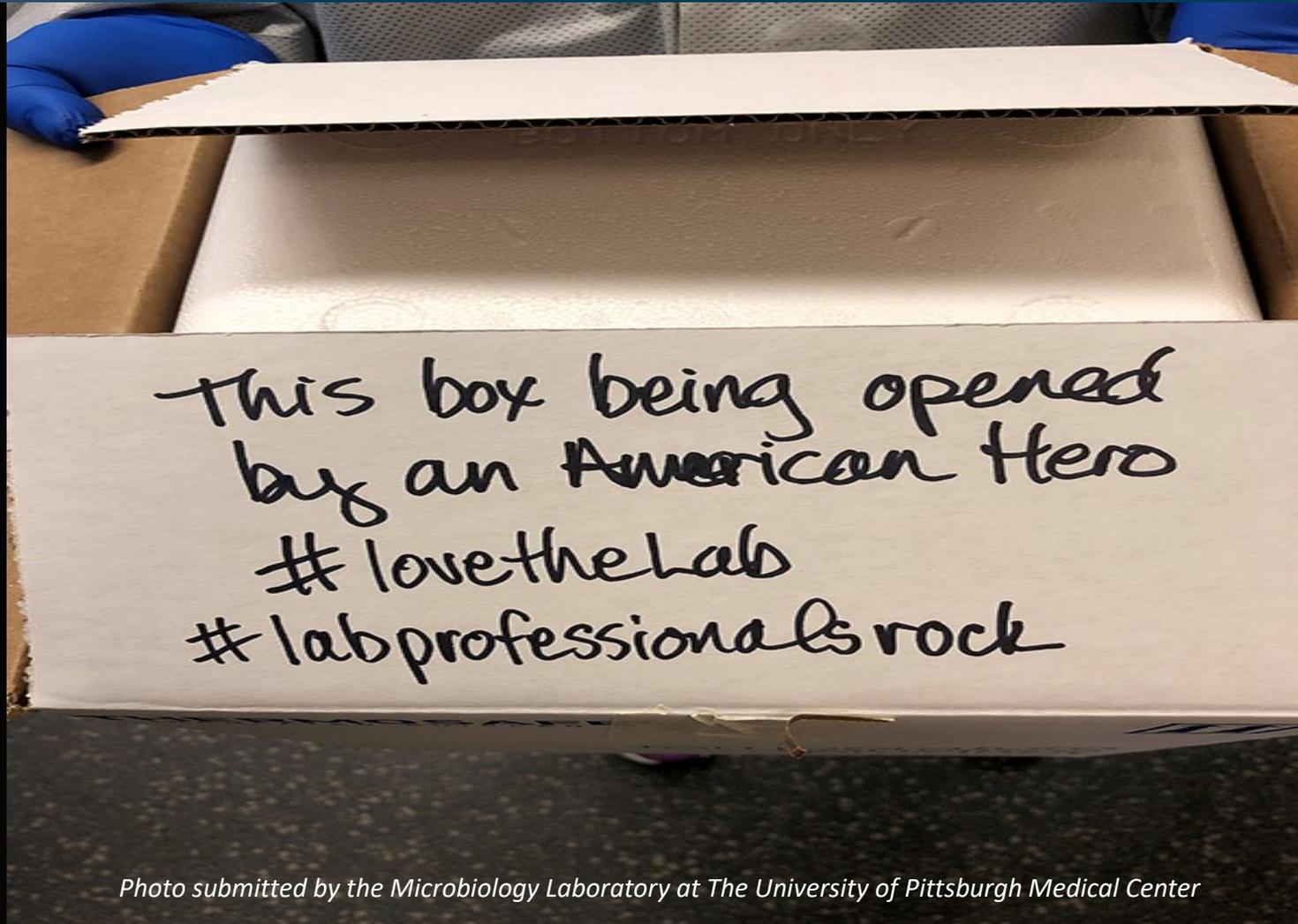
<https://twitter.com/cdcgov>

<https://www.instagram.com/cdcgov>



<https://www.linkedin.com/company/cdc>

# Thank You For Your Time!



*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*