Clinical Laboratory COVID-19 Response Call
Monday, August 31st, 2020 at 3:00 PM EDT

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

• AMP SARS-CoV-2 Molecular Testing Follow-up Survey
  – Robyn Temple-Smolkin, Association for Molecular Pathology (AMP)

• CMS Update—CLIA Rule for Reporting COVID-19 Test Results
  – Regina Van Brakle and Amy Zale, Centers for Medicare & Medicaid Services (CMS)

• Laboratory Training Update
  – Joe Rothschild, CDC Division of Laboratory Systems (DLS)

• FDA Update
  – Tim Stenzel, U.S. Food and Drug Administration (FDA)
The next call is scheduled for Monday, September 14th, 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
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 – be sure to include your email address so we can get back to you
  ▪ 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
Live Audience Poll
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
New COVID-19 Resources for Laboratories

• Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes

• New Antigen Testing Guidance

• New Additions to the Frequently Asked Question (FAQs) about COVID-19 for Laboratories
  – False Negatives and False Positives from COVID-9 Testing
  – Surveillance, Screening, and Diagnostic Testing for COVID-19
AMP SARS-CoV-2 Molecular Testing Follow-up Survey

Robyn Temple-Smolkin
Association for Molecular Pathology (AMP)
WE NEED YOUR HELP!
Take AMP’s **NEW** SARS-CoV-2 Molecular Testing Survey!

https://www.surveymonkey.com/r/AMPCV19Testing

Target Audience: laboratory professionals in clinical and public health labs offering SARS-CoV-2 molecular testing
CMS Update—CLIA Rule for Reporting COVID-19 Test Results

Regina Van Brakle and Amy Zale
Centers for Medicare and Medicaid Services (CMS)
DLS Laboratory Training Update

Joe Rothschild
Health Communication Specialist
CDC Division of Laboratory Systems

August 31, 2020
CDC just made it easier to find the right lab training course for you!

New search tool, active filters, and improved course page layouts

www.cdc.gov/labtraining
NOW LIVE

PACKING AND SHIPPING DANGEROUS GOODS:
What the Laboratory Staff Must Know

Division of Laboratory Systems
NOW LIVE

Available on
CDC TRAIN
and
STEAM®

cdc.gov/labtraining
Virtual Reality Laboratory Training

Public health emergencies demand the availability of diverse and effective distance-based education and training options for public health and clinical laboratory professionals. To keep pace with the evolving training needs, DLS has blended innovative technology and instructional design principles by adding Virtual Reality, or VR, to its laboratory training and workforce development toolbox.

VR offers laboratory professionals the opportunity to apply, assess, and improve their skills in a safe and controlled learning environment. In other words, VR simulations allow learners to make costly mistakes while learning new skills with no real-world consequences.

NOW AVAILABLE
COMING SOON

LAB TRAINING
BIOSAFETY CABINET EDITION

VERSION 2.0
NEW SCENARIOS & OBJECTIVES
VIDEO DEMO (01:06)

https://www.youtube.com/watch?v=Kmq_cBn_7Yk
COMING SOON

LAB TRAINING

PPE EDITION

LAB TRAINING

MULTIPLAYER LAB
SHARE YOUR TRAINING NEEDS

E-mail LabTrainingNeeds@cdc.gov
For more information, contact CDC 1-800-CDC-INFO (232-4636)  

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.
FDA Update

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

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

- COVID-19 In Vitro Diagnostic EUAs

- COVID-19 Frequently Asked Questions

- COVID-19 Updates

- FDA Townhall Meetings

- Independent Evaluations of COVID-19 Serological Tests
  https://open.fda.gov/apis/device/covid19serology/
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 (*)
Thank You For Your Time!

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