Clinical Laboratory COVID-19 Response Call
Monday, May 11th, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Lab Reporting to Government Health Agencies During a Pandemic**
  - Corrisa Miliander, Mayo Clinic Laboratories
- **State Reporting Requirements for COVID-19**
  - Janet Hamilton, Council of State and Territorial Epidemiologists (CSTE)
- **Laboratory Reporting Requirements**
  - Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
- **CLIA Updates**
  - Karen Dyer, Centers for Medicare and Medicaid Services (CMS)
- **Updated Policy for Serology Testing**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)
Share Your Feedback!

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

Take the Survey Here:
https://www.surveymonkey.com/r/CLCR0511

Questions? Contact DLSinquiries@cdc.gov
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/

• 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

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

• COVID-19 Information for Laboratories page:

• Interim Laboratory Biosafety Guidelines:

• Laboratory Biosafety Frequently Asked Questions:

Send inquiries to: DLSInquiries@cdc.gov
“We want to hear from you!”

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
  ▪ Submit your question
  ▪ Please do not submit a question using the chat button

• For media questions, please contact CDC Media Relations at media@cdc.gov.
Lab Reporting to Government Health Agencies During a Pandemic

Corrisa Miliander, Mayo Clinic Laboratories
Background

- Reporting lab findings for all Mayo Clinic sites
- Mayo Clinic Laboratories (MCL) performs testing for clients across all states
- Each state defines a list of reportable conditions
  - Specific reporting criteria for COVID-19 established in some states
  - COVID-19 reporting requirement falls under outbreak reporting in other states
How It’s Done

• New tests are established
  • New rules established in Reportable Disease application

• Transmissions are set up with each state agency:
  • Electronic Laboratory Reporting (ELR)
  • Fax Reporting
COVID Reporting Issues

- Prioritized test implementation
- State reporting requirements
- Frequency of reporting
- ELR vs. other reporting options
- New partnerships cause new challenges
COVID-19 Opportunities

- Missing patient demographics/information on lab orders
- Onboard ELR for remaining state agencies
  - DLMayoELRTeam@mayo.edu
- Standardization
- Continuing teamwork

Number of Transmissions by month

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Thank you
Laboratory Reporting Requirements

Jason Hall

CDC Division of Preparedness and Emerging Infections (DPEI)
Reporting COVID-19 Laboratory Data

- All U.S. hospital laboratories should submit their COVID-19 testing information to their state or local health department

- State or local health departments will send deidentified reports to CDC

- CDC will handle submission to the HHS Protect System
Electronic Laboratory Reporting

Need Help?
Hospital laboratories that are not currently reporting electronically to their state or local health department and want assistance can contact CDC at eocevent405@cdc.gov
CDC COVID Data Tracker

www.cdc.gov/covid-data-tracker
CLIA Updates

Karen Dyer
Centers for Medicare and Medicaid Services (CMS)

• FAQs Only: https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus
Updated Policy for Serology Testing

Tim Stenzel
U.S. 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:
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 (*)
https://www.facebook.com/CDC

https://twitter.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

This box being opened by an American Hero
#lovethelab
#labprofessionalsrock