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

Clinical Laboratory Surge Testing Survey
– Corey Meyer, Gryphon Scientific

Electronic Laboratory Reporting for COVID-19: Summary Findings from the CSTE COVID-19 ELR Capabilities and Needs Assessment
– Brooke Beaulieu, Council of State and Territorial Epidemiologists (CSTE)

Updates from the Infectious Diseases Pathology Branch
– Jana Ritter and Hannah Bullock, CDC Division of High-Consequence Pathogens and Pathology (DHCPP)

Q&A Panel
– Ren Salerno, CDC Division of Laboratory Systems (DLS)
– Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
– Tim Stenzel, U.S. Food and Drug Administration (FDA)
– Amy Zale, Centers for Medicare & Medicaid Services (CMS)
New SARS-CoV-2 Antigen Testing Infographics

BD Veritor™ Plus System

Quidel® Sofia® and Sofia 2®

Abbott BinaxNOW™
COVID-19 Resources for Laboratories

- 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/

- Antigen Testing Guidance

- Frequently Asked Questions about COVID-19 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 Laboratory Outreach Communication System (LOCS)
  https://www.cdc.gov/csels/dls/locs/
Find CLCR call information, transcripts, and audio recordings on the Preparedness Portal

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, January 11th**
from **3:00 PM to 4:00 PM ET**
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
Clinical Laboratory Surge Testing Survey

Presented by Corey Meyer, Ph.D.

December 28, 2020
Clinical Laboratory Surge Testing Survey

– On behalf of CDC’s Division of Laboratory Systems, Gryphon Scientific is conducting a national survey of clinical laboratories

– Purpose is to understand whether and how laboratories would choose to participate in surge testing during a public health emergency

– Gryphon’s teammates provide strong subject matter expertise
What topics will be covered in the survey?

- **Capability**
  - What types of testing does your lab perform?
  - What are your lab’s informatics capabilities?

- **Capacity**
  - What challenges would your lab face in increasing testing capacity to meet surge demands?

- **Willingness**
  - What factors influence your lab’s willingness to perform surge testing?
  - How would your lab like to communicate with CDC during an emergency?

- **COVID-19**
  - What business, logistical, and technical challenges has your lab faced in performing COVID-19 testing?

Questions will cover issues relevant to chemical, radiological, and biological (deliberate and natural) incidents.
How will the survey data be used?

**Evaluate**

*Engage stakeholders* from the public health and clinical lab sectors to discuss the survey findings and options for operationalizing them.

**Synthesize**

Develop evidence-based findings for how to *strengthen partnerships* between the public health and clinical lab sectors to improve surge testing.

**Share**

Share survey findings with the community via peer-reviewed publications.
Survey Details

WHO  A **random sample** of clinical labs that are:

- CLIA-certified to perform moderate and/or high-complexity testing in specialties relevant to CBR incidents
- Independent or hospital-associated

HOW  Labs that are selected for participation in the survey will receive an invitation letter in the mail.

WHEN The first batch of invitation letters will be mailed on January 4, 2021.

- Additional batches will be mailed approximately monthly, through July 2021.

Please watch your lab’s mail and encourage your lab to respond if selected for the survey!
Questions or Feedback?

Jasmine Chaitram (CDC DLS)

ClinicalLabSurvey@gryphonscientific.com
Electronic Laboratory Reporting for COVID-19
Summary Findings from the CSTE COVID-19 ELR
Capabilities and Needs Assessment
CDC DLS Call, Monday December 28th, 2020

Brooke Beaulieu, MPH
Surveillance and Informatics Program
brooke@cste.org
CSTE: Who we are and what we do
• Professional home for applied epidemiologists working at the state, local, tribal, and territorial level across the country
• Robust community, 2000+ members that convene via regular subcommittee and workgroup calls
• Focus on capacity building and information sharing, developing case definitions for reportable and nationally notifiable diseases.

Lab data are the driving force for public health surveillance and action.
• Public health agencies use these data for case ascertainment, classification, and investigation and follow-up.
• For COVID-19, a lab report is often the first (and sometimes only) indication of a case.
In June 2020, HHS released guidance for reporting COVID-19 lab test data per the CARES Act, including a list of required and optional data elements for reporting to public health.

In October 2020, CSTE sought to systematically capture jurisdictions’ capabilities and needs regarding several electronic lab reporting (ELR) topics related to the HHS reporting requirements, including:
- Mandated reporting of demographic information*
- Ability to receive, process, and consume required data elements*
- Ask on Order (AOE) questions*
- Reporting from nursing homes
- Challenges and barriers*
- Technical assistance needs

Responses received from 44 jurisdictions (78% response rate)
Key Findings
Mandated Reporting of Demographic Data

• Complete demographic data are **critical** for case investigation and follow up, for determining disease trends in populations, and for resulting guidance.

• 82% of jurisdictions explicitly require reporting demographic data via state law, rule, or regulation.
  o 18% do not require through law, rule, or regulation

• **Outside of the 18 required HHS data elements**, the most frequently stipulated data elements within jurisdiction mandates were:
  o Patient full name
  o Patient date of birth
  o Patient phone number
  o Full patient address
  o Ordering provider phone number
Ability to Receive Lab Data

• 100% of respondents can technically **receive** all 18 required data elements if a facility is able to send them.
  - Even if surveillance systems do not have the ability to **process** or **consume** all the data elements
• 72% of jurisdictions are able to receive, process, or consume the optional **Ask on Order Entry (AOE)** questions, with 21% in process by the end of the year.
• How are AOE data used?
  - **Prioritizing case investigation when volume is high**
  - Data analysis
  - Filling in data gaps, special fields, or empty fields
  - Contact tracing and case investigation
  - Reporting out to State leadership, fulfilling data requests

These are successes!
All respondents (100%) are able to receive data sent via HL7 message. However, in reality jurisdictions are receiving data via a patchwork of methods:

- State-produced CSV (89%)
- National ELR CSV file (57%)
- Faxed spreadsheets (45%)
- Other (48%):
  - ASCII file format
  - Manual entry, including for entry of faxed individual results (not spreadsheets)
  - Secure File Transfer Protocol (SFTP), secure email messages
  - Online web application or disease reporting portal
  - Sender-produced flat file
  - REDCap
## Opportunities for Improvement

<table>
<thead>
<tr>
<th>Response</th>
<th>Frequency as Top 3 Barrier (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume of onboarding</td>
<td>25 (57%)</td>
</tr>
<tr>
<td>Quality control (e.g., identifying missed files, timeliness of files, etc.)</td>
<td>19 (43%)</td>
</tr>
<tr>
<td>Technical barriers at sender end</td>
<td>17 (39%)</td>
</tr>
<tr>
<td>Manual steps/processes to prepare the data after files have been received</td>
<td>12 (27%)</td>
</tr>
<tr>
<td>Keeping up with the changing HHS guidance and technical specifications</td>
<td>10 (23%)</td>
</tr>
<tr>
<td>Collecting all data elements</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>Hiring/training people to manage increase in volume</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>Identifying all potential providers</td>
<td>8 (18%)</td>
</tr>
<tr>
<td>Maintaining a consistent stream (e.g., not receiving data routinely, but rather in batches)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Automating files into the surveillance application</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Technical barriers at the public health agency.</td>
<td>2 (5%)</td>
</tr>
</tbody>
</table>
Next Steps and Discussion
Summary and Next Steps

- Lab data are **extremely important** for public health surveillance and action.
- Jurisdictions have developed multiple solutions to receive data from the avalanche of new and existing reporters.
  - Some ideal (HL7), some not (paper or fax), and everything in between
  - Additional support needed for consuming and using the data
- Volume of onboarding testing facilities and incoming data, quality control, and the need for additional processing to be able to use the data are top barriers.
- CSTE appreciates the continued partnership with labs to adapt to the evolving challenges of this pandemic (and beyond) as public health agencies work to technically receive these data.
Questions?
Email: brooke@cste.org

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Clinical Laboratory COVID-19 Response Call
28 December 2020

Updates from the Infectious Diseases Pathology Branch

Jana M. Ritter, DVM, DACVP
Hannah Bullock, PhD

IDPB/DHCPP/NCEZID/Centers for Disease Control and Prevention

cdc.gov/coronavirus
Updates from IDPB:

- Histopathologic findings in pediatric deaths
- Antibodies for immunohistochemistry (IHC)
- Postmortem guidance
- Electron microscopy for SARS-CoV-2
Histopathologic findings in pediatric deaths

- Clinical signs: upper respiratory infection, found unresponsive, other
- Antemortem or postmortem NP swabs + for SARS-CoV-2
- Histopathology:
  - Tracheobronchitis
  - Pulmonary edema/hemorrhage
  - Aspiration
  - Rare:
    - Mild interstitial or alveolar inflammation
    - Myocarditis
    - *NO* diffuse alveolar damage (DAD)
- Tracheobronchitis
- Hemorrhage, Edema, Aspiration

Images from IDPB
- Myocarditis

Images from IDPB
- Eosinophilic myocarditis

Images from IDPB
# Immunohistochemistry for SARS-CoV-2

## Commercial antibodies

<table>
<thead>
<tr>
<th>#Ab</th>
<th>Catalogue</th>
<th>Identity</th>
<th>2020-0290 (SARS-CoV-2 Control)</th>
<th>2005-1596 (SARS)</th>
<th>Host</th>
<th>Best Pri</th>
<th>Best Diln</th>
<th>Primary Ab</th>
<th>Additional information</th>
<th>Comments 1</th>
<th>Comments 2 (Ab tested with 2020-0290A and 2020-0239C, 2010-0541 B (Joy’s heart case))</th>
</tr>
</thead>
<tbody>
<tr>
<td>1843</td>
<td>NB100-56562</td>
<td>100% to YP_009724392.1 (a.a. 1-10)</td>
<td>0-</td>
<td>0-</td>
<td>Rabbit</td>
<td>NA</td>
<td>NA</td>
<td>SARS Env</td>
<td>Polyclonal</td>
<td>No to use</td>
<td>NA</td>
</tr>
<tr>
<td>1844</td>
<td>NB100-56569</td>
<td>93% to YP_009724393.1</td>
<td>4+</td>
<td>4+</td>
<td>Rabbit</td>
<td>AR</td>
<td>1:50</td>
<td>SARS Memb</td>
<td>Polyclonal</td>
<td>Not a good option</td>
<td>NA</td>
</tr>
<tr>
<td>1845</td>
<td>NB100-56683</td>
<td>100% to YP_009724397.2</td>
<td>4+ extensive</td>
<td>4+ extensive</td>
<td>Rabbit</td>
<td>AR</td>
<td>1:100</td>
<td>SARS Nucleocapsid</td>
<td>Polyclonal</td>
<td>Good to test in SARS-CoV-2 cases</td>
<td>Positive 4; extensive</td>
</tr>
<tr>
<td>1846</td>
<td>NB100-56050</td>
<td>71% to YP_009724397.2</td>
<td>4+ rare</td>
<td>4+, rare; 2020-0338</td>
<td>Rabbit</td>
<td>AR</td>
<td>1:50</td>
<td>SARS Nucleocapsid</td>
<td>Polyclonal</td>
<td>Not a good option</td>
<td>NA</td>
</tr>
<tr>
<td>1847</td>
<td>NB100-56049</td>
<td>94% to YP_009724397.2</td>
<td>4+</td>
<td>4+</td>
<td>Rabbit</td>
<td>AR</td>
<td>1:50</td>
<td>SARS Nucleocapsid</td>
<td>Polyclonal</td>
<td>Good to test in SARS-CoV-2 cases</td>
<td>Positive 4; extensive</td>
</tr>
<tr>
<td>1848</td>
<td>NBP2-24745</td>
<td>100% to YP_009724397.2</td>
<td>Neg</td>
<td>Neg</td>
<td>Mouse</td>
<td>NA</td>
<td>NA</td>
<td>SARS Nucleocapsid</td>
<td>Monoclonal</td>
<td>Not to use</td>
<td>NA</td>
</tr>
<tr>
<td>1849</td>
<td>NBP2-24808</td>
<td>100% to YP_009724390.1</td>
<td>4+</td>
<td>4+</td>
<td>Rabbit</td>
<td>PK</td>
<td>1:25</td>
<td>SARS Spike</td>
<td>Polyclonal</td>
<td>Promising</td>
<td>Positive 2; Negative 2; Negative heart</td>
</tr>
<tr>
<td>1850</td>
<td>NBP2-24942</td>
<td>100% to YP_009724390.1</td>
<td>4+</td>
<td>4+ (2003-0262)</td>
<td>Mouse</td>
<td>AR</td>
<td>1:50</td>
<td>SARS Spike</td>
<td>Monoclonal</td>
<td>It was tested in the cases and we got rare weak staining</td>
<td>NA</td>
</tr>
<tr>
<td>1883</td>
<td>GTX632604</td>
<td>4+</td>
<td>4+</td>
<td>4+</td>
<td>Mouse</td>
<td>AR</td>
<td>1:250</td>
<td>SARS Spike</td>
<td>Monoclonal</td>
<td>Good to use</td>
<td>Positive 4; Multifocal</td>
</tr>
<tr>
<td>1886</td>
<td>GTX635686</td>
<td>4+</td>
<td>4+</td>
<td>Rabbit</td>
<td>AR</td>
<td>1:1000</td>
<td>SARS-CoV-2 nucleocapsid recombinant protein</td>
<td>Monoclonal</td>
<td>Good to use</td>
<td>Positive 4; extensive</td>
<td></td>
</tr>
</tbody>
</table>
SARS-CoV nucleocapsid - Novus Bio

SARS-CoV-2 nucleocapsid - GeneTex
Postmortem Specimen Collection and Submission Recommendations

- Critical resource for medical examiners, coroners, pathologists, health departments
- Over 745,000 page visits since Feb. 2020
- Updates posted 12/2/2020:
  - Incorporating considerations for newer assays - antigen testing, multiplex SARS-CoV-2 and influenza nucleic acid amplification test (NAAT)
  - Revised criteria for autopsy tissue specimen submission to CDC
  - Refined autopsy tissue specimen collection recommendations
  - Updated PPE recommendations -- extended use and limited reuse measures, selecting proper eye protection and respirator
  - Refined content regarding EPA cleaning solutions, facility design considerations

Instructions for submission to CDC IDPB

- Contact pathology@cdc.gov
- Healthcare providers, pathologists, medical examiners, and coroners should first contact your health department.

Submission of Fixed Autopsy Tissue Specimens to CDC

Fixed Autopsy Tissue Specimen Pre-Approval and Submission Instructions
For cases meeting the above criteria, follow the steps outlined below to obtain pre-approval from CDC's Infectious Diseases Pathology Branch to submit specimens for evaluation:

1. Reminder—Healthcare providers, pathologists, medical examiners, and coroners—please first contact your state, tribal, local, or territorial health department for approval for specimen submission to CDC.
2. Contact CDC’s Infectious Diseases Pathology Branch at pathology@cdc.gov for pre-approval. Include the following information in the email:
   a. Brief clinical history
   b. Description of gross or histopathologic findings in the tissues to be submitted
   c. Listing of available formalin-fixed tissues

In your email correspondence, do not include patient identifiers such as name, date of birth, or medical record number. You must follow all applicable federal, state, tribal, local, and territorial regulations to adhere to patient confidentiality and privacy protections.

Ultrastructure Characteristics of Coronaviruses

**Appearance**
- Negative stain vs thin section
- Generally spherical
- Peplomers (spikes)
- Cross sections through helical nucleocapsid

**Size**
- ~80 nm without spikes
- ~100 nm with spikes

**Cellular Location**
- Bud through cisternae of endoplasmic reticulum-golgi complex
- Found in membrane-bound vacuoles in the cytoplasm

Images from IDPB
Misidentification of Coronaviruses by EM

Visualization of severe acute respiratory syndrome coronavirus 2 invading the human placenta using electron microscopy

Myocardial localization of coronavirus in COVID-19 cardiogenic shock

Ultrastructural Evidence for Direct Renal Infection with SARS-CoV-2
Structures Commonly Misidentified as Coronavirus

Clathrin-coated vesicles

Vesiculating rough ER

Multivesicular body

Images from IDPB
Structures Commonly Misidentified as Coronavirus

- Clathrin-coated vesicles
- Vesiculating rough ER
- Multivesicular body
- Clathrin-coated vesicles & viral particles

Images from IDPB
Structures Commonly Misidentified as Coronavirus

- Clathrin-coated vesicles
- Vesiculating rough ER
- Multivesicular body
- Extracellular negative stain and thin section viral particles

Images from IDPB
Structures Commonly Misidentified as Coronavirus

- Clathrin-coated vesicles
- Vesiculating rough ER
- Multivesicular body
- Clathrin-coated vesicles & viral particles
- Extracellular negative stain and thin section viral particles
- Vacuole with viral particles

Images from IDPB
Disclaimer

- The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Q&A Panel

Ren Salerno, CDC Division of Laboratory Systems (DLS)
Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
Tim Stenzel, U.S. Food and Drug Administration (FDA)
Amy Zale, Centers for Medicare & Medicaid Services (CMS)
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