Clinical Laboratory COVID-19 Response Call  
Monday, April 27, 2020 at 3:00 PM EDT

- **Welcome**  
  - Jasmine Chaitram, CDC Division of Laboratory Systems

- **Diagnostic and Serology Testing: Addressing Problems and Challenges**  
  - Carmen L. Wiley, President, AACC

- **Serology Testing Available at Quest Diagnostics**  
  - Ann Salm, Quest Diagnostics

- **LabCorp Pixel Home Self-Collection Overview**  
  - Brian Krueger, LabCorp

- **Laboratory Biosafety Update**  
  - Bill Arndt, CDC Division of Laboratory Systems

- **Update on Serology Testing, Point-of-Care Testing, and Laboratory Data Harmonization**  
  - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)
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.
Diagnostic and Serology Testing: Addressing Problems and Challenges

Carmen Wiley, PhD, DABCC
ACCCC President
Diagnostic Testing: Ongoing Problems

• Access to supplies
  • Collection, assay components, PPE
• Access to equipment
  • Analyzers, cartridges/reagents
• Coordination of resources
  • Labs competing for same materials
Diagnostic Testing: Ongoing Problems

- Staffing
  - Too few trained personnel for tasks
- Finances
  - Costs high, revenues declining
- Provider education
  - Clearer understanding needed of different tests
Serology Testing – The Challenges We Face

• Need for serological testing
  • IgM, IgG, IgA post-infection
  • Sub-clinical or mild infection
  • Surveillance and research
Serology Testing – The Challenges We Face

- Several serological tests developed/in-process
  - Sensitivity/specificity
  - Qualitative/quantitative
  - Cross reactivity
  - Aggressive vendors/unreliable serological tests
What AACC is Doing

- On serology:
  - CA State Taskforce
  - Taskforce developing serology testing guide
- More generally:
  - Resource site
  - Discussion forum
  - Directory
Thank you.
Questions?
Serology Testing Available at Quest Diagnostics

Ann Salm, Quest Diagnostics
**Quest Diagnostics – Useful Links**

Quest COVID-19 Web Page:  

*For questions, email COVID19@QuestDiagnostics.com*

Quest Press Release for Serology Testing:  

Quest Serology Frequently-Asked Questions:  
http://education.questdiagnostics.com/faq/FAQ219
LabCorp Pixel Home Self-Collection Overview

Brian Krueger, LabCorp
LabCorp COVID-19 RT-PCR Test

Qualitative RT-PCR Test

✓ High Throughput Implementation of CDC Assay
  o EUA Granted March 16, 2020
  o Amended and approved as a multiplex assay April 14, 2020
✓ Assay Specifics
  o Multiplexed by changing probe dyes
    o N1-FAM
    o N2-Yakima Yellow
    o Rnase P – Cy5
    o N3 dropped as an assay target at the recommendation of FDA and CDC
  o 100% Sensitivity and Specificity on multiplex validation Clinical Samples
  o Tested against 26 potentially interfering respiratory organisms
  o LOD of 6.25 cp/μL (from extraction)
✓ Approved for the detection of COVID-19 in symptomatic patients
Pixel Self-Collection Testing

Direct to Consumer COVID-19 Portal

- Available at: [https://pixel.labcorp.com](https://pixel.labcorp.com)
  - Participants answer a short questionnaire
  - Reviewed by a doctor prior to approval and shipping
  - Results available within 1-2 days of kit receipt
    - Detected results are communicated by physician

- Home Collection Kit

- Tested exclusively on the FDA Authorized LabCorp COVID-19 RT-PCR Test
  - First released to Healthcare workers and first responders
**Validation Overview**

**Stability Study**

- Experimental Design
  - 20 positives and 20 negatives
  - 0hr, 24hr RT, 72hr 2-8C
  - Positives spiked with 1e3cp/uL virus to a final concentration of 10 cp/uL
  - No degradation of expected Ct over the time-course
  - No False Positives or False Negatives

<table>
<thead>
<tr>
<th></th>
<th>N1</th>
<th>N2</th>
<th>RP</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>STDEV</td>
<td>Mean</td>
</tr>
<tr>
<td>0hr 10cp/uL (20)</td>
<td>34.94719</td>
<td>1.107074</td>
<td>34.8628</td>
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<tr>
<td>24hr 10cp/uL (20)</td>
<td>34.96442</td>
<td>0.445445</td>
<td>34.86464</td>
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<td>96hr 10cp/uL (20)</td>
<td>35.00282</td>
<td>0.341642</td>
<td>35.55211</td>
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Validation Overview

Temperature Excursion Study

- Experimental Design
  - 20 positives and 20 negatives
  - Positives spiked with $1e3$ cp/uL virus to 10 cp/uL final concentration
  - Cycled in an oven to replicate “worst case” shipping scenario

<table>
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<tr>
<th>Temperature</th>
<th>Cycle Period</th>
<th>Cycle Period Hours</th>
<th>Total Time Hours</th>
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<tbody>
<tr>
<td>40°C</td>
<td>1</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>22°C</td>
<td>2</td>
<td>16</td>
<td>22</td>
</tr>
<tr>
<td>40°C</td>
<td>3</td>
<td>2</td>
<td>24</td>
</tr>
<tr>
<td>35°C</td>
<td>4</td>
<td>22</td>
<td>46</td>
</tr>
<tr>
<td>40°C</td>
<td>5</td>
<td>4</td>
<td>50</td>
</tr>
</tbody>
</table>

- No degradation of expected Ct over the 50hr time-course
- No False Positives or False Negatives

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<tr>
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<th>RP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>STDEV</td>
<td>Mean</td>
</tr>
<tr>
<td>50hr Excursion 10cp/uL (20)</td>
<td>31.66844</td>
<td>1.465225</td>
</tr>
</tbody>
</table>
Validation Overview

Self-Collect and Shipping Study

- Experimental Design
  - 30 lay participants collected 2 samples (tubes) each
  - 30 tubes spiked with clinical positives
  - Shipped via FedEx to the lab (72hr transit time)
  - No degradation of expected Ct over the time-course
  - No False Positives or False Negatives
Improving Health, Improving Lives
Laboratory Biosafety Update for COVID-19

Bill Arndt, PhD
CDC Division of Laboratory Systems
COVID-19 Information for Laboratories page:

Interim Laboratory Biosafety Guidelines:

Laboratory Biosafety Frequently Asked Questions:

Send Inquiries to: DLSInquiries@cdc.gov
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/
FDA Agenda Item

Tim Stenzel, MD, PhD
Sara Brenner, MD, MPH
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 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 (*)
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Twitter: https://twitter.com/cdcgov

LinkedIn: 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