

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 DLInquiries@cdc.gov

CDC Information for Laboratories

- Interim Guidance for Collecting, Handling, and Testing Clinical Specimens
<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>
- Diagnostic Tools and Virus
<https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html>
- 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:
<https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>
- Interim Laboratory Biosafety Guidelines:
<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>
- Laboratory Biosafety Frequently Asked Questions:
<https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

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

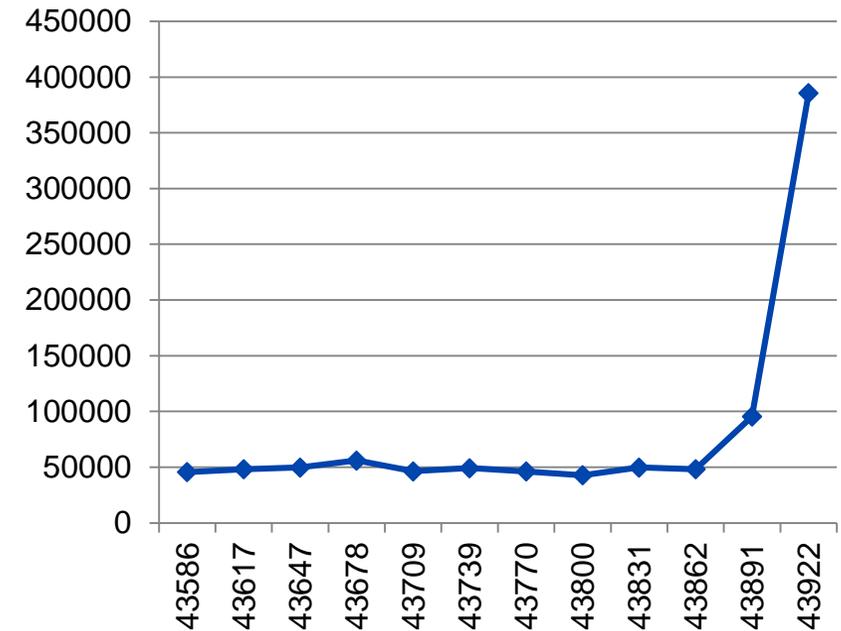
COVID Reporting Issues

- 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



MAYO
CLINIC



Thank you

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)



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

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

Explore and understand Coronavirus (COVID-19).
Maps, charts, and data provided by the Centers for Disease Control and Prevention

- U.S. Cases
- U.S. COVID Testing
- U.S. Cases and Deaths by County
- Social Impact
- School Closures
- Learn More

CDC COVID Data Tracker Powered by Geospatial Research, Analysis, and Services Program (CDC/ATSDR/GRASP)

United States Laboratory Testing

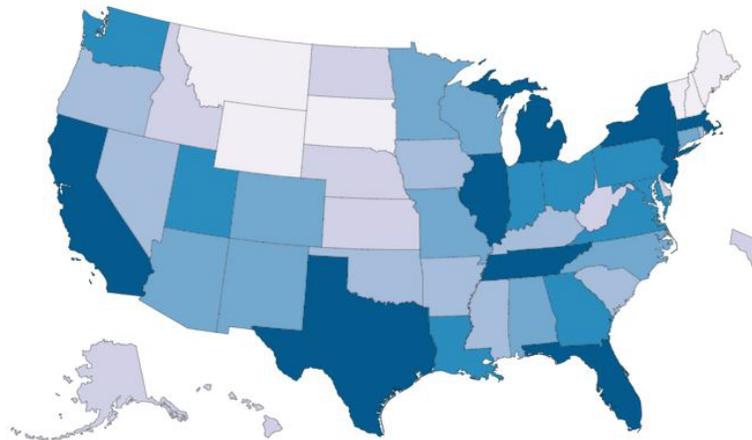
Commercial and Reference, Public Health, and Hospital Laboratories

USA
8,375,138
TESTS REPORTED
CDC | Updated: May 9 2020 5:45PM

USA
1,341,881
POSITIVE TESTS
CDC | Updated: May 9 2020 5:45PM

USA
16%
OVERALL % POSITIVE
CDC | Updated: May 9 2020 5:45PM

Specimens Tested and Reported by US Laboratories: Commercial and Reference, Public Health, and Hospital



Territories
AS GU PR VI

Cumulative Tests Performed

COVID-19 Tests Performed by State (Commercial and Reference, Public Health, and Hospital)

State	# Tests Performed	% Positive
New York	1,089,916	21-30%
Florida	702,515	6-10%
California	700,466	6-10%
Massachusetts	460,859	11-20%
Illinois	349,652	21-30%
Tennessee	300,721	6-10%
New Jersey	285,890	31-40%
Texas	283,843	11-20%
Michigan	265,590	11-20%
Pennsylvania	254,183	11-20%
Louisiana	237,233	11-20%
Georgia	223,289	11-20%
Washington	219,453	11-20%
Indiana	188,905	21-30%
Ohio	187,936	6-10%
Maryland	186,757	21-30%
Virginia	145,044	11-20%
Utah	144,320	0-5%
Arizona	139,565	11-20%
Alabama	136,031	11-20%
Colorado	128,059	11-20%
North Carolina	120,368	11-20%
New Mexico	114,239	6-10%
Missouri	106,874	6-10%
Connecticut	106,857	21-30%

CDC COVID Data Tracker

www.cdc.gov/covid-data-tracker

CLIA Updates

Karen Dyer
Centers for Medicare and Medicaid Services (CMS)



Centers for Medicare and Medicaid Services (CMS)

- CLIA Laboratory Guidance During COVID-19 Memo and FAQs:
<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>
- 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)



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

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:
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>
- COVID-19 Updates:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

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 (*)

CDC Social Media



<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

