Clinical Laboratory COVID-19 Response Call

Monday, June 27, 2022, at 3:00PM ET

- **Welcome**
  - Sean Courtney, Division of Laboratory Systems, CDC
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, Division of Viral Diseases, CDC
- **Pneumatic Tube Transport Guidance Update**
  - Alicia Branch, Division of Laboratory Systems, CDC
- **FDA Update**
  - Tim Stenzel, US Food and Drug Administration (FDA)
- **Monkeypox Testing Update**
  - Wendi Kuhnert, Monkeypox Response, CDC
- **Monkeypox Biosafety Update**
  - Alicia Branch, Division of Laboratory Systems, CDC

About 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.

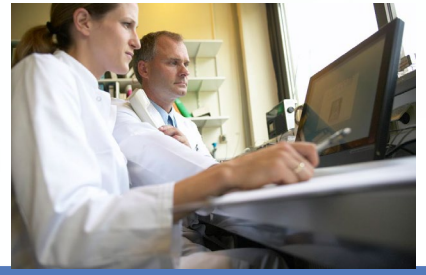
Four Goal Areas

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

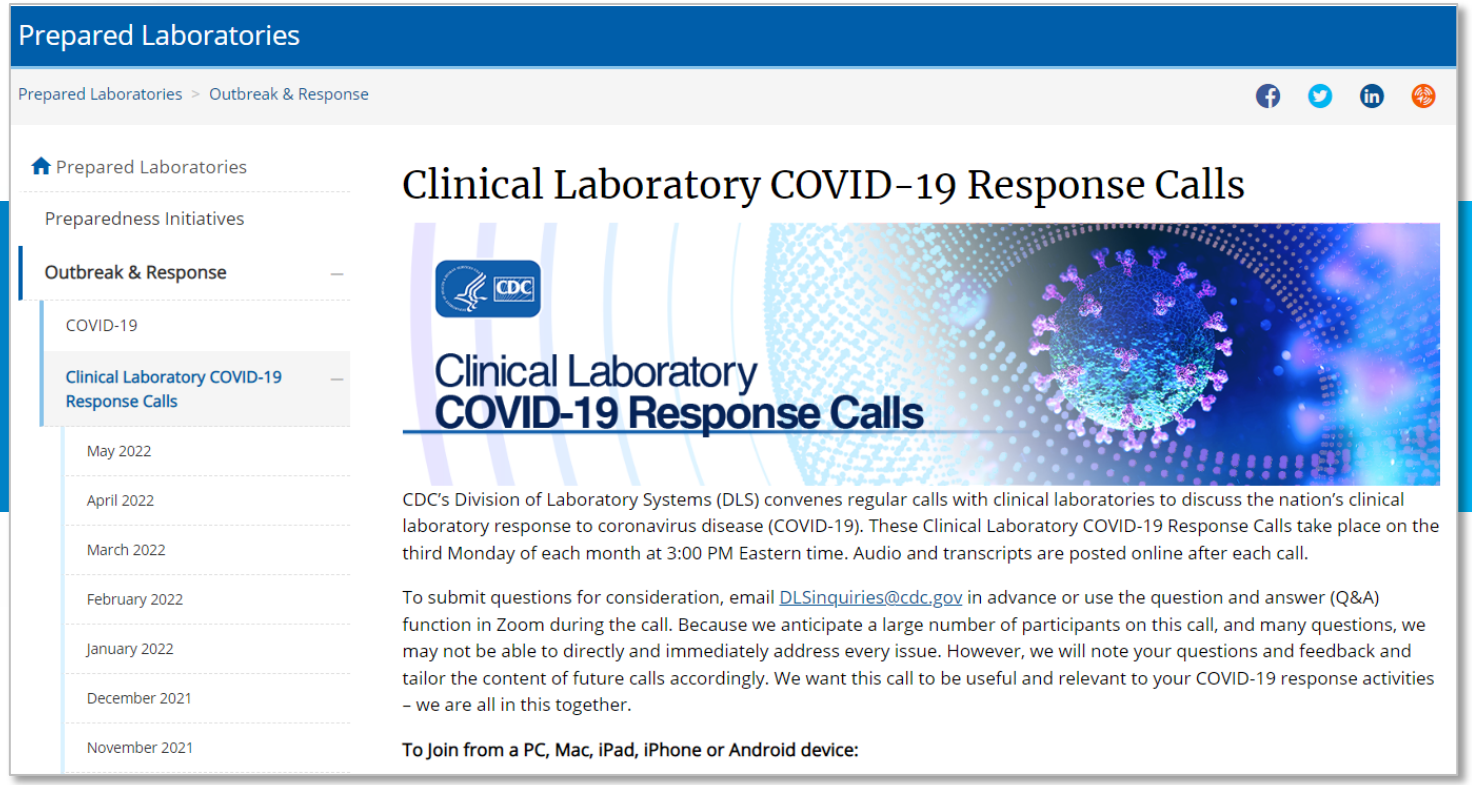
Accessible and Usable Laboratory Data

- 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 this page



Next Scheduled Call

The next call will be on

Monday, July 18 @ 3:00 PM to 4:00 PM ET

We Want to Hear From You!

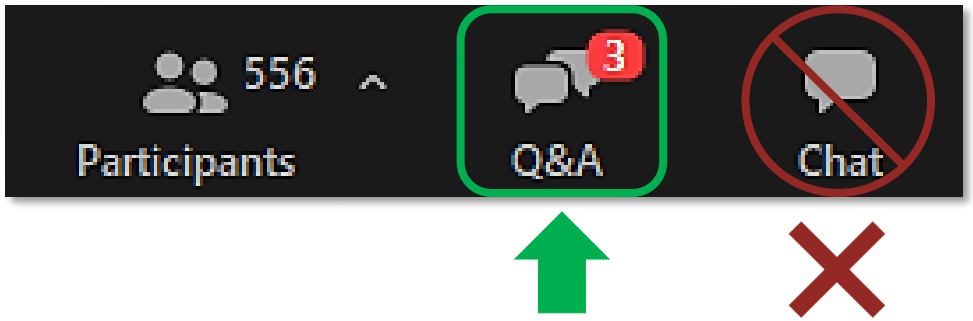
Training and Workforce Development

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.

SARS-CoV-2 Variants Update

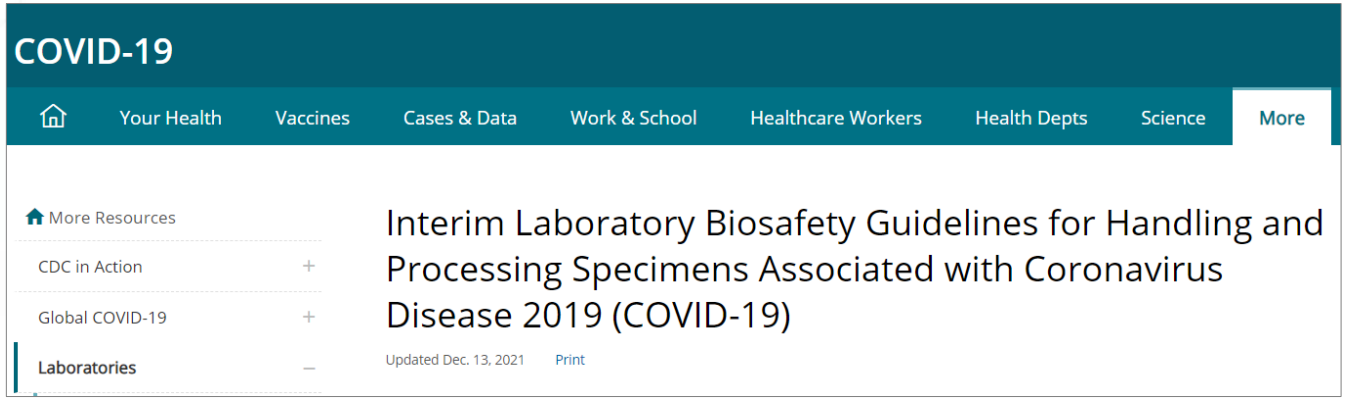
Natalie Thornburg
Division of Viral Diseases, CDC

Pneumatic Tube Transport Guidance Update

Alicia Branch
Health Scientist Safety Specialist
Quality and Safety Systems Branch
Division of Laboratory Systems, CDC

General Biosafety Guidance

- Follow Standard Precautions
- Implement biosafety practices
- Conduct a risk assessment before using the pneumatic tube system



Interim Guidelines for Biosafety and COVID-19 | CDC

Site-specific and Activity-specific Risk Assessment Process

- The specimen type and any known hazards associated with the specimen
- Identify the hazards involved in the process, such as the specimen carrier and specimen container
- The competency level of the personnel using the pneumatic tube system and the specimen type
- Adherence to any manufacturer quality and recommendations and the facility design

Biological Risk Assessment: General Considerations for Laboratories | CDC | DLS

Resources

- Biological Risk Assessment: General Considerations for Laboratories, Centers for Disease Control and Prevention (CDC), 2021

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, Section II – Biological Risk Assessment, pages 9-20.

- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories MMWR, Supplement / Vol. 61 January 6, 2012

Thank you!

Monkeypox Testing Update

Wendi Kuhnert
Monkeypox Response, CDC

Monkeypox Biosafety Update

Alicia Branch
Health Scientist Safety Specialist
Quality and Safety Systems Branch
Division of Laboratory Systems, CDC

General Biosafety Considerations

- All current U.S. Monkeypox cases are associated with the West African clade.
- Laboratories should perform a site-specific and activity-specific risk assessment and follow standard, contact, and droplet precautions when handling clinical specimens.
- Limit the number of laboratory personnel working during the manipulation of monkeypox specimens.

Vaccination

- Personnel vaccinated within the past 3 years with the smallpox vaccine should perform laboratory work that involves handling lesion specimens processed for monkeypox virus testing.
- The smallpox vaccine is not recommended for personnel handling and processing routine clinical specimens (e.g., blood for CBC, urine for urinalysis) from monkeypox patients.
- When only unvaccinated personnel are available, a combination of personal protective equipment (PPE) and additional precautions should be used to reduce the risk of exposure.

Biosafety Level and Personal Protective Equipment (PPE)

- Manipulate suspected monkeypox virus specimens in a BSL-2 facility using BSL-3 practices.
- BSL-3 practices include but are not limited to:
  - N-95 respirator
  - Solid front gown with cuffed sleeves
  - Double gloves
  - Eye protection (safety glasses or snug fitted goggles), or
  - Face protection (face shield)
  - Use a Class II Biosafety Cabinet (BSC)

If Procedures Can Not Be Performed in a BSC

- Use a combination of PPE and additional precautions to provide a barrier between the specimen and laboratory personnel.
- Examples of additional precautions include:
  - Aseptic containment isolator
  - Centrifuge safety cup or sealed rotor
  - Benchtop splash shield

Biosafety Levels and Laboratory Procedures

- Routine diagnostic testing can be handled in a BSL-2 laboratory using standard BSL-2 practices, for example,
  - Validated extracted viral DNA for molecular analysis of extracted nucleic acid preparations
  - Specimens such as blood and urine from suspected monkeypox virus patients
- Clinical and diagnostic laboratories should not perform monkeypox virus culture-based testing as a routine diagnostic procedure.
- Only laboratories with a BSL-3 facility, validated virus culture protocol, and vaccinated staff should perform monkeypox virus culture-based testing.

Specimen Packing and Shipping

- Pack and ship as UN3373 Biological substance Category B, in accordance with the current edition of the U.S. Department of Transportation's (DOT) Transporting Infectious Substances Safely or International Air Transport Association (IATA) Dangerous Goods Regulations.

- Personnel should be trained based on their role-specific packing and shipping responsibility.

Decontamination and Waste Management

- Decontaminate using any U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant or any product on List Q with an emerging viral pathogen label claim. Some examples are:
  - Sodium hypochlorite wipes and ready-to-use spray
  - Hydrogen peroxide wipes and ready-to-use spray
- Package waste as UN 3291 Regulated medical waste (Monkeypox waste).
  - Treat and/or dispose of such waste in accordance with applicable state, local, tribal, and/or territorial laws and regulations for regulated medical waste.

Resources

- Dangerous Goods Regulations. International Air Transport Association (IATA), 63rd Edition
- Disinfectants Emerging Viral Pathogens. U.S. Environmental Protection Agency (EPA), 2022
- Emerging Viral Pathogens Policy. U.S. Environmental Protection Agency, 2022
- Managing Solid Waste Contaminated with a Category A Infectious Substance. U.S. Department of Transportation (DOT), 2022
- Monkeypox. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), 2022.
- Standard, Contact, and Droplet Precautions. Transmission-Based Precautions, CDC, 2016
- Transporting Infectious Substances Safely. DOT, 2022

Thank you!

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!

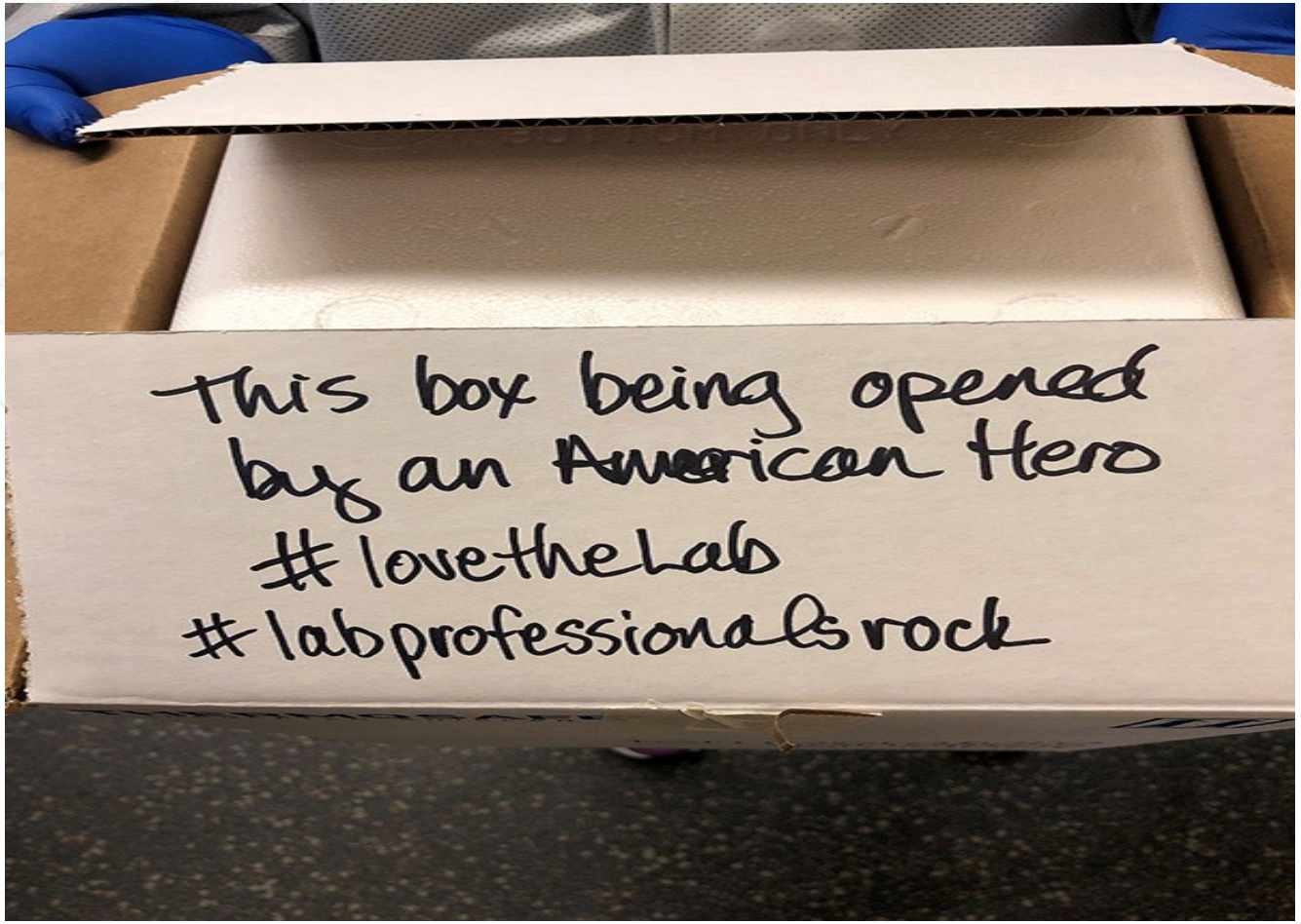


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center

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