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

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, July 12** from 3:00 PM to 4:00 PM EDT.
We Want to Hear from You!

Training and Workforce Development

Questions about education and training?
Contact 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
- 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
COVID-19 POC TESTING FOR PUBLIC HEALTH IN NON-TRADITIONAL TESTING SITES

Best practices and Regulatory Considerations

Sanjib Bhattacharyyya, 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

CDC Division of Laboratory Systems Clinical Laboratory COVID-19 Response Call
June 28, 2021

@MKEhealth
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
W. Wisconsin Department of Agriculture, Trade & Consumer Protection (DATCP)
W. 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)

CITY OF MILWAUKEE HEALTH DEPARTMENT

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
COVID-19 RESPONSE
PRESS RELEASE
First Coronavirus (COVID-19) Case Confirmed in the City of Milwaukee

By City of Milwaukee Health Department - Mar 13th, 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.”

Figure courtesy: Erika Petterson

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

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
INCREASING CAPACITY FOR PUBLIC HEALTH

1 ID NOW Analyzer + 5 day week, 8 hour operation test site = 160 increase in test capacity

15 ID NOW Analyzers + 15-5 day week, 8 hour operation test sites = 2,400 increase in test capacity
<table>
<thead>
<tr>
<th>Location Type</th>
<th># of locations</th>
<th>Population Served</th>
<th>Benefits</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homeless Shelter/Isolation Facility</td>
<td>2</td>
<td>Residents and staff at shelters</td>
<td>Allow for housing placement</td>
<td>Qualified staff to perform testing Appropriate physical space</td>
</tr>
<tr>
<td>Student Health Center</td>
<td>2</td>
<td>College students including those in dorm setting</td>
<td>Mitigate spread in dormitory and non-compliant population</td>
<td>Streamlining reporting requirements</td>
</tr>
<tr>
<td>Correctional Facility</td>
<td>2</td>
<td>Inmates and staff</td>
<td>Able to place inmates sooner and limit need for isolation</td>
<td>Establishing dedicated super users to ensure regulatory &amp; reporting requirements met</td>
</tr>
<tr>
<td>Fire Department/EMS</td>
<td>1</td>
<td>Emergency personal</td>
<td>Mitigate spread and determine quarantine needs rapidly to prevent spread to other EMS personnel; support other agencies</td>
<td>Creating employee/workplace testing policy/procedures</td>
</tr>
<tr>
<td>Clinical Service Provider</td>
<td>4</td>
<td>Un- &amp; Underinsured, employees caring for vulnerable populations</td>
<td>Provide access to underserved populations</td>
<td>On-going manual data submission</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Does the site have a CLIA license?</th>
<th>□ Yes</th>
<th>□ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, what is their CLIA certificate #?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there medical oversight?</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td>If yes, name and credentials?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is the educational/training background for &quot;super-user&quot;?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## 2. Operational Location Considerations

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

Initial site identified....

Site identified at same building after quality/safety and test training visit...
### 3. Safety Considerations

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the facility have the ability to dispose of biohazardous waste?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 4. Reporting

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the facility have the ability to fax or email daily count of tests performed including positive/negative/invalid patient results?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the facility have access or a mechanism in place for reportable result reporting to MHD/DHS/WEDSS? <strong>Testing facilities are required</strong> to report all positive and negative results to the appropriate health authorities.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 5. Partner Acknowledgement

<table>
<thead>
<tr>
<th>Partner acknowledgment</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partner acknowledges that all requirements above have been, or will be, implemented prior to system installation and training.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partner acknowledges that all testing will follow manufacturer's guidelines for performing COVID-19 testing on the Abbott ID NOW instrument.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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:  
  - has lived in or has recently traveled to a high prevalence COVID-19 location  
  - has been in close contact with a suspected or confirmed case of COVID-19 |     |    |
| Partner acknowledges that a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, 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. |     |    |

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

WORKLOAD

Community site distributions

2020 - Number of Tests Performed

- Homeless Shelter: 7,209
- Correctional Facilities: 2,759
- Clinical Service Providers: 3,519
- Student Health Centers: 383,488
- Fire Dept./Clare Hall: 2,112

2021 - Number of Tests Performed

- Homeless Shelter: 1,928
- Correctional Facilities: 261
- Clinical Service Providers: 457
- Student Health Centers: 2,759
- Fire Dept./Clare Hall: 2,112

City of Milwaukee Health Department
CONTINUOUS QUALITY IMPROVEMENT

- Confirmatory PCR Test Support
- Continued Communication & Site Visits
- On-Going Quality Activities
- Reporting System Reviews for Compliance
- Weekly Test Data Review

<table>
<thead>
<tr>
<th>Week</th>
<th>Pos</th>
<th>Neg</th>
<th>Inval</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>1</td>
<td>308</td>
<td>25</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>201</td>
<td>38</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>307</td>
<td>42</td>
</tr>
<tr>
<td>11</td>
<td>3</td>
<td>290</td>
<td>17</td>
</tr>
<tr>
<td>12</td>
<td>2</td>
<td>256</td>
<td>5</td>
</tr>
</tbody>
</table>
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
1. Important to establish that the site is a 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
Over-the-Counter Tests and CLIA

Amy Zale
Centers for Medicare & Medicaid Services (CMS)
• CLIA Laboratory Guidance During COVID-19 Memo and FAQs

• FAQs Only
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