

# 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

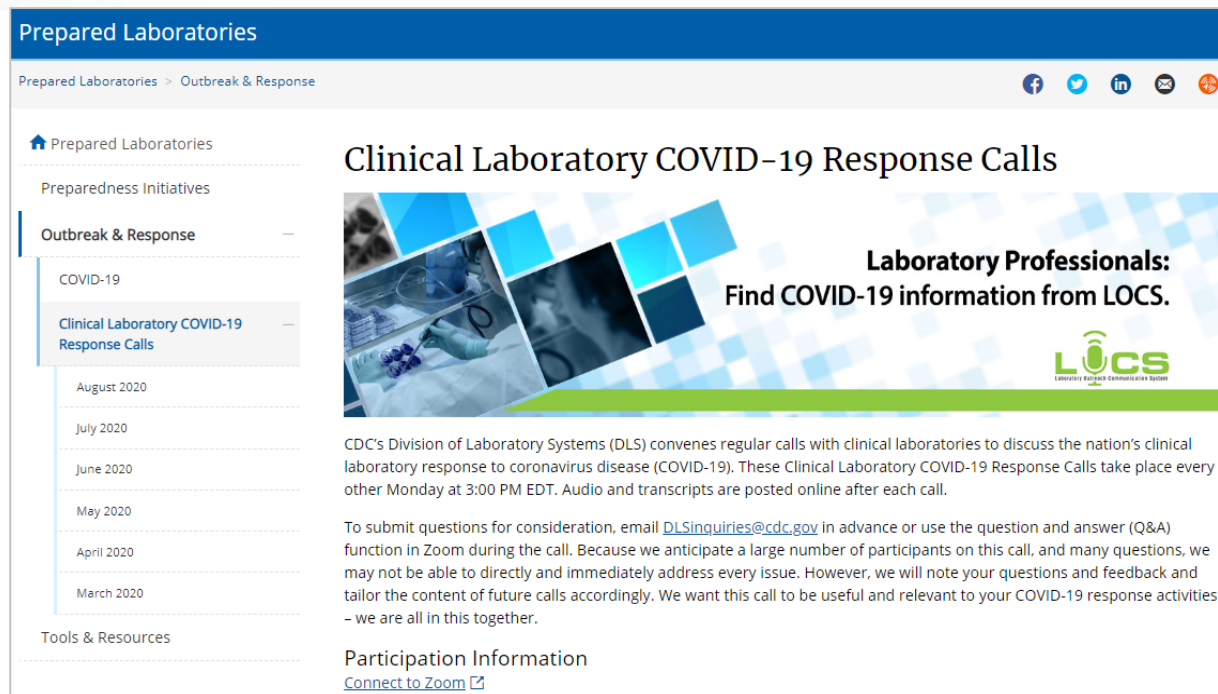
<https://www.cdc.gov/csels/dls/preparedlabs>

The screenshot shows the homepage of the CDC Division of Laboratory Systems preparedness portal. At the top, it features a banner for a "FREE ONLINE COURSE" titled "Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know". Below the banner are three main sections: "Initiatives and Partnerships", "Outbreak & Response", and "Tools & Resources". A "Resources" section lists several links, including the Laboratory Outreach Communication System (LOCS), Clinical Laboratory COVID-19 Response calls, and the Information for Laboratories about Coronavirus (COVID-19) website. A "Contact Us" section at the bottom provides an email address: [DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov).

The screenshot shows a page titled "Information for Laboratories about Coronavirus (COVID-19)". It includes a date "Updated Aug. 16, 2020" and a "Print" button. A featured article titled "Using Antigen Tests" provides interim guidance for SARS-CoV-2 rapid antigen testing. Below this, a "Resources for Laboratories" section is divided into "Diagnostic Tests" and "Other Resources". Under "Diagnostic Tests", there are two links: "Multiplex Assay for Flu and COVID-19, Supplies, and Fact Sheets" and "Diagnostic Test for COVID-19 Only, Supplies, and Fact Sheets". Under "Other Resources", there are two links: "Using Antigen Tests" and "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 content area contains a paragraph about the CDC's Division of Laboratory Systems (DLS) convening regular calls with clinical laboratories to discuss the nation's clinical laboratory response to COVID-19. It also includes a paragraph about how to submit questions for consideration and a link to 'Participation Information' with a 'Connect to Zoom' button. On the left side, there is a navigation menu with 'Prepared Laboratories' at the top, followed by 'Preparedness Initiatives', 'Outbreak & Response', 'COVID-19', 'Clinical Laboratory COVID-19 Response Calls', and 'Tools & Resources'. A list of months from August 2020 to March 2020 is visible under the 'Clinical Laboratory COVID-19 Response Calls' section.

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)



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

# 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*

September 14, 2020

Michael Waters, Ph.D.

COVID-19 National Response Operations: HHS Data Strategy and Execution Workgroup (DSEW)

*SHIELD<sub>x</sub> 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)*

***FOUO – For Official Use Only***

# Reportable Data Elements for All COVID-19 Tests

*(summary; reportable to federal/state/local authorities, as appropriate)*

## Test orders:

- Test ordered
- Ordering provider name & NPI
- Ordering provider location/contact

## Test results:

- Test result
- Device Identifier
- Specimen source
- Date specimen collected
- Test Result date
- Accession #/Specimen ID
- Performing facility name/CLIA#
- Performing facility location

## Patient Demographics:

- Unique patient identifier
- Patient name
- Patient date of birth/age
- Patient race
- Patient ethnicity
- Patient sex
- Patient location/contact
- Patient occupation
- Patient congregate care/living setting
- Patient symptoms
- Patient test & hospitalization history
- Patient pregnancy status

## Harmonization Tools

### HHS COVID-19 Guide:

#	Data Element	Reporting Requirement	Technical Specifications	Notes	Example	HL7 Field
1	Test ordered	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test ordered by provider
2	Test result performed	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result performed by lab
3	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
4	Test result date	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result date
5	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
6	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
7	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
8	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
9	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
10	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
11	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
12	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
13	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
14	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
15	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
16	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
17	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
18	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
19	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result
20	Test result	Yes	Yes	Required	Use the appropriate LOINC code. When available, use the LPTSP or LINC ID. When not available, use the LINC ID.	Test result

### COVID-19 Test Code Mapping:

Test Code	LOINC Code	Test Name	Test Type	Test Method	Test Result	Test Date	Test Location	Test Facility
1	2838-1	COVID-19, IgG antibody (serum)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab A	Facility A
2	2838-2	COVID-19, IgM antibody (serum)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab A	Facility A
3	2838-3	COVID-19, total antibody (serum)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab A	Facility A
4	2838-4	COVID-19, IgG antibody (urine)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab B	Facility B
5	2838-5	COVID-19, IgM antibody (urine)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab B	Facility B
6	2838-6	COVID-19, total antibody (urine)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab B	Facility B
7	2838-7	COVID-19, IgG antibody (saliva)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab C	Facility C
8	2838-8	COVID-19, IgM antibody (saliva)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab C	Facility C
9	2838-9	COVID-19, total antibody (saliva)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab C	Facility C
10	2838-10	COVID-19, IgG antibody (nasal secretions)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab D	Facility D
11	2838-11	COVID-19, IgM antibody (nasal secretions)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab D	Facility D
12	2838-12	COVID-19, total antibody (nasal secretions)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab D	Facility D
13	2838-13	COVID-19, IgG antibody (sweat)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab E	Facility E
14	2838-14	COVID-19, IgM antibody (sweat)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab E	Facility E
15	2838-15	COVID-19, total antibody (sweat)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab E	Facility E
16	2838-16	COVID-19, IgG antibody (tear fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab F	Facility F
17	2838-17	COVID-19, IgM antibody (tear fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab F	Facility F
18	2838-18	COVID-19, total antibody (tear fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab F	Facility F
19	2838-19	COVID-19, IgG antibody (blood)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab G	Facility G
20	2838-20	COVID-19, IgM antibody (blood)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab G	Facility G
21	2838-21	COVID-19, total antibody (blood)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab G	Facility G
22	2838-22	COVID-19, IgG antibody (cerebrospinal fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab H	Facility H
23	2838-23	COVID-19, IgM antibody (cerebrospinal fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab H	Facility H
24	2838-24	COVID-19, total antibody (cerebrospinal fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab H	Facility H
25	2838-25	COVID-19, IgG antibody (synovial fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab I	Facility I
26	2838-26	COVID-19, IgM antibody (synovial fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab I	Facility I
27	2838-27	COVID-19, total antibody (synovial fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab I	Facility I
28	2838-28	COVID-19, IgG antibody (peritoneal fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab J	Facility J
29	2838-29	COVID-19, IgM antibody (peritoneal fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab J	Facility J
30	2838-30	COVID-19, total antibody (peritoneal fluid)	Antibody	Enzyme immunoassay	Positive/Negative	2020-03-15	Lab J	Facility J

## COVID-19 Lab Data Reporting Implementation Specifications

#	Data Element	Reporting Requirement*			Technical Specifications	Notes	Example	HL7 Field
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				
2	Test result (performed)  Test result (values)	Yes	Yes	Requested	<p>Must use <a href="#">harmonized LOINC codes</a>, when available</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column F: 'LOINC Code'</i></p> <p>Qualitative tests: Must use <a href="#">harmonized SNOMED-CT</a> value set codes</p> <p>Quantitative tests: Must use <a href="#">harmonized UCUM units</a>, when available.</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column E: 'Vendor Result'</i></p>	Test conducted by lab	<p>Example LOINC: <a href="#">94640-0</a>: SARS coronavirus 2 S gene [Presence] in Respiratory specimen by NAA with probe detection</p> <p>Example SNOMED-CT Qualitative Values:</p> <ul style="list-style-type: none"> <li>• <a href="#">260373001</a> Detected</li> <li>• <a href="#">260415000</a> Not detected</li> <li>• <a href="#">895231008</a> Not detected in pooled specimen                             <ul style="list-style-type: none"> <li>• # of specimens pooled</li> </ul> </li> <li>• <a href="#">462371000124108</a> Detected in pooled specimen                             <ul style="list-style-type: none"> <li>• # of specimens pooled</li> </ul> </li> <li>• <a href="#">419984006</a> Inconclusive</li> </ul>	<p><a href="#">Click here for HL7 V2 Guidance</a></p> <p><a href="#">OBX-3</a></p> <p><a href="#">OBX-5</a></p>
7	Device Identifier	Yes	Yes	Requested	<p>Must use <a href="#">harmonized Device Identifiers (DI)</a>, when available. The DI is contained within the unique device identifier (UDI), created by manufacturer</p> <p><i>See LIVD file 'LOINC Mapping' Tab, column M: 'TestkitName ID' for assay and column O: 'Equipment UID' for instrument</i></p>	<p>Manufacturer <a href="#">requests UDI issuance</a>, then provides DI, or pull from <a href="#">GUDID database</a></p> <p>If DI unavailable: Use 'Trade Name_Manufacturer Name' (a unique element controlled under <a href="#">21 CFR 209.10(b)(1)</a>)</p>	<p>Example DI: 01234567891011</p> <p>Example Trade Name: SARS-CoV-2 Test_Company</p>	<p><a href="#">OBX-17</a></p> <p><a href="#">OBX-18</a> (barcode)</p>

Location of data element in LIVD SARS-CoV-2 mapping file

Reporting using codes for pooled specimens

Link to HL7 V2 Guidance

## COVID-19 Lab Data Reporting Implementation Specifications

#	Data Element	Reporting Requirement*			Technical Specifications	Notes	Example	HL7 Field
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				
33	AOE: Pregnant	Requested	Requested		Pregnant Not Pregnant UNK - Unknown		LOINC: <a href="#">82810-3</a>  SNOMED-CT Pregnancy Status: <ul style="list-style-type: none"> <li>• <a href="#">77386006</a> Pregnant</li> <li>• <a href="#">60001007</a> Not Pregnant</li> <li>• <a href="#">261665006</a> Unknown</li> <li>• <a href="#">276727009</a> Null</li> </ul>	<a href="#">Click here for HL7 V2 Guidance</a>  <a href="#">OBX-5</a>
<p><b>Reporting Requirements:</b>  <i>This table represents a visual, side-by-side comparison of which entities ultimately receive each of the reported data elements. For example, not all data elements reported to the State/Local PHD are reported to the Federal authorities.</i></p> <ul style="list-style-type: none"> <li>This table is <u>not</u> meant to indicate <u>how</u> data elements are reported in terms of their flow between entities. Current information on reporting requirements for laboratories and associated FAQs are available on CDC's website: "<a href="#">How to Report COVID-19 Laboratory Data</a>"</li> </ul> <p><i>Requirement/Request Level:</i></p> <ul style="list-style-type: none"> <li>Yes = Required to be reported by August 1<sup>st</sup>, 2020</li> <li>Requested = Every reasonable effort should be made to achieve reporting by August 1<sup>st</sup>, 2020</li> <li>Optional = Strongly encouraged to begin reporting by August 1<sup>st</sup>, 2020, if possible</li> <li>No = Not required to be reported</li> </ul>								

New - National ELR Flat File and HL7 Generator Tool Package

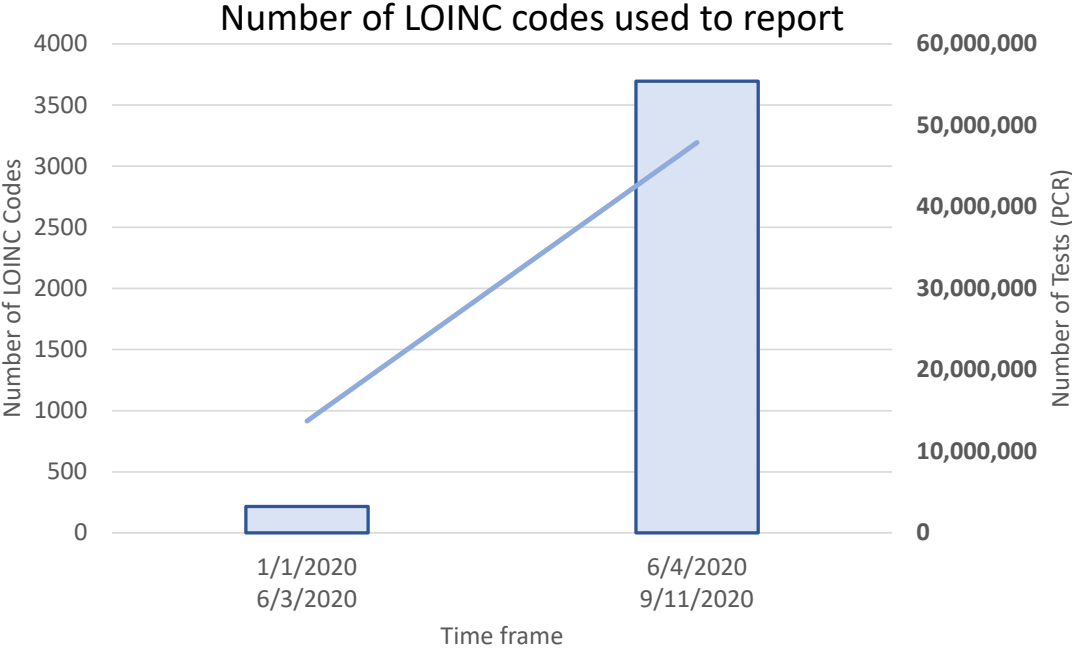
[https://preparedness.cste.org/?page\\_id=136](https://preparedness.cste.org/?page_id=136)



# Completeness and Harmonization of One Data Element

~ 77 million reported PCR test results \*as of 9/11

>99% of transmitted results report data element "Test Result"



12.4% of test results don't use harmonized LOINC codes



Top three codes

- 1. NOVELCORONAPCR
- 2. COVID19
- 3. Null (empty field)

**Data harmonization is improving!**



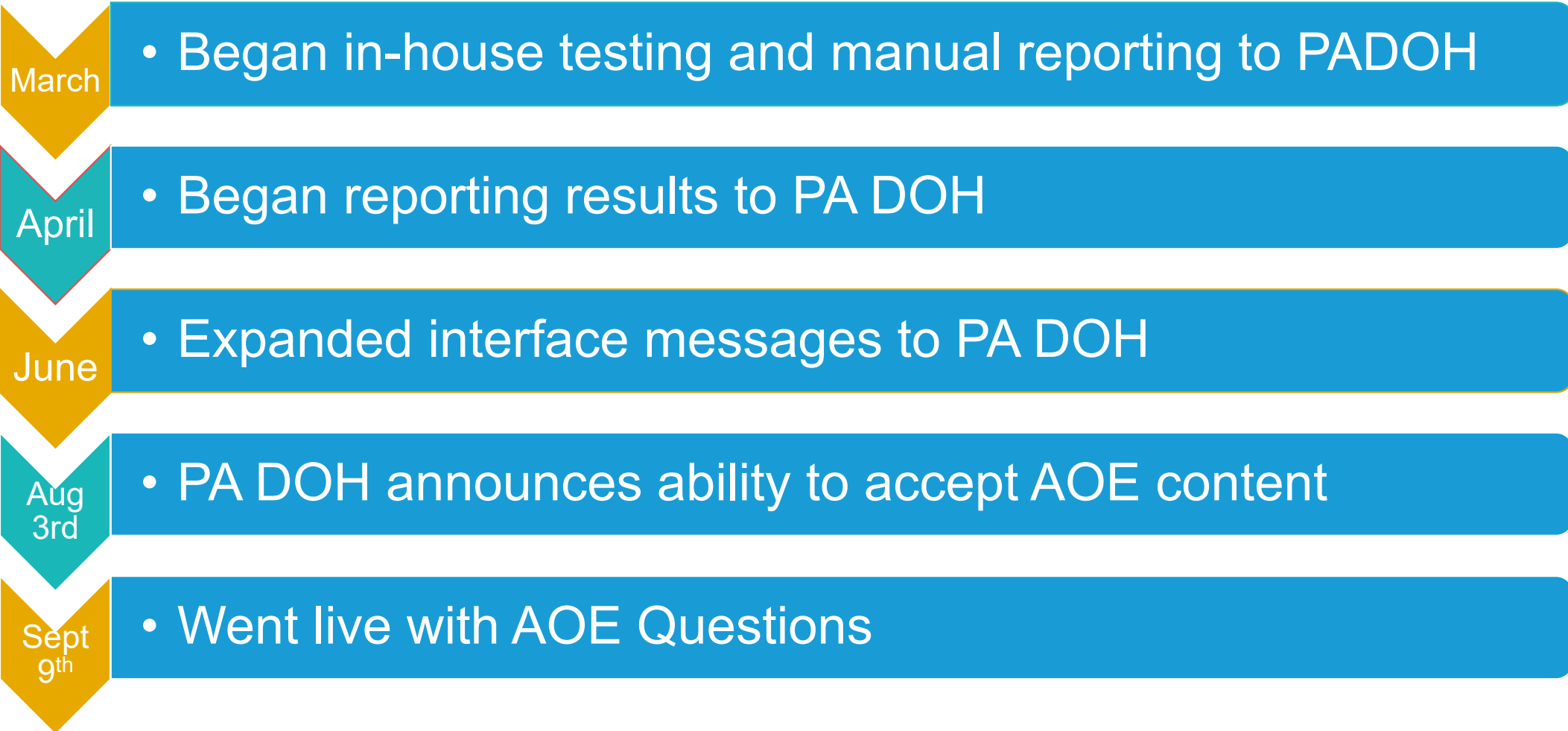
# **HHS Answer-On-Entry (AOE) Question Implementation:** *Geisinger Health System's Experience*

**Geisinger**

**Jordan Olson M.D., FCAP FASCP**  
**September 14<sup>th</sup> 2020**  
**D.M. Wolk, Ph.D., D(ABMM)**

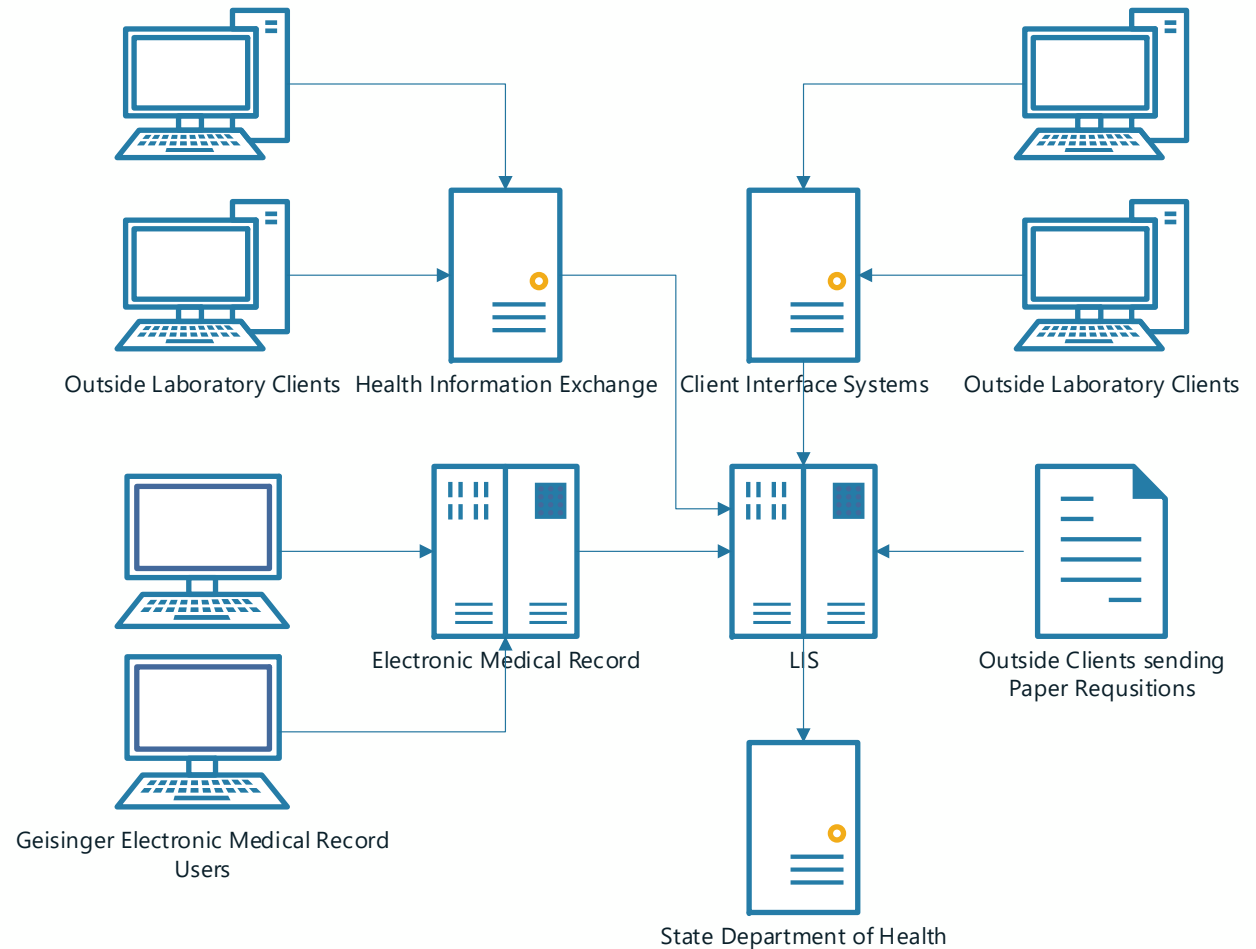


# Timeline



- 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?

Hospitalized for COVID-19?

Admitted to ICU for COVID-19?

Employed in healthcare setting?

Resident in a congregate care/living setting?

Pregnant?

First COVID-19 test?

Symptomatic for COVID-19 as defined by CDC?

🔴 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?

Admitted to ICU for COVID-19?

Employed in healthcare setting?

Resident in a congregate care/living setting?

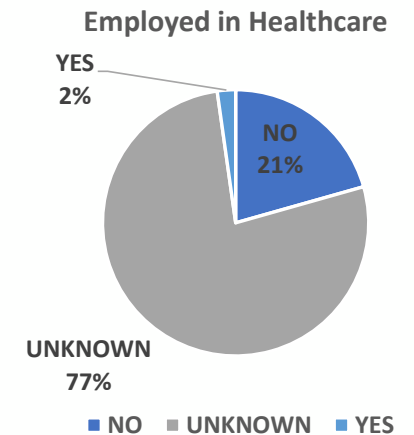
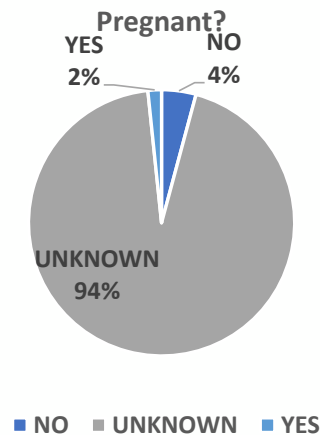
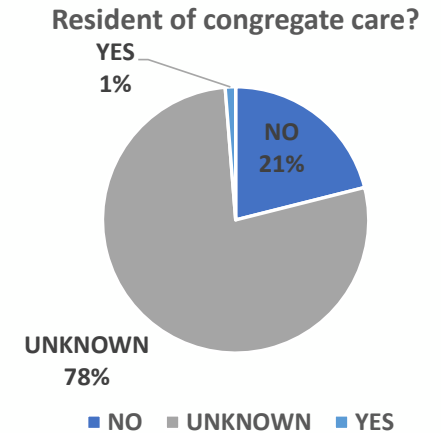
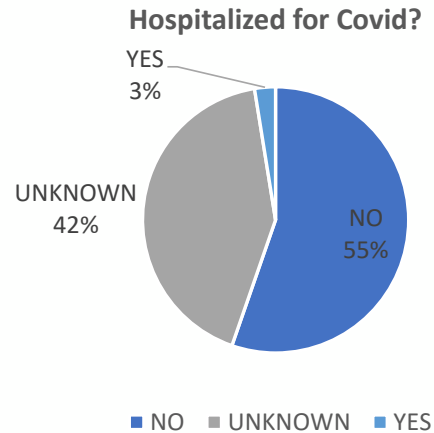
Residence type

Pregnant?

First COVID-19 test?

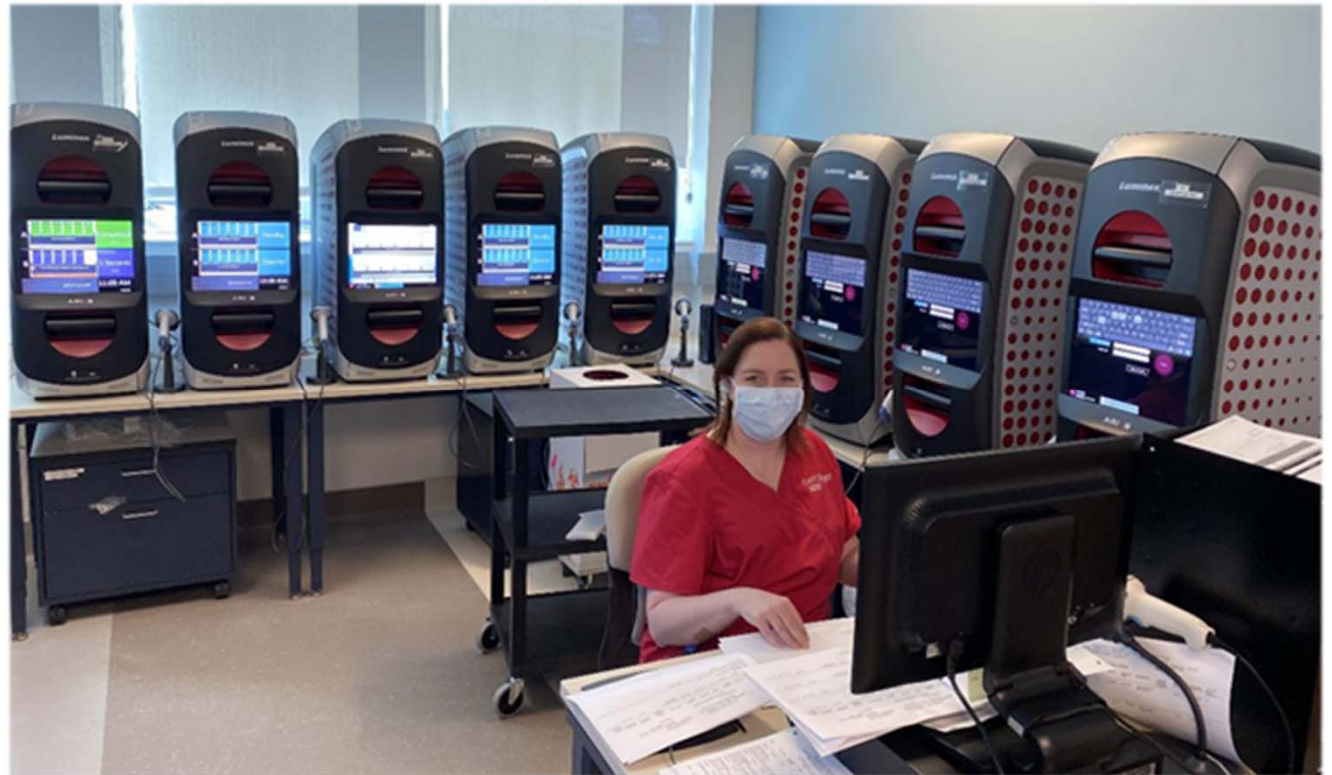
# AOE Answers

- 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>

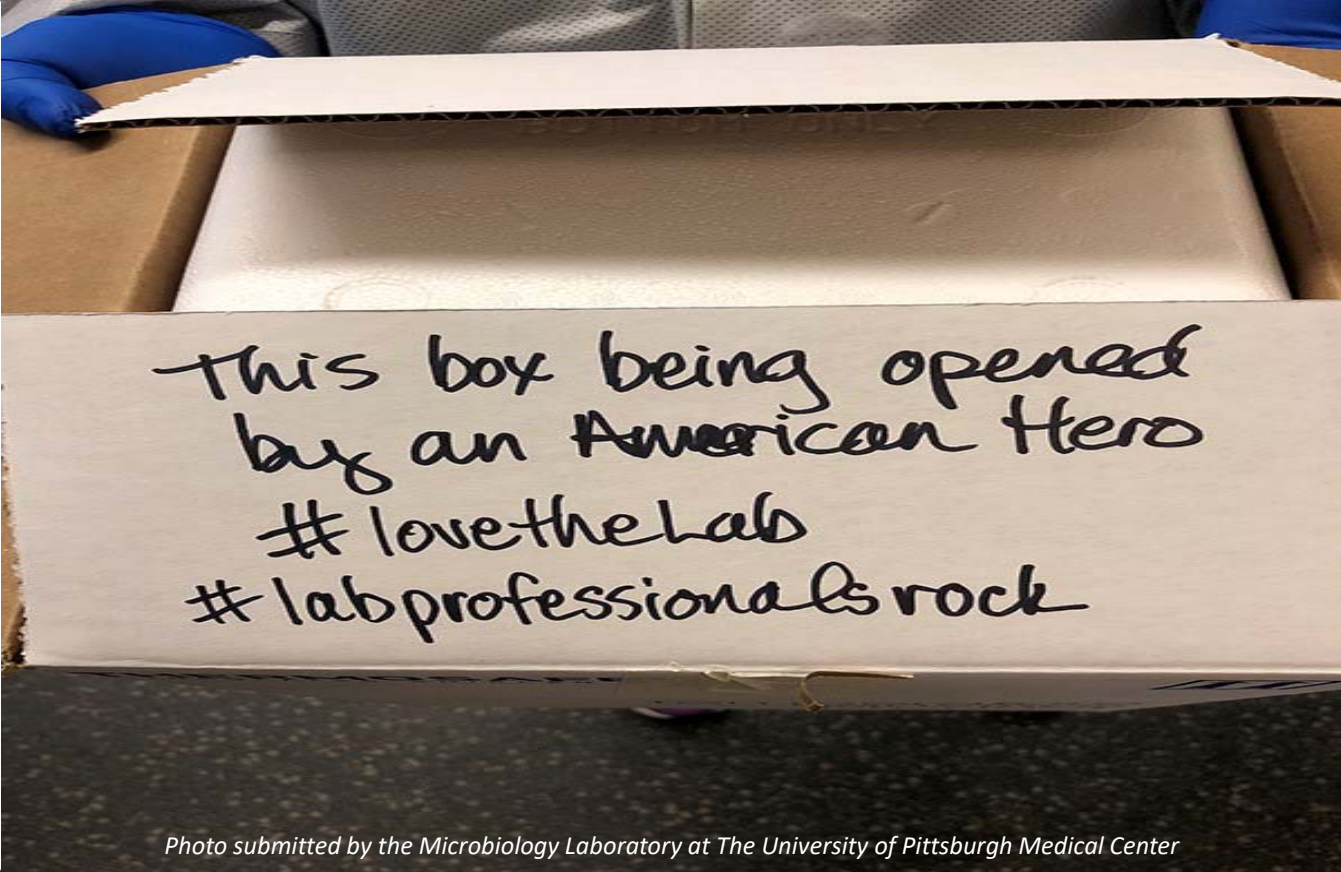


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# Thank You For Your Time!



This box being opened  
by an American Hero  
#lovethelab  
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*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*