Clinical Laboratory COVID-19 Response Call

- Welcome and Introductions
  Jasmine Chaitram, CDC Division of Laboratory Systems

- Performance Evaluation of Commercially Developed Serology Tests
  Michele Owen, CDC Laboratory Task Force

- Updates and Responses to Submitted Questions on Diagnostics and Testing
  Tim Stenzel, U.S. Food and Drug Administration (FDA)

- Additional CLIA Guidance for Testing Laboratories
  Karen Dyer, Centers for Medicare & Medicaid Services (CMS)

- COVID-19 Response – Hospital System on the Front Lines
  James (Jim) Crawford, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health, Lake Success, New York

- Nebraska’s Public Health Laboratory Response
  Peter Iwen, Nebraska State Public Health Laboratory

- Reporting Testing Data to CDC
  Jasmine Chaitram, CDC Division of Laboratory Systems

- Laboratory Biosafety Update for COVID-19
  Bill Arndt, CDC Division of Laboratory Systems
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](mailto:media@cdc.gov).
CDC Laboratory Task Force – COVID-19 Testing

CDC guidance on specimen collection and transport for COVID-19 testing

CDC guidance on evaluating and testing persons for coronavirus disease
For laboratories using the CDC EUA assay, please contact respvirus@cdc.gov for laboratory testing guidance.
COVID-19 Emergency Use Authorization (EUA)
Information: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations


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 (*)
CLIA Laboratory Guidance During COVID-19 Memo and FAQs:


FAQs Only

COVID-19 Data
Northwell Health Laboratories
Update April 6, 2020
James M Crawford, MD PhD
jcrawford1@northwell.edu
Northwell: COVID-19 Daily Test Positivity Rates

- Hospital
- GoHealth
- Other
Blood Culture Bottles per Day, vs. COVID-19 Test Orders

- **X-axis (Date):** 01/01 (Wed) to 03/05 (Thu)
- **Y-axis (Blood cultures #):** 0 to 3500
- **Graph:** Daily volume and Covid Testing
COVID-19 Laboratory Considerations (in progress)

• Negative Predictive Value (NPV) of [COVID-19 PCR] “Not Detected”
• Serologic Testing for COVID-19 Immunoreactivity
• Point-of-Care (POC) Testing for COVID-19
• [COVID-19 PCR] Testing at Hospital Sites (vs. Core Lab)
• “Need to know” [COVID-19 PCR] testing (e.g., Pre-Surgical Testing)
• Preparing for “Convalescent Plasma”
Nebraska’s Response to COVID-19
Timeline of Important Events

12-01-19  First human case of nCoV (Wuhan, China)
01-22-20  Repatriation of Americans from China to NQU in Omaha
          -began validation of the WHO assay
01-29-20  Discussion to repatriate 250 individuals to Omaha
01-30-20  WHO declared nCoV a PH emergency of International Concern
02-02-20  Omaha designated as one of four sites for federal quarantine
02-06-20  US declared nCoV a National PH Emergency
02-07-20  NPHL ordered the nCoV 2019 EUA from IRR
02-08-20  57 people arrived in Omaha for federal quarantine
          -Received the EUA
02-09-20  Completed the verification process for the EUA
02-17-20  Received 14 people from the Diamond Princess
          -12/14 positive for nCoV
          -2 admitted to the Nebraska Biocontainment Unit
03-13-20  Governor declared a State of Emergency in Nebraska
STATE OF NEBRASKA

Proclamation

WHEREAS, Commencing on March 6, 2020 and continuing, the Coronavirus (COVID-19) has impacted the entire State of Nebraska. COVID-19 has spread across the country with cases being confirmed within the borders of Nebraska. This emergency can strain the abilities of state and local governments to meet the needs of the citizens and respond to the pandemic; and

WHEREAS, The actions necessary to assist in meeting the emergency conditions and subsequent impacts of these events present a burden upon the entire State of Nebraska and

NOW THEREFORE, Under the provisions of Neb. Rev. Stat. §§81-2294, which confers emergency responsibilities and powers upon the Governor, I, Pete Ricketts, Governor of the State of Nebraska do hereby declare that a state of emergency exists within the State of Nebraska; and

NOW, In addition to the powers conferred upon me by law, I may suspend the provisions of any regulatory statute prescribing the procedures for conduct of state business or the orders, rules, or regulations of any state agency if strict compliance with the provisions would produce, hinder, or delay necessary action in coping with the emergency. This could include waiving regulations to expedite measures in order to protect the life, health, and safety of our citizens and to mitigate the impact of the pandemic; and

I HERBY DIRECT, The Nebraska Adjutant General, who also serves as State Disaster Coordinator, to activate appropriate State emergency plans and to take such steps as he deems necessary to meet these emergencies, and to continue these actions until such time as the threat to life and property created by these situations has been alleviated; and

I FURTHER DIRECT OR REQUEST, State and appropriate Federal agencies to cooperate with the Adjutant General of Nebraska upon his request, as may be appropriate and lawful; and

I HEREBY AUTHORIZE, The Adjutant General of Nebraska to activate such elements of State Government and Emergency Management resources as are appropriate to deal with this emergency and to expend such funds, within the limitations of availability, from the Governor’s Emergency Fund to support these actions.

IN WITNESS WHEREOF, I hereunto set my hand and cause the Seal of the State of Nebraska to be affixed this 13th day of March, 2020.

Done at the State Capitol, Lincoln, Nebraska, on this Thirteenth Day of March in the Year of Our Lord, Two Thousand Twenty.

ATTEST: Secretary of State
Governor
Federal Quarantined Travelers
Federal Quarantined Travelers

14 Diamond Princess travelers quarantined
Medium 21 days (range 14d to 33d)

Day 1  12/14 NP+  7/14 OP+

Day 10 9/14 NP+  2/14 OP+

Serial testing, 3 negative specimens before released

Total 205 specimens
100 Negative
77 Positive
28 Inconclusive
March 24, 2020

Dr. Jeffrey P. Gold, Chancellor
University of Nebraska Medical Center
507400 Nebraska Medical Center
Omaha, NE 68198-7400

Dear Dr. Gold:

I write in response to your March 24, 2020 letter concerning the conservation of reagents used for COVID-19 testing at the Nebraska Public Health Laboratory. I give my full authorization to explore and proceed with all reasonable measures to expand testing at this time.

Thank you for all of your help.

Sincerely,

Pete Ricketts
Governor

cc: Peter Iwen, Ph.D., D(ADMN), Lab Director, NPHL
Steven H. Hinrichs, M.D., Clinical Consultant, NPHL

Non-UNMC email

Dear Dr. Hinrichs,

Taking into consideration the current shortage of testing reagents and medical supplies and the supporting information you provided, FDA will not object to your laboratory testing pools of five specimens while the positive test rate is below 10%. However, if the positive rate for SARS-CoV-2 in the testing population exceeds 10%, pooling of clinical specimens should no longer be performed at your testing site.

Best regards,

Iwen, Peter C

FDA, U.S. Food & Drug Administration
FDA.gov
Group Testing of Pooled Specimens

24Mar – 3April

Began 24March

Pooled specimens 939
No. of pools 189
No. pools positive 50
Extraction/PCR reagents used 441
Extraction/PCR reagents saved 498 (53.0%)

*Predictor variables Low risk specimens vs high risk

Note:
Pooling will not work if the rate of infection exceeds 15%.
Loss of sensitivity seems to be minimal (1.5 to 2.5 CTs)
Splitting any pool with late CT amplification (40 to 45 CTs)
### Number of Positive and Not Detected Tests (N = 4,618) on Nebraska Residents by Performing Laboratory – Nebraska, February-April 2020

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<thead>
<tr>
<th>Laboratory</th>
<th>Not Detected</th>
<th>Positive</th>
<th>Grand Total</th>
</tr>
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<tbody>
<tr>
<td>Performing laboratory</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>The Nebraska Medical Center Clinical Lab</td>
<td>1,578</td>
<td>80</td>
<td>1,658</td>
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<tr>
<td>Nebraska Public Health Laboratory</td>
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<td>103</td>
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<td>LabCorp</td>
<td>551</td>
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<td>CHI/Creighton</td>
<td>320</td>
<td>26</td>
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<td>Avera Laboratories</td>
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<td>PLAB</td>
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<tr>
<td>Other</td>
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<td>6</td>
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<tr>
<td>Total</td>
<td>4,356</td>
<td>262</td>
<td>4,618</td>
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</tbody>
</table>

**Result to 1Apr2020**

**Roche Cobas**

**Abbott m2000**
COVID-19 Information for Laboratories page:

Interim Laboratory Biosafety Guidelines:

Laboratory Biosafety Frequently Asked Questions:

Send Inquiries to: 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/
CDC Social Media

Facebook: https://www.facebook.com/CDC

Twitter: https://twitter.com/cdcgov

LinkedIn: https://www.linkedin.com/company/cdc
Thank You For Your Time!

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