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**
  - Dean Winslow, U.S. Department of Health and Human Services (HHS) Testing and Diagnostics Working Group (TDWG)
- **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.

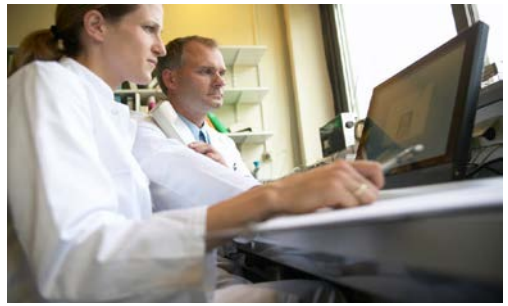
Four Goal Areas of DLS

Quality Laboratory Science

Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance

Highly Competent Laboratory Workforce

Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

Enhance the safety and response capabilities of clinical and public health laboratories

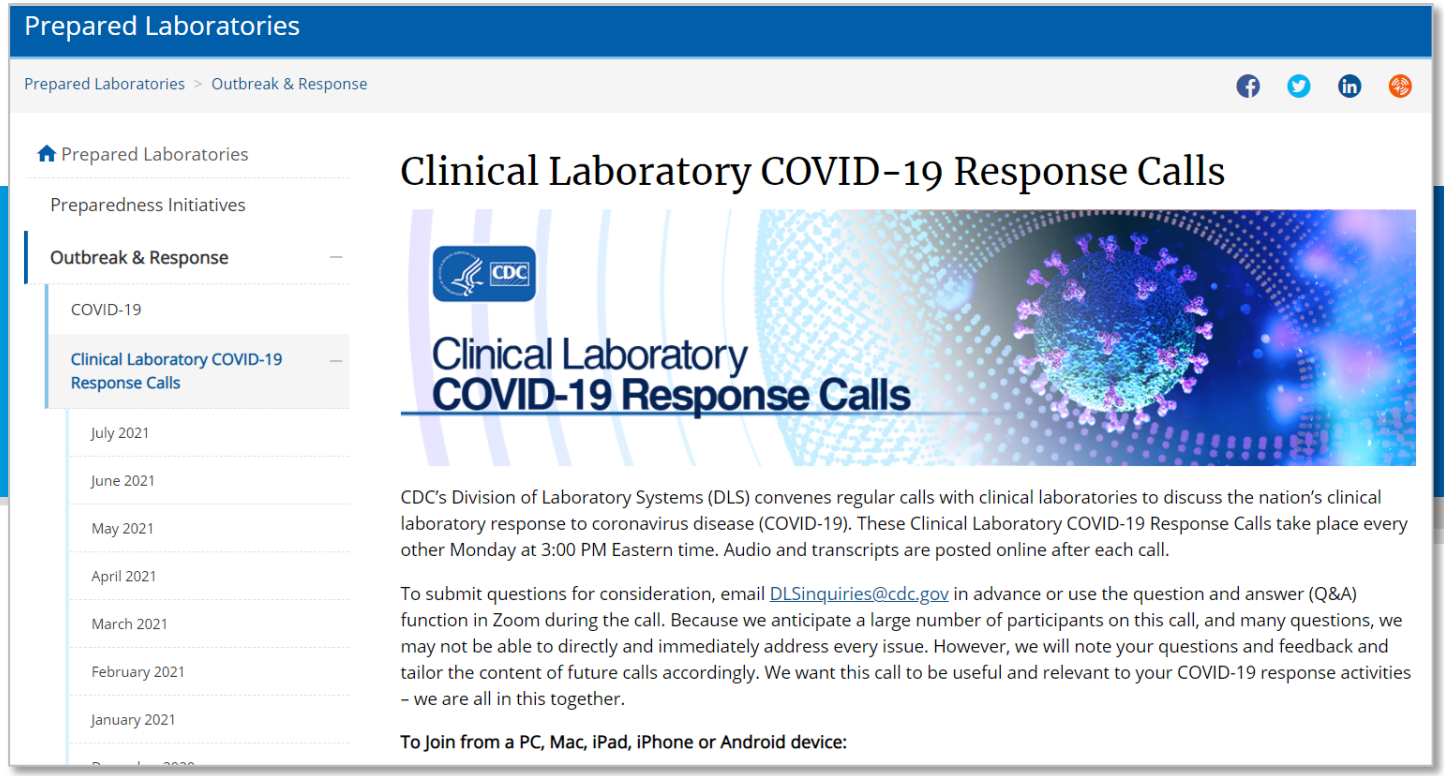
Accessible and Usable Laboratory Data

Increase access and use of laboratory data to support response, surveillance, and patient care

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



Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, September 20**

from **3:00 PM to 4:00 PM EDT**

We Want to Hear from You!

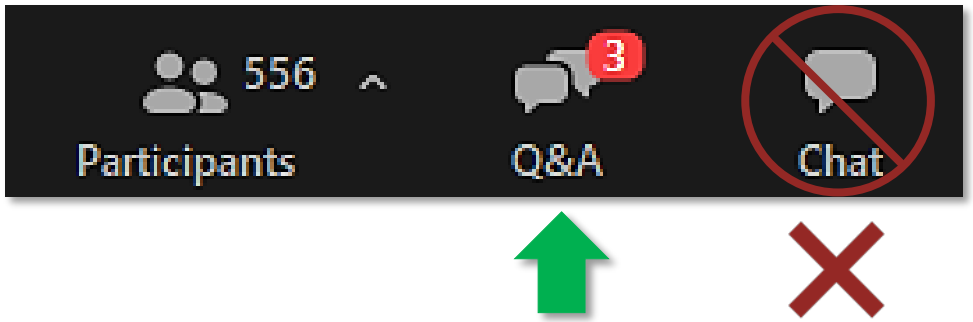
Training and Workforce Development

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



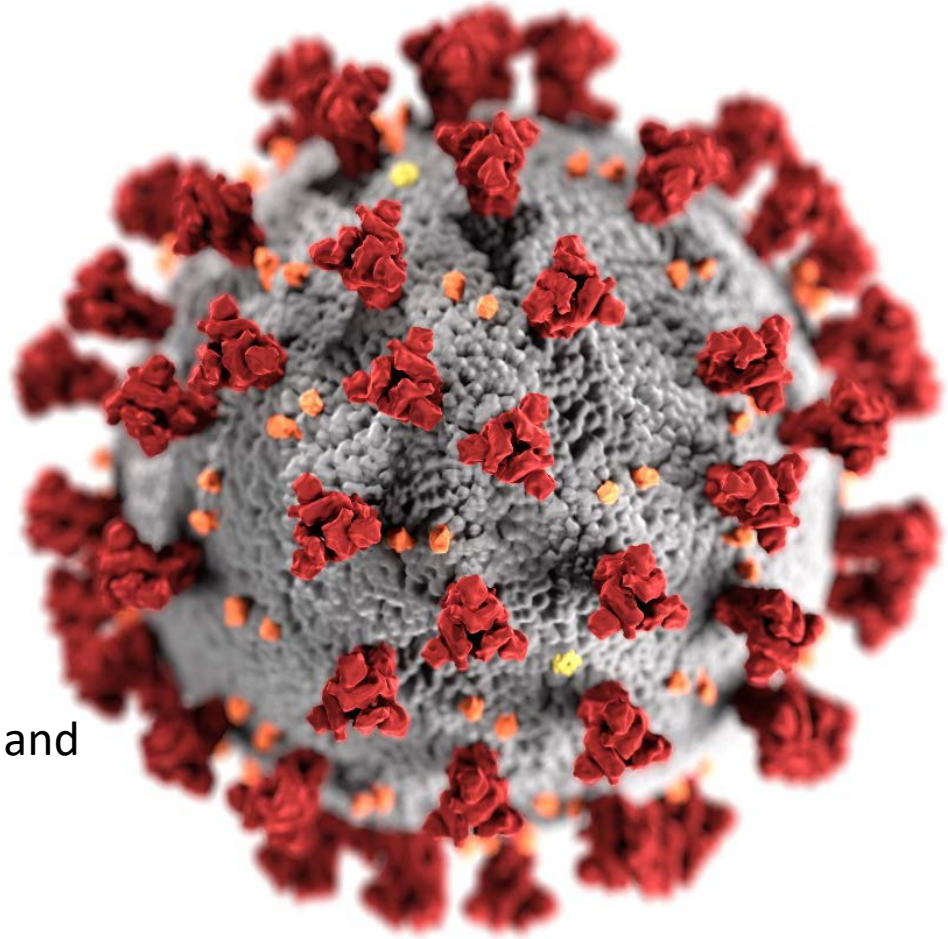
- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

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

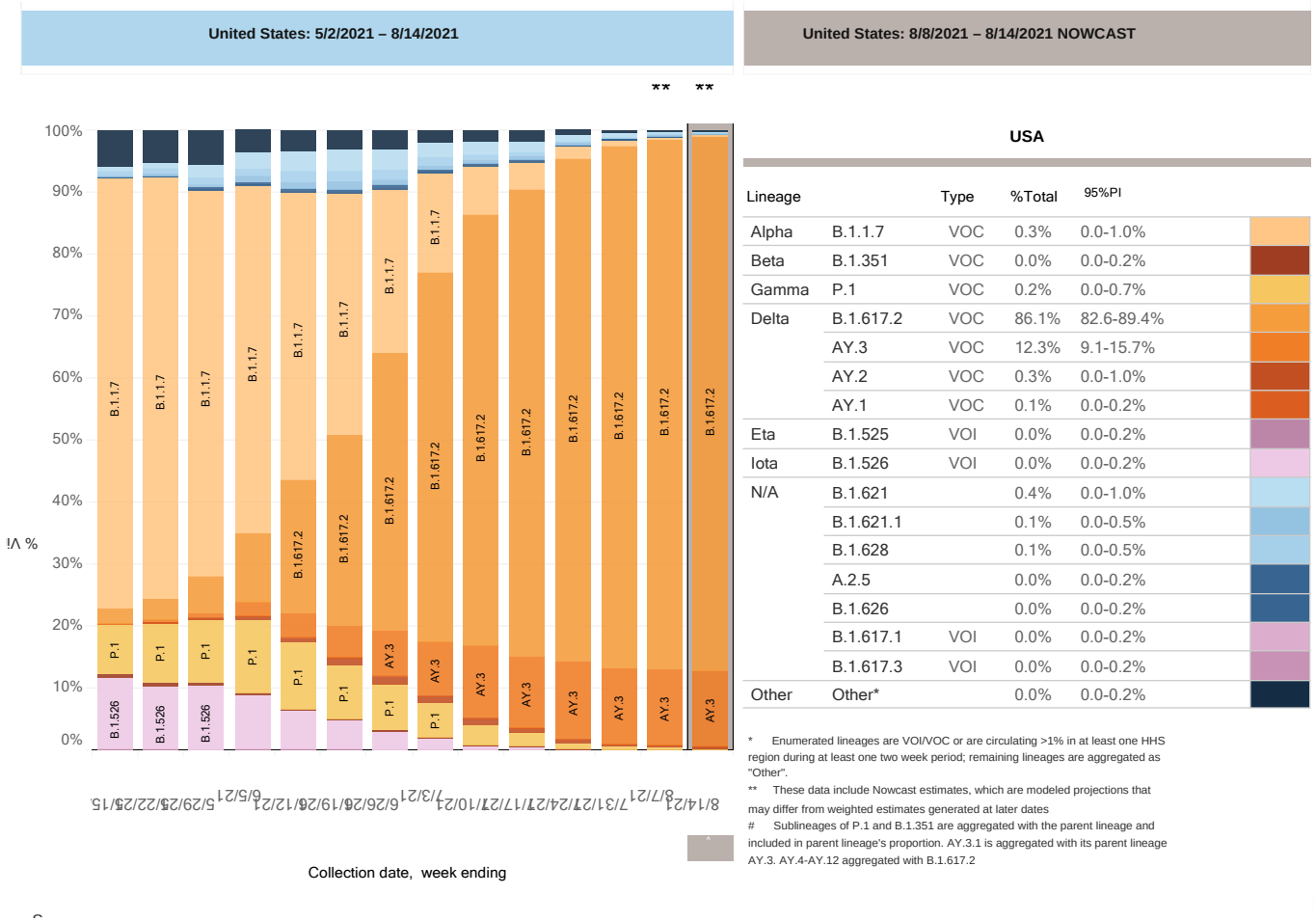


Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.

cdc.gov/coronavirus

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



USA

Lineage		Type	%Total	95%PI
Alpha	B.1.1.7	VOC	0.3%	0.0-1.0%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	0.2%	0.0-0.7%
Delta	B.1.617.2	VOC	86.1%	82.6-89.4%
	AY.3	VOC	12.3%	9.1-15.7%
	AY.2	VOC	0.3%	0.0-1.0%
	AY.1	VOC	0.1%	0.0-0.2%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.0%	0.0-0.2%
N/A	B.1.621		0.4%	0.0-1.0%
	B.1.621.1		0.1%	0.0-0.5%
	B.1.628		0.1%	0.0-0.5%
	A.2.5		0.0%	0.0-0.2%
	B.1.626		0.0%	0.0-0.2%
	B.1.617.1	VOI	0.0%	0.0-0.2%
	B.1.617.3	VOI	0.0%	0.0-0.2%
Other	Other*		0.0%	0.0-0.2%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

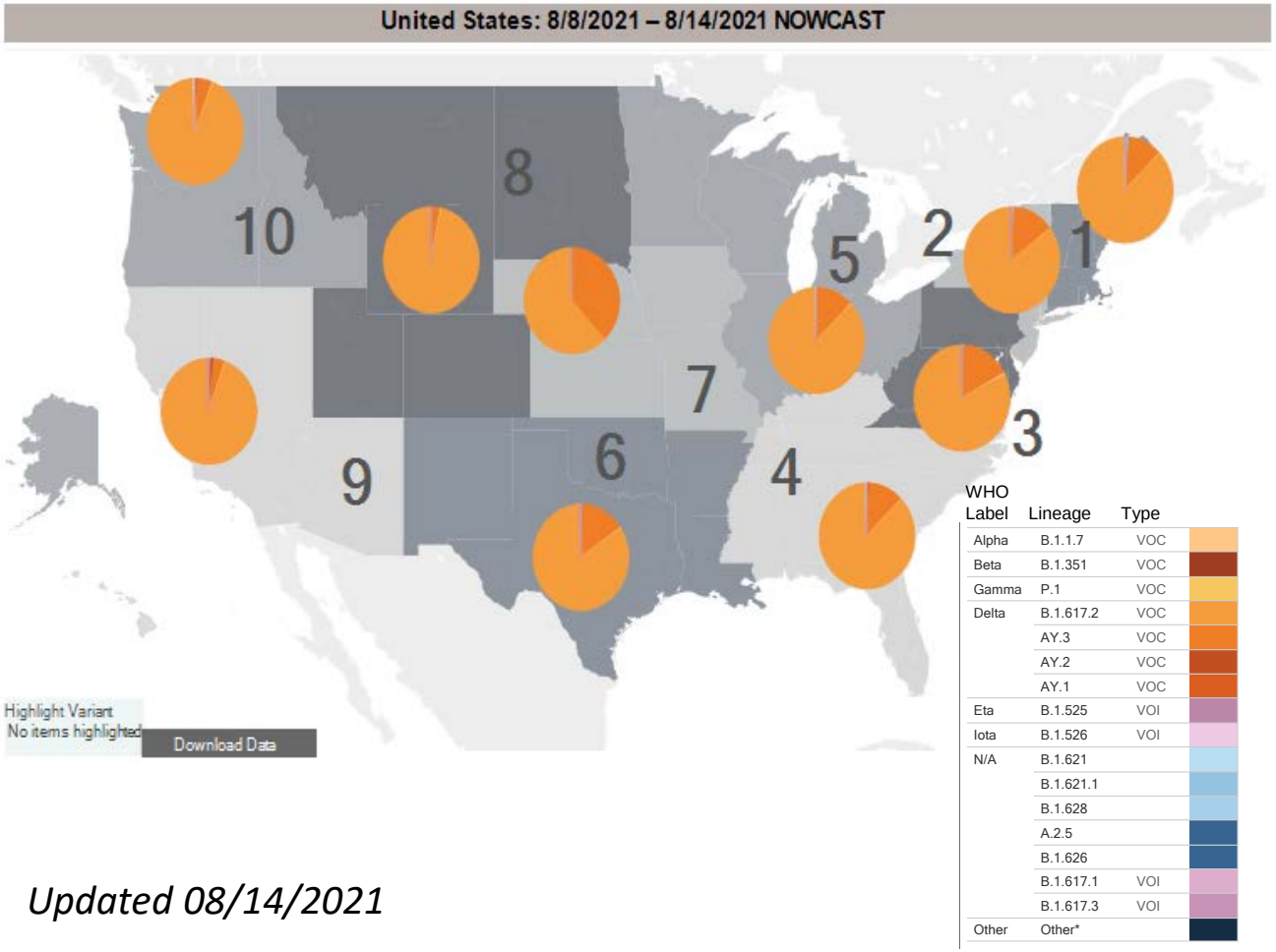
Sublineages of P.1 and B.1.351 are aggregated with the parent lineage and included in parent lineage's proportion. AY.3.1 is aggregated with its parent lineage AY.3. AY.4-AY.12 aggregated with B.1.617.2

[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

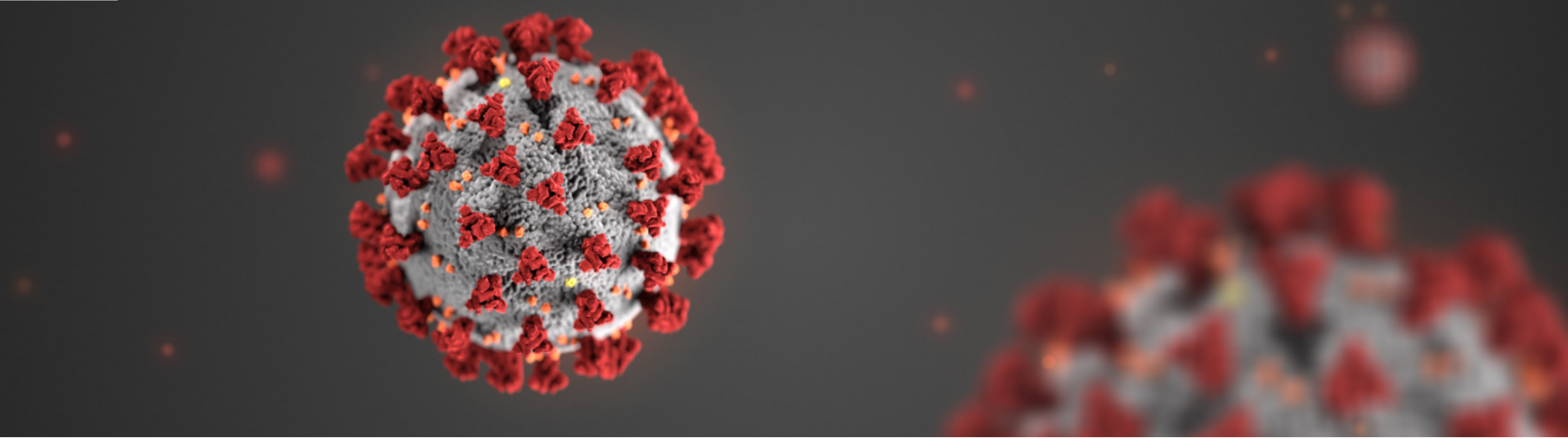
Regional Nowcast Proportion of SARS-CoV-2 Lineages

- 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



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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

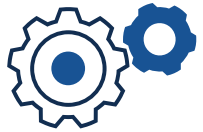
Support test development

Invested in testing technology

Focus of innovation has shifted overtime as technologies authorized

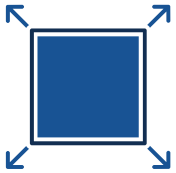
Scale up manufacturing

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

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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…

>90%

of the testing market share

- Manufacturers share data with TDWG monthly
- Monthly engagement with ~20 manufacturers and ad-hoc engagement with 20+ manufacturers

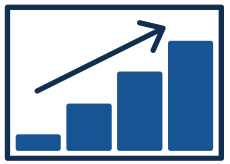
~10

Commercial labs

- Monthly engagement with 50% of commercial labs in addition to ad hoc
- Weekly engagement with APHL[1] 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

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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

TDWG can support surge scenarios by…

		Procuring and distributing supplies		Facilitating testing implementation		Supporting coordination and logistics	
	Levers	Upstream Supply	Test Supply	Sample Collection	Test Processing	Result Reporting	Ops/Decision Support
Testing Programs	**ICATT**	✓	✓	✓	✓	✓	
	OpET	✓	✓	✓	✓	✓	
Procurement & Distribution	**Provision of Testing Supplies**	✓	✓				
	FSS		✓				
	Supply Exchange	✓	✓				✓

✓ *Core objective*

✓ *Addresses need as part of broader program*

TDWG supporting more than 12 states in surge testing response

State	ICATT: New pharmacy sites	ICATT: Pharmacy sites adding POC capability	ICATT: Pharmacy sites expanding hours	Op ET enrollment[2]	Purchase of BinaxNOW from FSS	Cue Procurement
Arizona	✓	✓	✓		✓	
Arkansas	✓	✓	✓	✓		
California				✓	✓	✓
Colorado						✓
Florida	✓	✓	✓		✓	✓
Georgia[1]	✓ [2]					
Louisiana	✓	✓				✓
Missouri	✓	✓		✓		
Nevada	✓	✓	✓	✓		
New Mexico		✓				
Oklahoma	✓	✓	✓		✓	
Texas	✓					

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

Agenda

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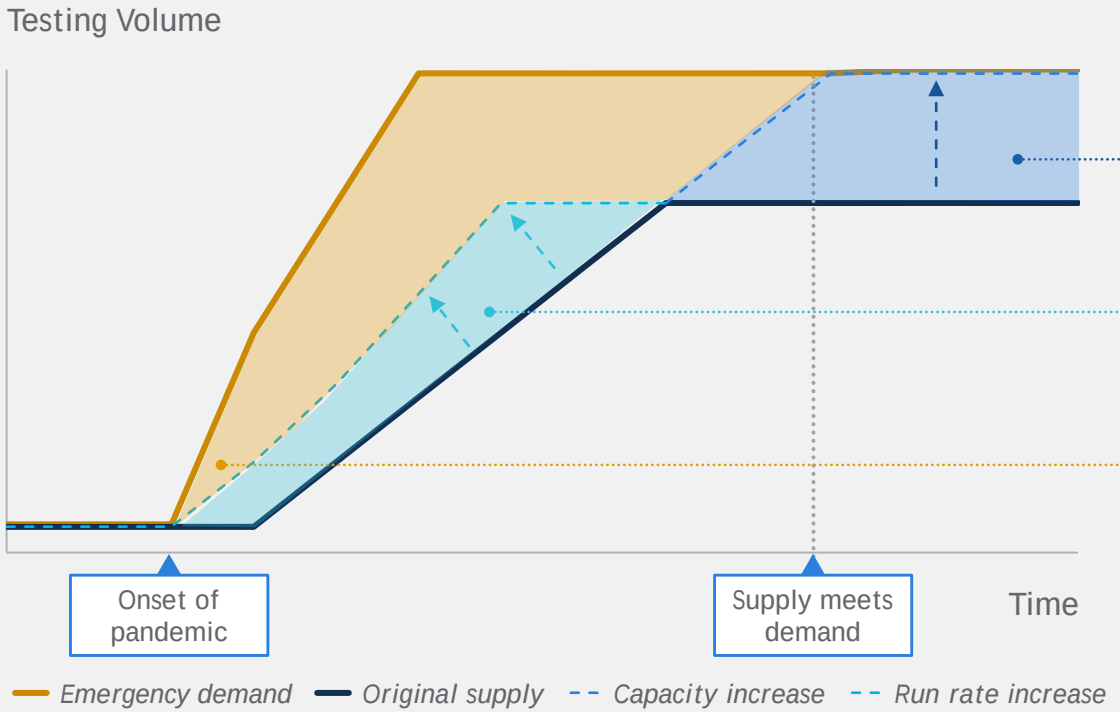
Major levers of future preparedness include long-term capacity increase, run-rate increase, and inventory coverage

Framework to map supply, demand, and levers

Illustrative framework of pandemic testing supply & demand



Supply levers for future preparedness

A **Long-term capacity increase**
Based on investments into industry capacity (eg, IBx)

B **Run rate increase**
Generated by production throughput that can be mobilized rapidly (eg, warm base)

C **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!

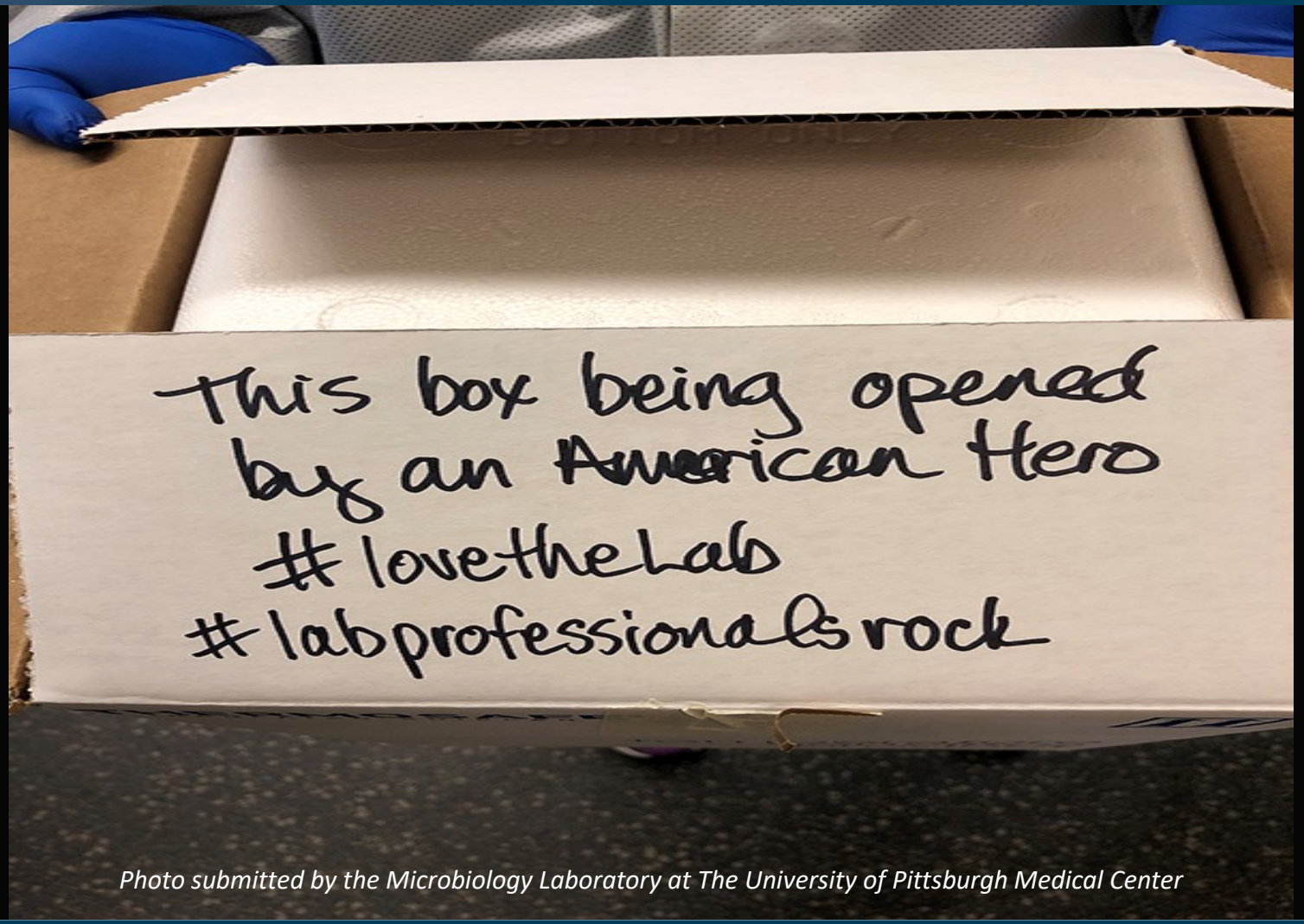


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center