Laboratory Outreach Communication System (LOCS) Call

Monday, March 20, 2023, at 3:00 P.M. EDT

- **Welcome**
  - Sean Courtney, CDC Division of Laboratory Systems
- **Marburg Virus Disease Update**
  - Joel Montgomery, CDC Division of High Consequence Pathogens and Pathology
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, CDC Coronavirus and Other Respiratory Viruses Division
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration
- **Use of Laboratory Preparedness Exercise (LPX) to Assess Rule-Out/Referral Capability of Clinical Laboratories**
  - Chris N. Mangal, Association of Public Health Laboratories

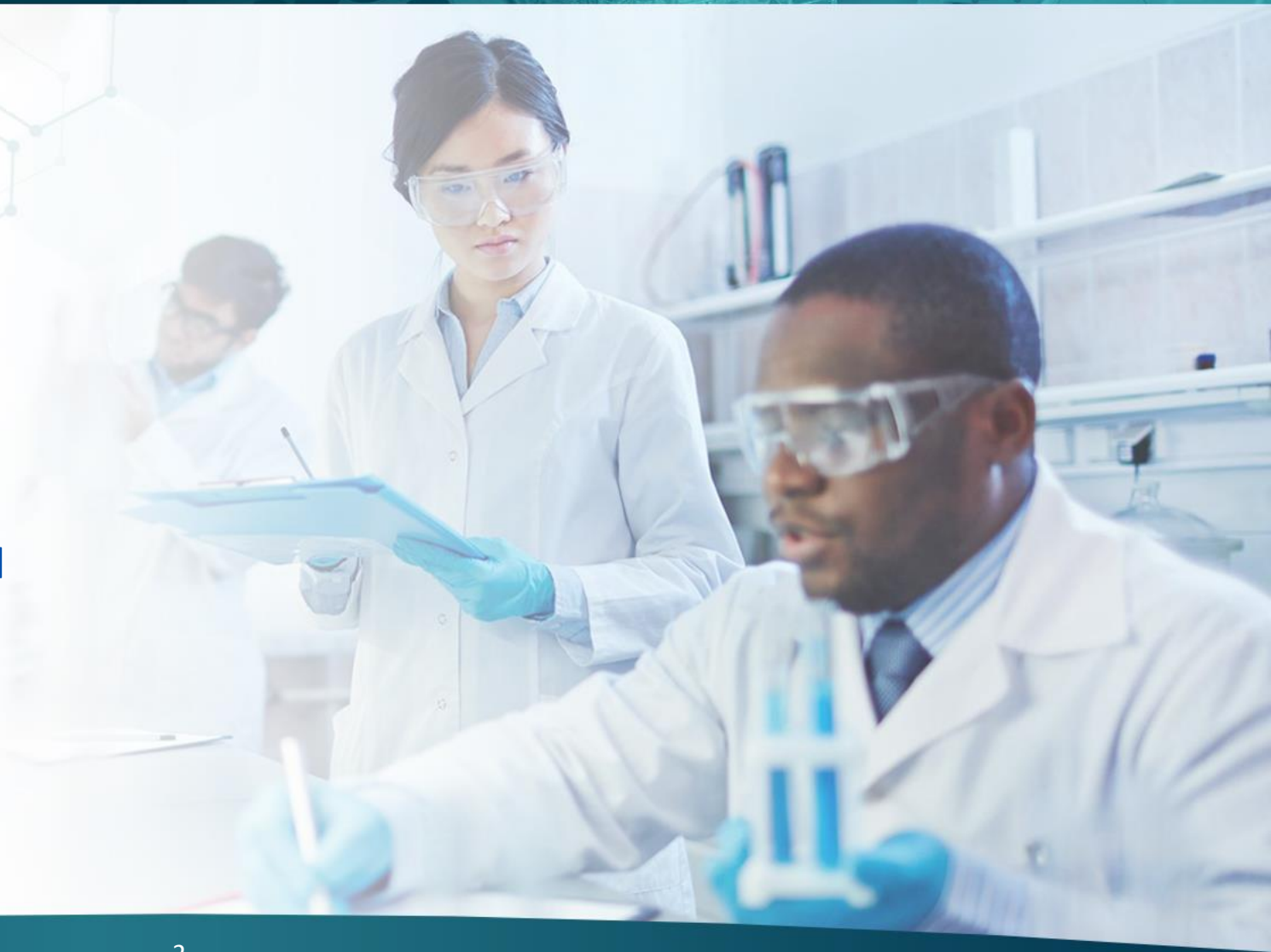
About DLS

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.



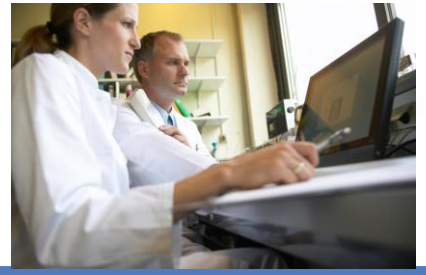
Four Goal Areas

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

CLIAC 2023 Spring Meeting

April 12-13, Virtual Meeting

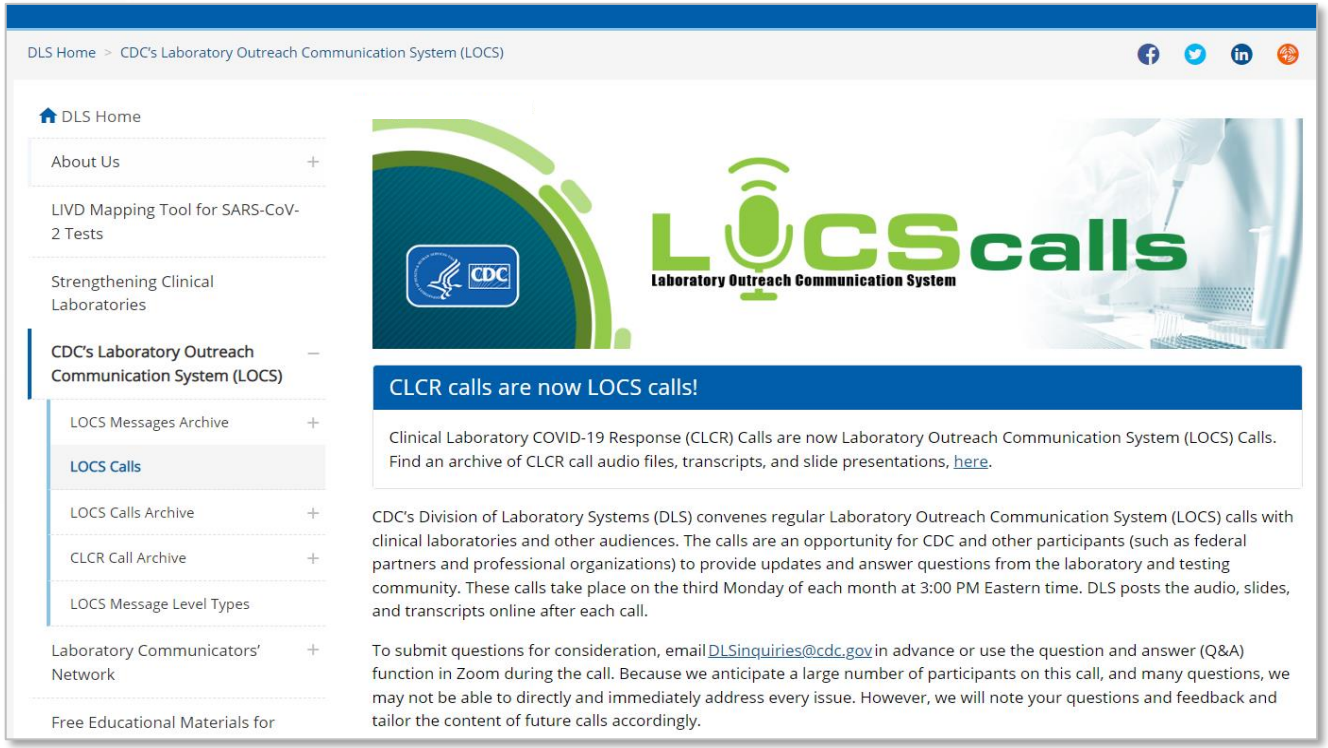
- Register for the meeting and save the date on CDC's CLIAC website
- Send oral and written comments to CLIAC@cdc.gov by Monday, April 10, 2023
- Topics include:
  - CLIA Regulations Assessment Workgroup Report
  - CLIA Certificate of Waiver and Provider-performed Microscopy Procedures Workgroup Report
  - The Laboratory's Role in Advancing Health Equity

https://www.cdc.gov/cliac/upcoming-meeting.html

LOCS Calls

https://www.cdc.gov/locs/calls

Find LOCS Call information, transcripts, and audio recordings on this page



We Want to Hear From You!

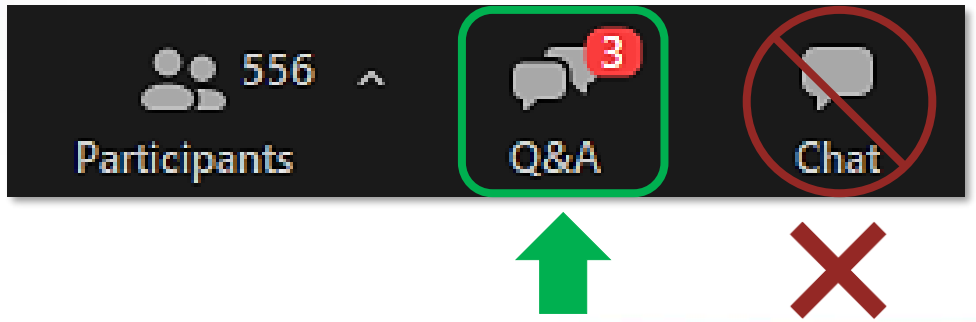
Training and Workforce Development

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.

Marburg Virus Disease Update

Joel Montgomery
CDC Division of High Consequence Pathogens and Pathology

SARS-CoV-2 Variants Update

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FDA Update

Timothy Stenzel
U.S. Food and Drug Administration

Use of Laboratory Preparedness Exercise (LPX) to Assess Rule-Out/Referral Capability of Sentinel Clinical Laboratories

Chris N. Mangal, MPH, Director, Public Health Preparedness and Response

CDC Laboratory Outreach Communication System (LOCS) Call

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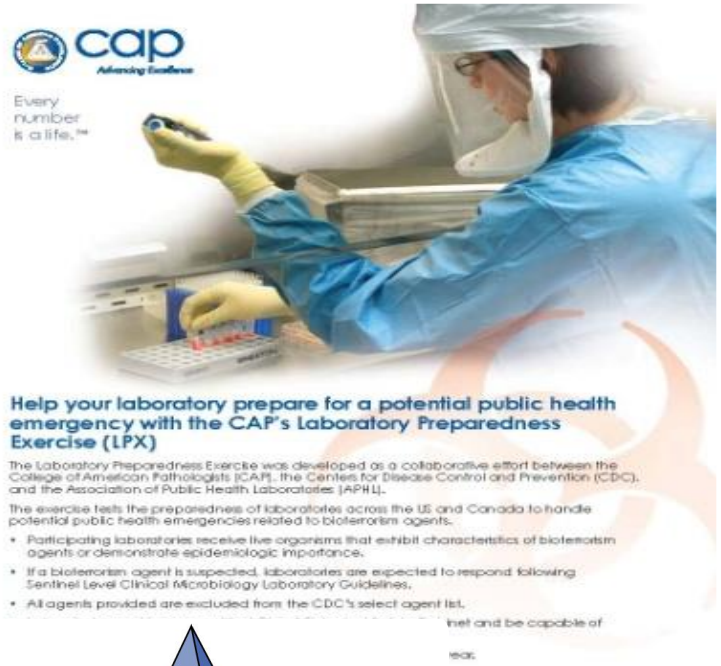
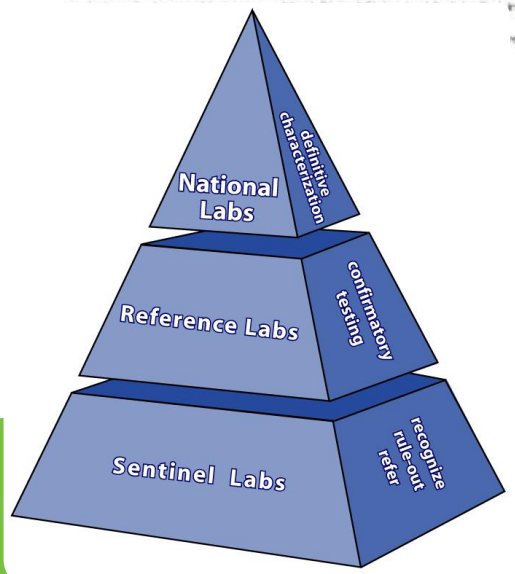




Laboratory Preparedness Exercise (LPX): History

- First issued by the College of American Pathologists (CAP) in 2003
- Needed tool to assess sentinel laboratory preparedness
- Concerns
  - Use of Photomicrographs
  - Choice of Organisms (e.g., fungus)
  - Final Critique did not reference Laboratory Response Network (LRN) Sentinel Level Clinical Laboratory Protocols
  - Notification of LRN Reference Laboratory (e.g., PHLs) Not Required
  - Terminology of Survey (seen as proficiency) – changed to Exercise in 2008

APHL Partnership with CAP and CDC

APHL	CAP	CDC
• Serves as main contact for PHLs • Provides subject matter expertise • Provides guidance to PHLs on the exercise and outreach to sentinel labs • Via the Public Health Preparedness and Response Committee, Sentinel Laboratory Partnerships and Outreach Subcommittee, provides input on the selection of organisms, reviews kit instructions, results forms and critiques • Provides educational webinars/other information to laboratories	• Through the Microbiology Committee, provides operational oversight for the LPX • Conducts and administers the exercise • Analyzes and publishes summary results • Shares data of pre-authorized sentinel lab results with APHL • Creates public announcements and leads in promotion and communication	• Provides technical assistance for issues related to content of the exercise shipments • Provides subject matter expertise • Ensures accuracy of the organisms • Provides antimicrobial susceptibility testing • Ensures safety of the organisms

MOU in place since 2006

Goals of the LPX

- Serves as an Educational Exercise
- Tests most aspects of lab BT response
  - Rule-out and refer using ASM sentinel protocols
  - Notification of nearest LRN Reference Lab
  - Appropriate packaging and shipping
  - Safe handling of organisms
- Assists LRN Reference Laboratories with:
  - Identifying gaps in preparedness
  - Revising training programs to address sentinel lab needs
  - Testing ability of sentinel labs to package and ship; assessing internal surge capacity*

Must have a certified Class II Biological Safety Cabinet in order to participate in this exercise

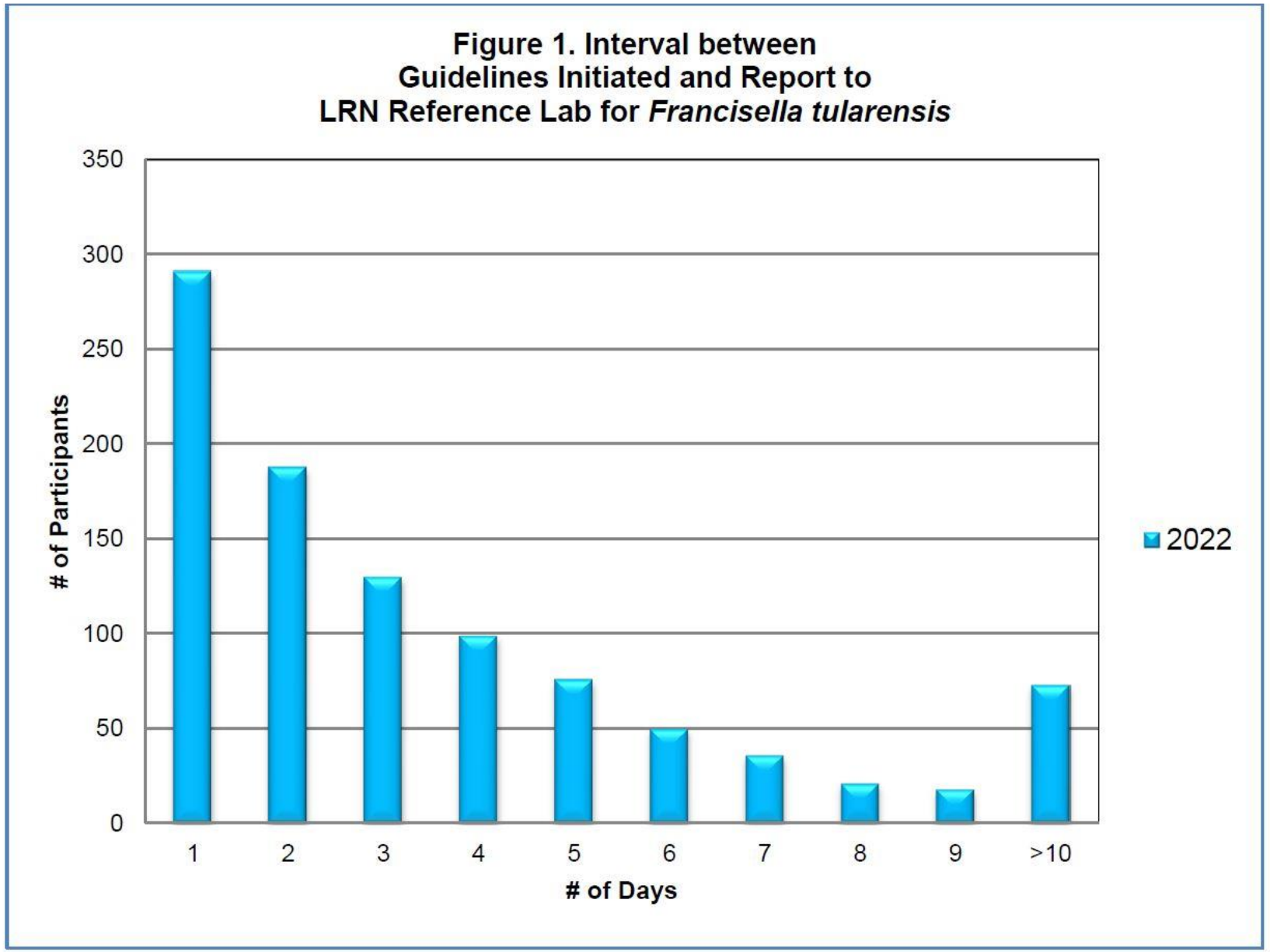
More about the LPX

- Biannual exercise, typically shipped in April and September to ~1,200 laboratories
- For labs that subscribe to the LPX, CAP sends live organisms that either exhibit characteristics of bioterrorism agents or demonstrate epidemiologic importance
- Labs are expected to respond following ASM Sentinel Level Clinical Laboratory Protocols For Suspected Biological Threat Agents And Emerging Infectious Diseases
- All agents provided are excluded from the CDC's select agent list

Challenges

- Shift from the use of biochemicals to more automated systems
- Use of automated systems such as MALDI-TOF could result in an erroneous identification e.g., *Bacillus anthracis* misidentified as *B. cereus; Yersinia pestis* misidentified as *Y. pseudotuberculosis*
- Safety: "*If automated systems, including MALDI-TOF mass spectrometry, are used, then extreme caution should be taken, as there is the potential risk for laboratory exposure by aerosolization or direct contact. If your laboratory uses MALDI-TOF for organism identification, the ASM LRN Sentinel Level Clinical Laboratory Protocols recommends that the specimen be prepared using a tube extraction method. The resulting extract should be filtered through a 0.2 µ (or less) filter prior to mass spectroscopy*.
- Communications: not contacting LRN Reference Laboratory (PHL) within a designated timeframe

Communications



Resources

- CAP: LABORATORY PREPAREDNESS EXERCISE-LPX (cap.org)
- ASM: LRN Sentinel Level Clinical Laboratory Protocols (asm.org)
- CDC: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratory Portal | CDC
- APHL:
  - Definition of Sentinel Clinical Laboratories (aphl.org)
  - Biothreat Agents Identification Bench Cards for Sentinel Laboratories (For Print) (aphl.org)
  - Biothreat Agent Poster (aphl.org)
  - Clinical Laboratory Preparedness and Response Guide (aphl.org)

Contact

Chris N. Mangal, MPH (She/Her)
Director, Public Health Preparedness and Response
Association of Public Health Laboratories
P: 240.485.2769
E: chris.mangal@aphl.org

Next Scheduled Call

Monday, April 17
3 PM - 4 PM ET

CDC Social Media

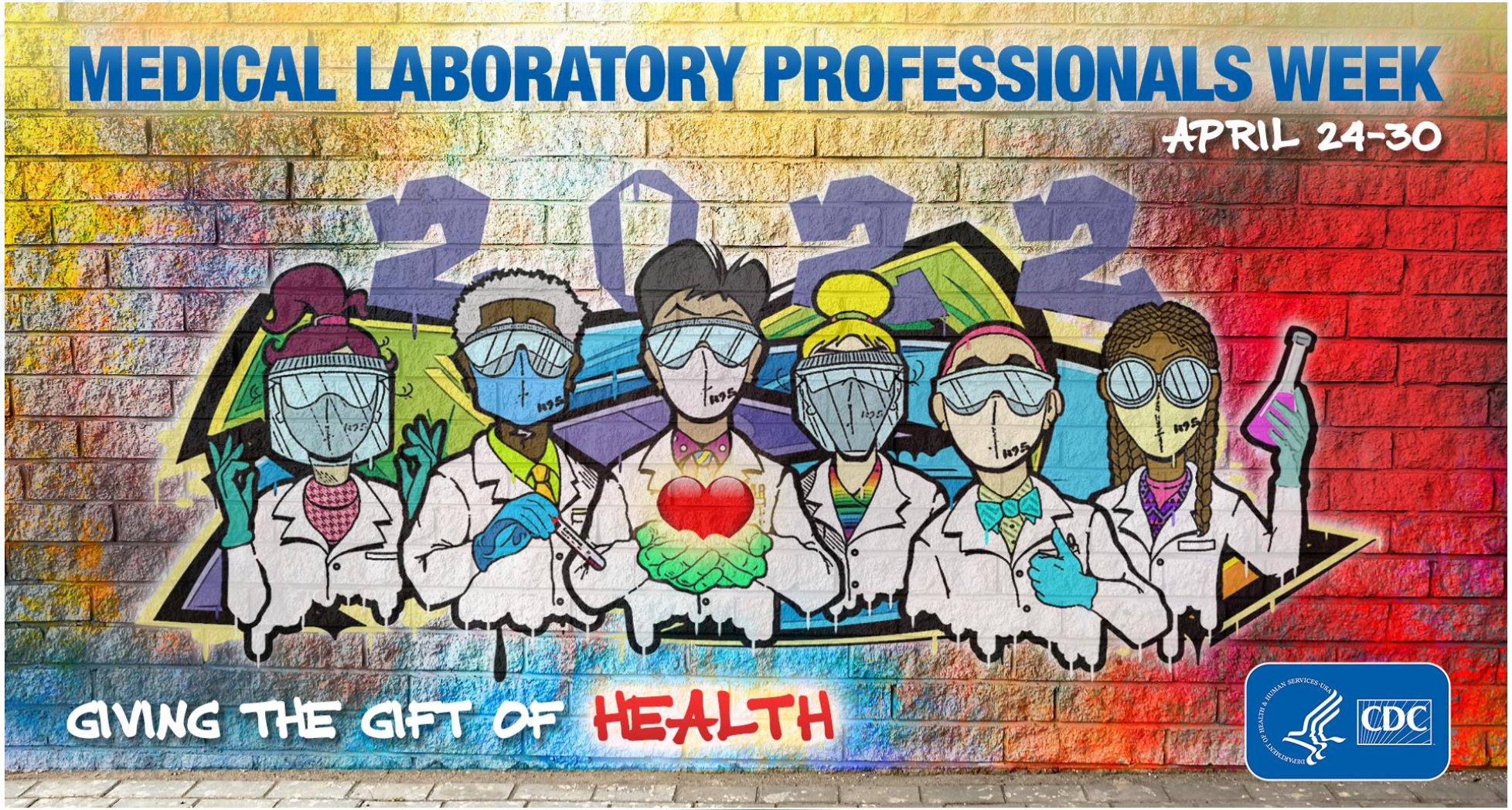
https://www.facebook.com/CDC

https://twitter.com/cdcgov

https://www.instagram.com/cdcgov

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

Thank You For Your Time!



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