Clinical Laboratory COVID-19 Response Call
Monday, August 23, 2021, at 3:00 PM EDT

• Welcome
  – Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

• SARS-CoV-2 Variants Update
  – John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response

• Testing and Diagnostics Working Group

• FDA Update
  – Tim Stenzel, U.S. Food and Drug Administration (FDA)
Division of Laboratory Systems (DLS)

Vision
Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission
Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.
## Four Goal Areas of DLS

<table>
<thead>
<tr>
<th>Quality Laboratory Science</th>
<th>Highly Competent Laboratory Workforce</th>
<th>Safe and Prepared Laboratories</th>
<th>Accessible and Usable Laboratory Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance</td>
<td>Strengthen the laboratory workforce to support clinical and public health laboratory practice</td>
<td>Enhance the safety and response capabilities of clinical and public health laboratories</td>
<td>Increase access and use of laboratory data to support response, surveillance, and patient care</td>
</tr>
</tbody>
</table>
Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal

The next call will be on **Monday, September 20**
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](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.
SSEV Update

John R. Barnes, Ph.D.

SSEV Deputy Lead, COVID-19 Laboratory Task Force

Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.
National Nowcast Estimates of SARS-CoV-2 Lineages

- Delta (including sublineages) increased\(^1\)
  - From 94% to 99%
    - B.1.617.2 (86%)
    - AY.3 (12%), AY.2 (0.3%), AY.1 (0.1%)
- Alpha (B.1.1.7) decreased
  - From 2.4% to 0.3%
- Gamma (P.1) decreased
  - From 1% to 0.2%
- B.1.427 and B.1.429
  - No longer considered VOI
  - Less than 0.1% nationally

\(^1\)Weighted estimates from period ending 07/24/2021 (as of 7/31/2021) used for comparison with Nowcast (as of 08/14/2021)

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
Regional Nowcast Proportion of SARS-CoV-2 Lineages

- Delta (B.1.617.2) predominates in all HHS Regions
  - AY.3 is highest in Region 7 (38%)
  - AY.1 and AY.2 are less than 1% for all HHS Regions and nationally
  - Alpha (B.1.1.7) decreasing in all Regions
    - Less than 1% in each Region

- Gamma (P.1)
  - Decreasing in all HHS Regions
    - Less than 1% in each Region

Updated 08/14/2021

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
HHS Testing & Diagnostics Working Group (TDWG)

Discussion with Jasmine Chaitram & Clinical Laboratories

AUGUST 23, 2021
Agenda

1. Overview of HHS TDWG
2. Short-term: supply readiness approach
3. Short-term: surge response capabilities
4. Long-term: future preparedness strategies
During the course of COVID-19 pandemic, USG has adapted its investment and support strategies to expand testing capacity

Support test development
- Invested in testing technology
- Focus of innovation has shifted overtime as technologies authorized

Scale up manufacturing
- Funded industrial base expansion to provide capital and physical infrastructure to increase production capacity

Respond to new market signals
- Monitored supply chain and demand signals and solved crucial issues through various USG levers (e.g., Supply Chain Areas of Interest)

Broaden testing access
- Support programs to expand access to testing for in-need populations

The Testing & Diagnostics Working Group (TDWG) provides support for all aspects of testing strategies
TDWG's Mission:

Accelerate and support U.S. testing capacity through three broad efforts

Understand testing supply and demand
- Engage with industry, states, and various end users to understand supply & demand of current and future testing landscape

Manage USG efforts to expand testing capacity & access
- Purchase constrained testing supplies & services, make strategic investments, and increase testing access across the country

Communicate objectives, policies, and progress
- Manage communications to federal partners, industry contacts, and recipients to support USG testing initiatives
Agenda

1. Overview of HHS TDWG

2. Short-term: supply readiness approach

3. Short-term: surge response capabilities

4. Long-term: future preparedness strategies
TDWG’s Industry Engagement emerged as a critical function during COVID-19 to serve as USG's main lever to engage industry and project supply.

TDWG active engagement with industry...

- Manufacturers share data with TDWG monthly
- Monthly engagement with ~20 manufacturers and ad-hoc engagement with 20+ manufacturers
- Monthly engagement with 50% of commercial labs in addition to ad hoc
- Weekly engagement with APHL¹ to engage public health labs

... allows TDWG to monitor testing supply chain

Supply projections

Inventory level projections

Data enables risk monitoring, roadblock removal, and capacity investments if needed

1. The Association of Public Health Laboratories
Agenda

1. Overview of HHS TDWG
2. Short-term: supply readiness approach
3. Short-term: surge response capabilities
4. Long-term: future preparedness strategies
In addition to supply readiness, TDWG directly supports states and jurisdictions on surge testing needs

**Testing Programs**

**Increasing Community Access to Testing (ICATT):**
- Provides no-cost testing to underserved populations
- Operates in pharmacies, schools, surge & pop-up sites, hot spots, and priority surveillance locations

**Operation Expanded Testing (Op ET):**
- Expands testing capacity in K-8 schools and underserved congregate settings
- Manages testing through regional "testing hubs"

**Procurement & Distribution**

**Provision of Testing Supplies**
- Purchases and stores constrained (BinaxNOW™) or novel (Cue & Ellume) supplies and distributes to target groups

**Federal Supply Schedule (FSS):**
- Supports the addition of tests to the FSS

**Supply Exchange:**
- Offers a forum for organizations to ask for or offer up testing supplies
TDWG surge levers support response across testing value chain

<table>
<thead>
<tr>
<th>Levers</th>
<th>Upstream Supply</th>
<th>Test Supply</th>
<th>Sample Collection</th>
<th>Test Processing</th>
<th>Result Reporting</th>
<th>Ops/Decision Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICATT</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>OpET</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provision of Testing Supplies</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply Exchange</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

TDWG can support surge scenarios by...

- Procuring and distributing supplies
- Facilitating testing implementation
- Supporting coordination and logistics

Core objective

Addresses need as part of broader program
TDWG supporting more than 12 states in surge testing response

<table>
<thead>
<tr>
<th>State</th>
<th>ICATT: New pharmacy sites</th>
<th>ICATT: Pharmacy sites adding POC capability</th>
<th>ICATT: Pharmacy sites expanding hours</th>
<th>Op ET enrollment</th>
<th>Purchase of BinaxNOW from FSS</th>
<th>Cue Procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Arkansas</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorado</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Florida</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Georgia¹</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Louisiana</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missouri</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Mexico</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oklahoma</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Texas</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Support in Atlanta  2. Community testing sites through CVS
Agenda

1. Overview of HHS TDWG
2. Short-term: supply readiness approach
3. Short-term: surge response capabilities
4. Long-term: future preparedness strategies
Major levers of future preparedness include long-term capacity increase, run-rate increase, and inventory coverage.

![Illustrative framework of pandemic testing supply & demand](image)

- **Long-term capacity increase**: Based on investments into industry capacity (eg, IBx)
- **Run rate increase**: Generated by production throughput that can be mobilized rapidly (eg, warm base)
- **Immediate inventory coverage**: Enabled by immediate availability of stock (eg, stockpiling)
Definitions of future preparedness levers

A. Long-term capacity increase
   Industrial Base Expansion (IBx)
   Government-funded investments to expand manufacturing capacity, reduce bottlenecks and reduce offshore manufacturing for supplies
   
   e.g. USG funds new facility for swab manufacturer in order to grow domestic supply

B. Run rate increase
   Warm base manufacturing
   Government purchases assurance of future capacity through support of facilities that enable rapid scale-up of production
   
   e.g. USG pays pipette tip manufacturer to maintain personnel and facilities to ensure readiness for immediate scale-up

C. Immediate inventory coverage
   Stockpiling
   Building reserves of critical supplies for future use, including both raw materials (e.g., resin, plastics, reagents) and finished goods (e.g., media, swabs, pipette tips, tests, instruments)

   e.g. USG owns reserves of test kits in case of a surge in demand, either stored by the USG or by a manufacturer (vendor-managed inventory)
Current issues impacting testing supply and demand

SUPPLY
While no imminent supply chain risks, monitoring signals on specific materials (eg, semiconductors) and their potential impact on testing supply

DEMAND
Demand increasing due to variant surge; issues related to test type preferences (eg, POC tests) and access (eg, coverage model)
FDA Update

Tim Stenzel
U.S. Food and Drug Administration (FDA)
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