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

• Opening Remarks
  – Dr. Robert Redfield, Director, CDC

• Supply Chain Update
  – Brad Smith, Centers for Medicare and Medicaid Services (CMS)
  – Tammy Beckham, U.S. Department of Health and Human Services (HHS)

• FDA Update
  – Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)

• Serology Testing Update
  – Chris Elkins and Vicki Olson, CDC Laboratory Task Force for the COVID-19 Response

• Maintaining Connections and Supporting Laboratories during the COVID-19 Pandemic
  – Kathy Nucifora, COLA
Opening Remarks

Dr. Robert Redfield
Director, CDC
CDC Information for Laboratories

• Interim Guidance for Collecting, Handling, and Testing Clinical Specimens

• Diagnostic Tools and Virus

• Emergency Preparedness for Laboratory Personnel
  https://emergency.cdc.gov/labissues/index.asp

• CDC's Laboratory Outreach Communication System (LOCS)
  https://www.cdc.gov/csels/dls/locs/

• IVD Industry Connectivity Consortium
  https://ivdconnectivity.org/livd/

• LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests
  https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html
Share Your Feedback!

Help us improve these calls by taking a short 5-minute survey!

Take the Survey Here:
https://www.surveymonkey.com/r/CLCR0601

Questions? Contact DLSinquiries@cdc.gov
We Want to Hear From You!

Training and Workforce Development

Questions about education and training?
Contact LabTrainingNeeds@cdc.gov
To Ask a Question?

- Using the 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.
Supply Chain Update

Brad Smith
Centers for Medicare and Medicaid Services (CMS)

Tammy Beckham
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

- COVID-19 Emergency Use Authorization (EUA) Information
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

- COVID-19 Frequently Asked Questions

- COVID-19 Updates

- FDA Townhall Meetings
Food and Drug Administration (FDA)

COVID-19 Diagnostic Development: CDRH-EUA-Templates@fda.hhs.gov

Spot Shortages of Testing Supplies: 24-Hour Support Available

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)
Serology Testing Update

Chris Elkins and Vicki Olson
CDC Laboratory Task Force for the COVID-19 Response
CDC Laboratory Task Force

• Interim Guidelines for COVID-19 Antibody Testing

• COVID-19 Emergency Use Authorization (EUA) Information
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

• EUA Authorized Serology Test Performance
Maintaining Connections and Supporting Laboratories During the COVID-19 Pandemic

Kathy Nucifora, MPH, MT(ASCP)
Chief Operating Officer, COLA

June 1, 2020
Laboratories have questions...we help them find answers

- Understanding Emergency Use Authorization
- Diagnostic testing vs. Antibody testing
- Availability of tests and associated supplies
- Upgrading from CLIA Certificate of Waiver to Certificate of Registration
- On-site survey delays
Connecting laboratories to resources

- Links to FDA FAQs and EUA information
- CMS guidance documents
- CDC website
- CDC weekly calls
- Laboratory Outreach Communication System (LOCS) alerts
- Webinars sponsored by laboratory professional organizations
COLA assistance

- Designated staff to respond to COVID-19 testing questions
- Technical bulletins and updates posted to customer portal
- Chat feature
- Pre-survey documentation review process
- “Soft launch” of surveys May 19
CDC Social Media

https://www.facebook.com/CDC
https://twitter.com/cdcgov
https://www.linkedin.com/company/cdc
Thank You For Your Time!

This box being opened by an American Hero

# love-the-lab
# lab-professionals-rock

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