

# Clinical Laboratory COVID-19 Response Call

Monday, September 14<sup>th</sup>, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **CMS Update on Interim Final Rule – Laboratory Reporting**
  - Regina Van Brakle and Amy Zale, Centers for Medicare & Medicaid Services (CMS)
- **Technical Guidance for Implementation of Laboratory Data Reporting**
  - Mike Waters, Testing and Diagnostics Task Force, U.S. Health and Human Services (HHS)
- **Laboratory Data Reporting for COVID-19 – A Clinical Laboratory Experience**
  - Jordan Olson, Geisinger Health System, Department of Laboratory Medicine
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

# Schedule for Clinical Laboratory COVID-19 Response Calls

The next call is scheduled for  
**Monday, Sept. 28 from 3:00 PM to 4:00 PM EDT**



# Share Your Feedback!

Help us improve these calls by taking a short 5-minute survey!

<https://www.surveymonkey.com/r/CLCRSept14>



The survey will close on Thursday, Sept. 17 at 8 AM

# We Want to Hear From You!

## Training and Workforce Development

Questions about education and training?

Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)



# COVID-19 Resources 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/>
- **IVD Industry Connectivity Consortium**  
<https://ivdconnectivity.org/livd/>
- **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>

# COVID-19 Resources for Laboratories (cont.)

- **Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes**  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>
- **Antigen Testing Guidance**  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>
- **Additions to the [Frequently Asked Questions \(FAQs\) about COVID-19 for Laboratories](#)**
  - **False Negatives and False Positives from COVID-19 Testing**  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Interpreting-Results-of-Diagnostic-Tests>
  - **Surveillance, Screening, and Diagnostic Testing for COVID-19**  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Testing-Strategies-for-SARS-CoV-2>

# New Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs>

CDC DIVISION OF LABORATORY SYSTEMS

## FREE ONLINE COURSE

### Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know

Initiatives and Partnerships  
Find out about initiatives and partnerships to support laboratories in a response.

Outbreak & Response  
Learn how CDC supports laboratories responding to disease outbreaks and pandemics such as COVID-19.

Tools & Resources  
Get products, tools, and resources to prepare laboratory staff and systems.

#### Resources

- Learn about CDC's [Laboratory Outreach Communication System \(LOCS\)](#) and find recent messages
- Get participant info and more for CDC's regular [Clinical Laboratory COVID-19 Response](#) calls
- Find CDC's [Information for Laboratories about Coronavirus \(COVID-19\)](#)
- Stay informed with CDC's [Coronavirus \(COVID-19\)](#) website

#### Contact Us

Please email [DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov) and use "Laboratory Preparedness and Response" in the subject line.

LABORATORIES

## Information for Laboratories about Coronavirus (COVID-19)

Updated Aug. 16, 2020 Print

Using Antigen Tests  
Interim guidance for SARS-CoV-2 rapid antigen testing for clinicians and laboratory professionals. [Learn More](#)

### Resources for Laboratories

#### Diagnostic Tests

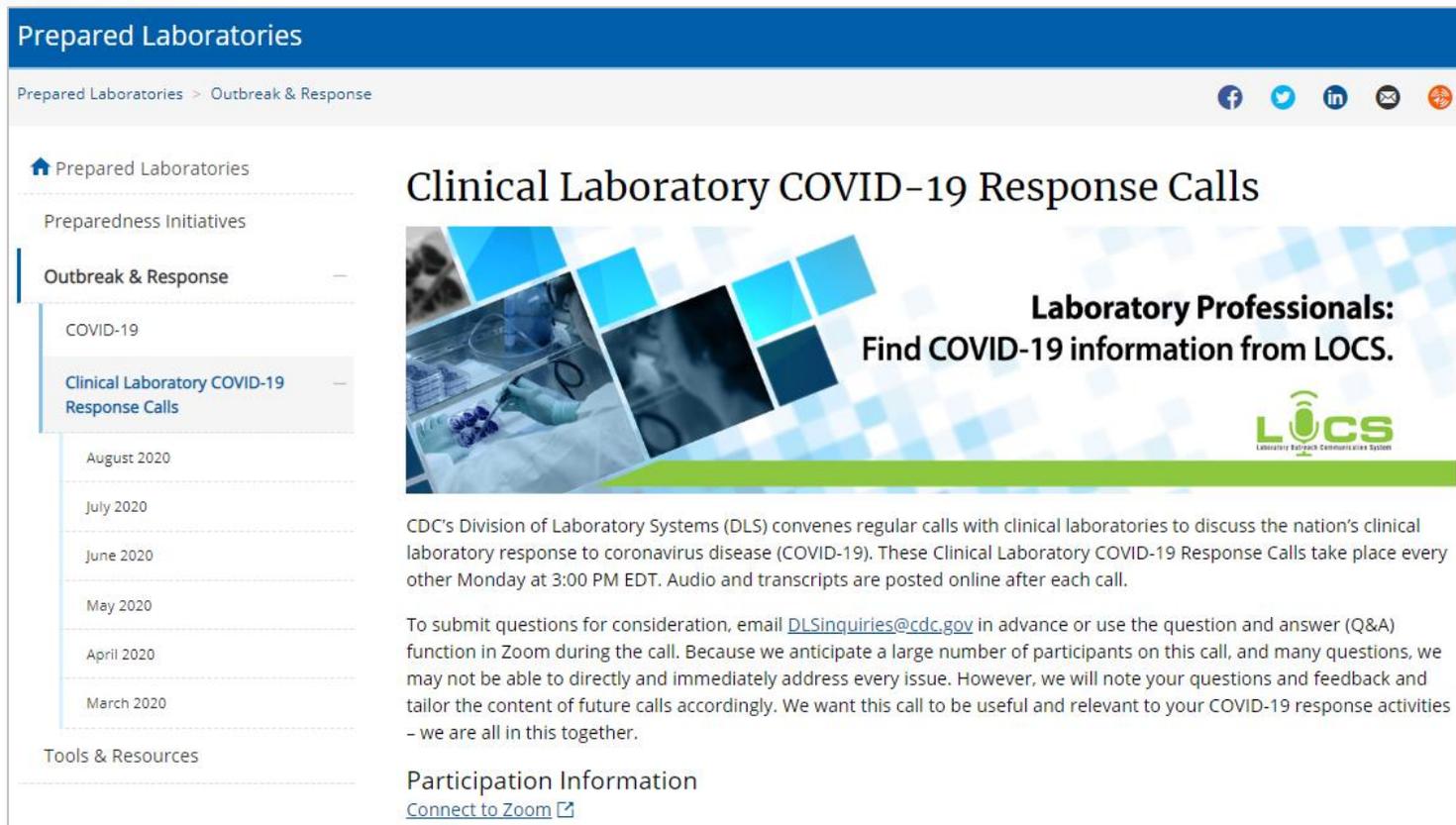
- [Multiplex Assay for Flu and COVID-19, Supplies, and Fact Sheets](#)
- [Diagnostic Test for COVID-19 Only, Supplies, and Fact Sheets](#)

#### Other Resources

- [Using Antigen Tests](#)
- [Pooling Procedures](#)

# We've Moved!

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>



The screenshot shows the 'Prepared Laboratories' section of the CDC website. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a banner image with the text 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. The main text describes the calls and provides contact information for questions. A sidebar on the left lists various preparedness initiatives, with 'Clinical Laboratory COVID-19 Response Calls' selected. A list of dates from March 2020 to August 2020 is visible in the sidebar. At the bottom, there is a 'Participation Information' section with a 'Connect to Zoom' link.

## Prepared Laboratories

Prepared Laboratories > Outbreak & Response

Prepared Laboratories

Preparedness Initiatives

Outbreak & Response

- COVID-19
- Clinical Laboratory COVID-19 Response Calls**
- August 2020
- July 2020
- June 2020
- May 2020
- April 2020
- March 2020

Tools & Resources

### Clinical Laboratory COVID-19 Response Calls

**Laboratory Professionals:  
Find COVID-19 information from LOCS.**

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM EDT. Audio and transcripts are posted online after each call.

To submit questions for consideration, email [DLSinquiries@cdc.gov](mailto:DLSinquiries@cdc.gov) in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities – we are all in this together.

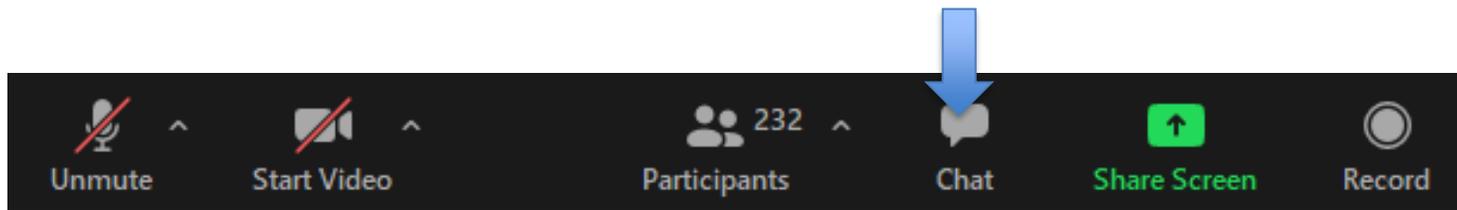
Participation Information  
[Connect to Zoom](#)

CLCR call information, transcripts, & audio recordings now live on the new Preparedness Portal

# How 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 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](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider



# CMS Update on Interim Final Rule – Laboratory Reporting

**Regina Van Brakle and Amy Zale**  
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/certificationgeninfo/policy-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>



# Technical Guidance for Implementation of Laboratory Data Reporting: Update

**Michael Waters, PhD**

SHIELDx Team Lead/OIR RWE Representative  
OHT7: Office of In Vitro Diagnostics & Radiological Health (OIR)  
Center for Devices & Radiological Health (CDRH)  
U.S. Food & Drug Administration (FDA)



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

# HHS Answer-On-Entry (AOE) Question Implementation: *Geisinger Health System's Experience*

**Geisinger**

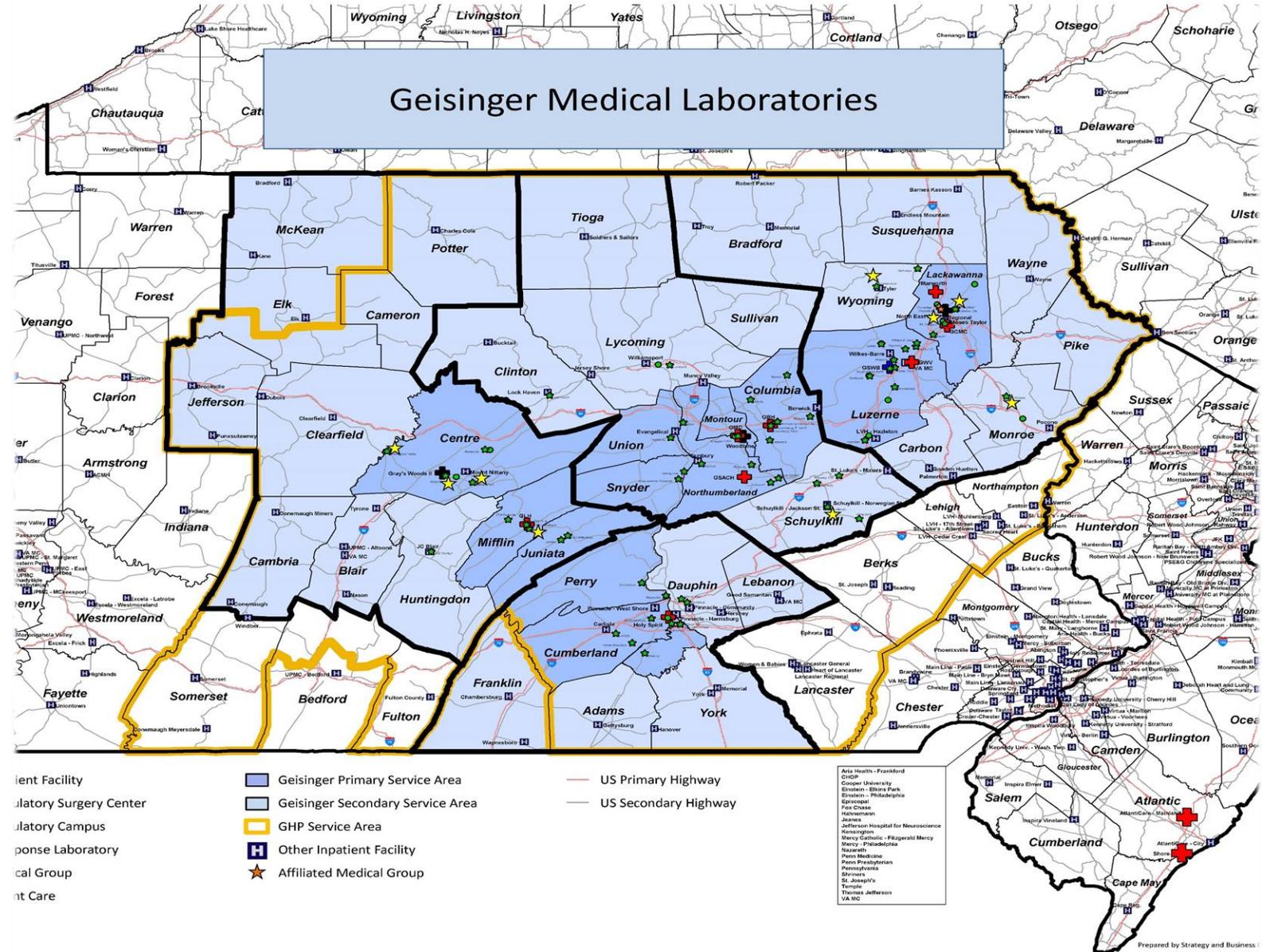
**Jordan Olson M.D., FCAP FASCP**

**September 14<sup>th</sup> 2020**

**D.M. Wolk, Ph.D., D(ABMM)**

# Geisinger Health System

- 9 hospital system in North Central PA
- 87 Office Sites
- 23 Urgent Care sites
- Started in-house COVID testing March 6, 2020
- August 2020 performed approx. 32,000 SARS-CoV-2 RT=PCR tests and 1,500 antibody tests



# Timeline

March

- Began in-house testing and manual reporting to PADOH

April

- Began reporting results to PA DOH

June

- Expanded interface messages to PA DOH

Aug  
3rd

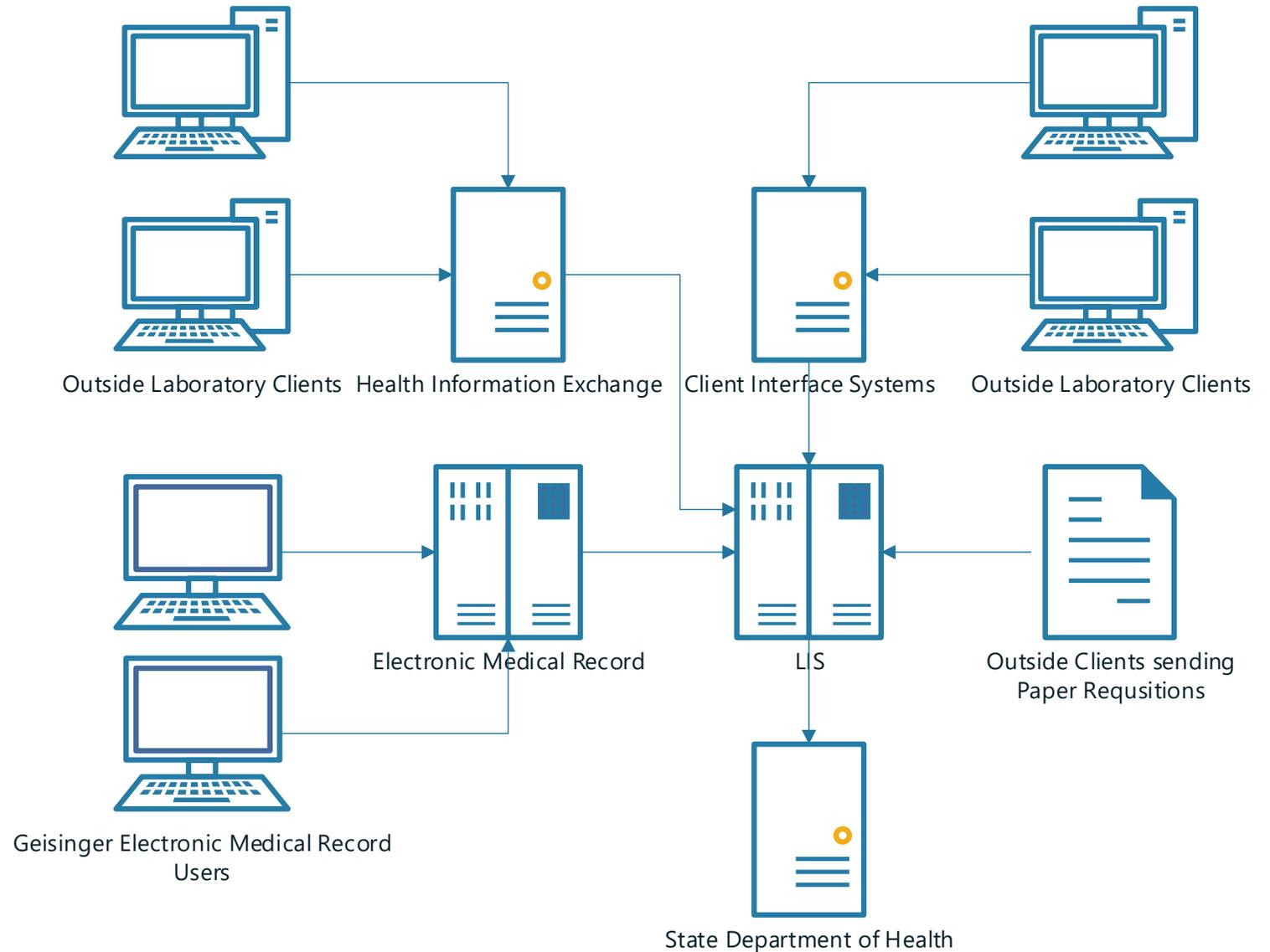
- PA DOH announces ability to accept AOE content

Sept  
9th

- Went live with AOE Questions

- Geisinger Medical Laboratory sits in a complex informatics environment
- Geisinger's EMR is only one source of orders
- IT changes to accommodate AOE questions must happen and be coordinated in all systems

## Simplified Informatics Topology: Answer-on-entry question data flow



- Geisinger Physician Informaticians have strict guidelines on AOE's

- Info available at time of order to clinician
- Info required to act on order
- Not transcription of information available elsewhere

- EMR vendor provided 'turbocharger packages' which *greatly* assisted with build in EMR

# Answer-on-entry questions

Symptomatic for COVID-19 as defined by CDC?  YES  NO  Unknown (UNK)

**Symptoms**

Fever over 100.4F (F104)  Feeling feverish (FFEV)  Chills (CHIL)  Cough (COUGH)  Shortness of breath (SOB)

Difficulty breathing (DB)  Fatigue (FATI)  Muscle or body aches (MBA)  Headache (ACHE)

New loss of taste (NLOT)  New loss of smell (NLOS)  Sore throat (ST)  Nasal congestion (NAC)

Runny nose (RN)  Nausea (NAUS)  Vomiting (VOM)  Diarrhea (DIAR)

**Date of Symptom Onset**

Hospitalized for COVID-19?  YES  NO  Unknown (UNK)

Admitted to ICU for COVID-19?  YES  NO  Unknown (UNK)

Employed in healthcare setting?  YES  NO  Unknown (UNK)

Resident in a congregate care/living setting?  YES  NO  Unknown (UNK)

Resident in a congregate care/living setting?  YES  NO  Unknown (UNK)

Residence type

Hospital (RHOSP)  Hospital ship (RHOSPS)  Long term care hospital (RLRCH)  Secure hospital (RSECH)

Nursing home (RNH)  Retirement home (RRH)  Orphanage (RORPH)  Prison-based care site (RPRISB)

Substance abuse treatment center (RSATC)  Boarding house (RBH)  Military accommodation (RMILTA)  Hospice (RHPICE)

Hostel (RHSTL)  Sheltered housing (RSH)  Penal institution (RPINS)  Religious institutional residence (RRIR)

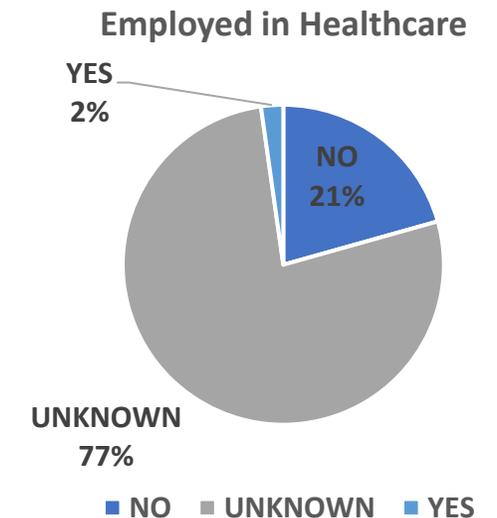
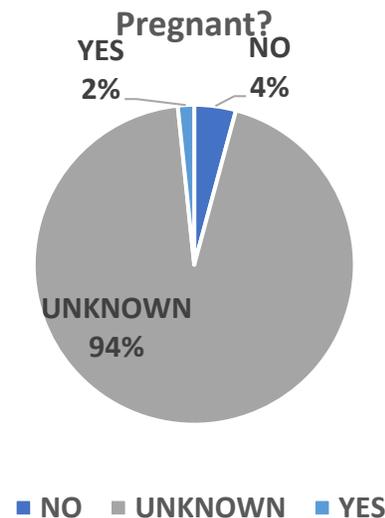
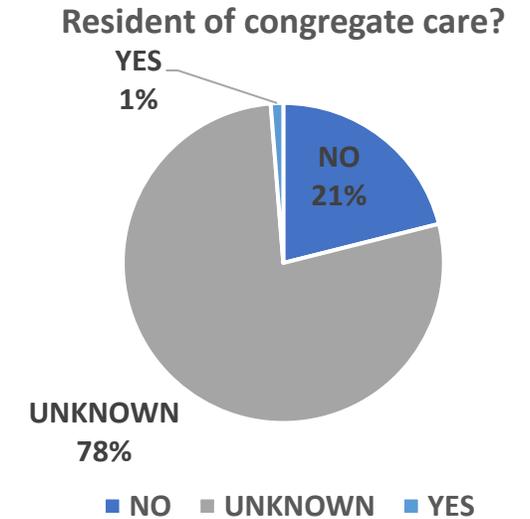
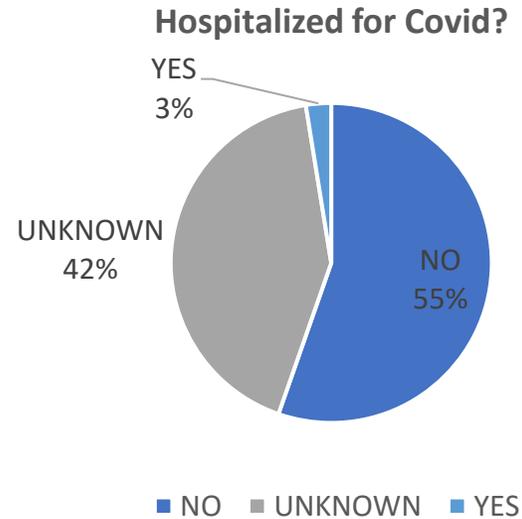
Work environment (RWE)  Unknown (UNK)

Pregnant?  YES  NO  Unknown (UNK)

First COVID-19 test?  YES  NO  Unknown (UNK)

# AOE Answers

- Both internal providers and outside clients unwilling to provide answers
- EMR build does assist with answering and helps capture more accurate data
- Answers often unavailable to laboratory
- LIS *requires* an answer
- Unknown is an acceptable answer in implementation guidelines - for most questions it is the most common answer reported



# Reporting to State

- COVID-19 results reported to State Department of Health



# Summary

- “Required” data elements straightforward to report
- Answer on order questions pose significant difficulty
  - Considered a burden by clinicians with no tangible benefit to patient
  - Significant build effort, although EMR vendor provided tangible support
  - Significant effort for lab staff to transcribe information when available
- “Unknown” reported often for AOE questions

# Thank you

Jordan Olson MD FCAP FASCP  
jeolson@Geisinger.edu



Geisinger

## FDA Update

**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 for Medical Devices**  
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
- **COVID-19 In Vitro Diagnostic EUAs**  
<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>
- **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>
- **FDA Townhall Meetings**  
<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>
- **Independent Evaluations of COVID-19 Serological Tests**  
<https://open.fda.gov/apis/device/covid19serology/>

# 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



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

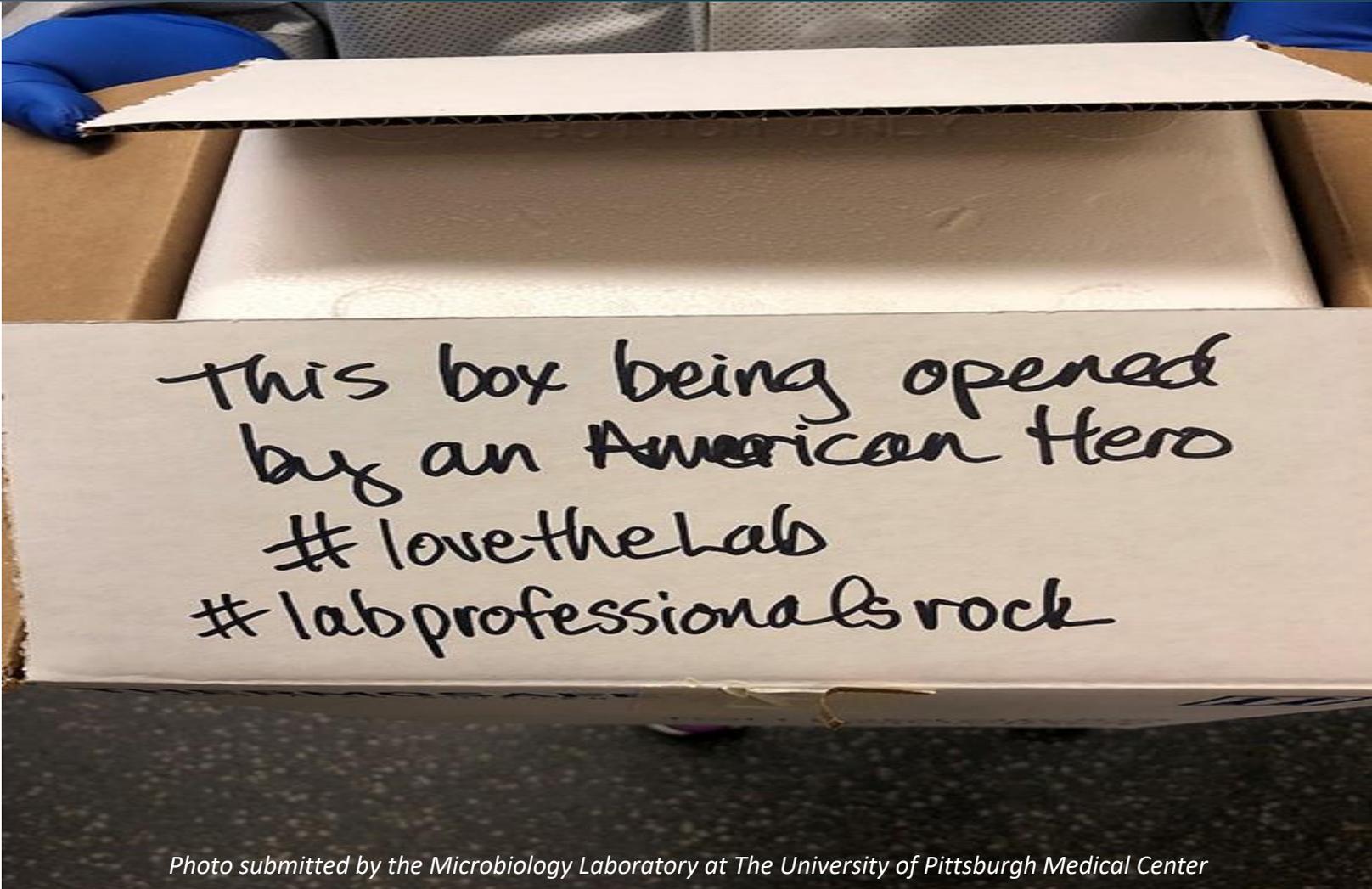


<https://twitter.com/cdcgov>



<https://www.linkedin.com/company/cdc>

# Thank You For Your Time!



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

*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*