

# 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](mailto:media@cdc.gov).

# Diagnostic and Serology Testing: Addressing Problems and Challenges

Carmen Wiley, PhD, DABCC  
ACCC 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 AACCC is Doing

- On serology:
  - CA State Taskforce
  - Taskforce developing serology testing guide
- More generally:
  - [Resource site](#)
  - [Discussion forum](#)
  - [Directory](#)



*Better health through  
laboratory medicine.*

**Thank you.  
Questions?**

# Serology Testing Available at Quest Diagnostics

Ann Salm, Quest Diagnostics



# Quest Diagnostics – Useful Links

Quest COVID-19 Web Page:

<https://www.questdiagnostics.com/home/Covid-19/>

\*For questions, email [COVID19@QuestDiagnostics.com](mailto:COVID19@QuestDiagnostics.com)

Quest Press Release for Serology Testing:

<https://questdiagnostics.sharepoint.com/sites/DigitalWorkplace/News/Pages/Quest-begins-to-perform-COVID-19-antibody-testing.aspx>

Quest Serology Frequently-Asked Questions:

<http://education.questdiagnostics.com/faq/FAQ219>

# LabCorp Pixel Home Self-Collection Overview

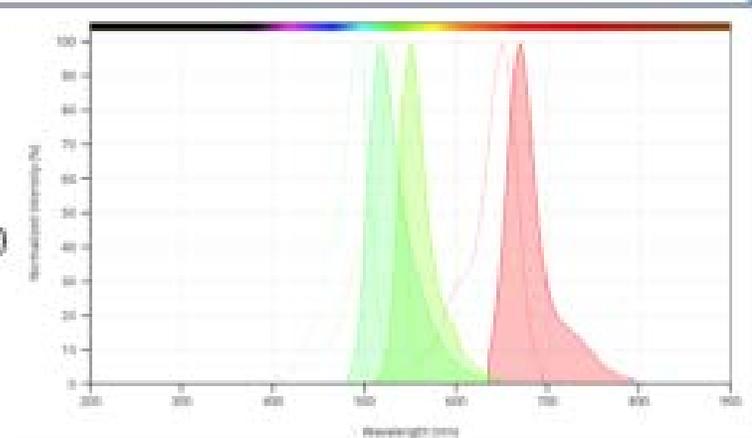
Brian Krueger, LabCorp



# LabCorp COVID-19 RT-PCR Test

## Qualitative RT-PCR Test

- ✓ High Throughput Implementation of CDC Assay
  - EUA Granted March 16, 2020
  - Amended and approved as a multiplex assay April 14, 2020
- ✓ Assay Specifics
  - Multiplexed by changing probe dyes
    - N1-FAM
    - N2-Yakima Yellow
    - Rnase P – Cy5
    - N3 dropped as an assay target at the recommendation of FDA and CDC
  - 100% Sensitivity and Specificity on multiplex validation Clinical Samples
  - Tested against 26 potentially interfering respiratory organisms
  - LOD of 6.25 cp/uL (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>
  - 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

	N1		N2		RP	
	Mean	STDEV	Mean	STDEV	Mean	STDEV
<b>0hr 10cp/uL (20)</b>	34.94719	1.107074	34.8628	1.471946	31.26584	1.2432
<b>24hr 10cp/uL (20)</b>	34.96442	0.445445	34.86464	0.642225	31.96352	1.559504
<b>96hr 10cp/uL (20)</b>	35.00282	0.341642	35.55211	0.928614	31.64471	0.928614

# Validation Overview

## Temperature Excursion Study

- ✓ Experimental Design
  - 20 positives and 20 negatives
  - Positives spiked with 1e3cp/uL virus to 10 cp/uL final concentration
  - Cycled in an oven to replicate “worst case” shipping scenario

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
40°C	1	6	6
22°C	2	16	22
40°C	3	2	24
35°C	4	22	46
40°C	5	4	50

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

	N1		N2		RP	
	Mean	STDEV	Mean	STDEV	Mean	STDEV
<b>50hr Excursion 10cp/uL (20)</b>	31.66844	1.465225	33.84067	2.06126	26.4825	2.702494

# 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

A male scientist in a white lab coat and blue gloves is looking through a microscope. In the background, a female scientist is also working. The scene is set in a bright laboratory.

*{ Improving Health, Improving Lives }*

# Laboratory Biosafety Update for COVID-19

Bill Arndt, PhD  
CDC Division of Laboratory Systems



# 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](mailto:DLSInquiries@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/>

## FDA Agenda Item

Tim Stenzel, MD, PhD  
Sara Brenner, MD, MPH

U.S. Food and Drug Administration (FDA)



# 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](mailto: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



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



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.*

