Clinical Laboratory COVID-19 Response Call

Monday, December 27, 2021, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Potential Increase in Testing Demand**
  - Henry Walke, CDC Center for Preparedness and Response (CPR)
- **SARS-CoV-2 Variants Update**
  - John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **FDA Update**
  - Tim Stenzel, US Food and Drug Administration (FDA)
- **LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests – Overview**
  - MariBeth Gagnon, CDC Division of Laboratory Systems (DLS)

Division of Laboratory Systems (DLS)

Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.

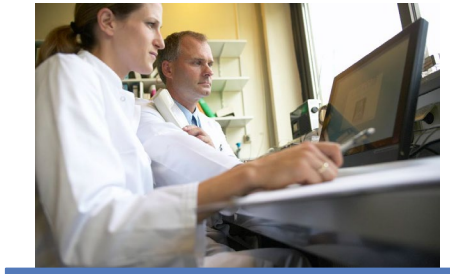
Four Goal Areas

Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance

Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories

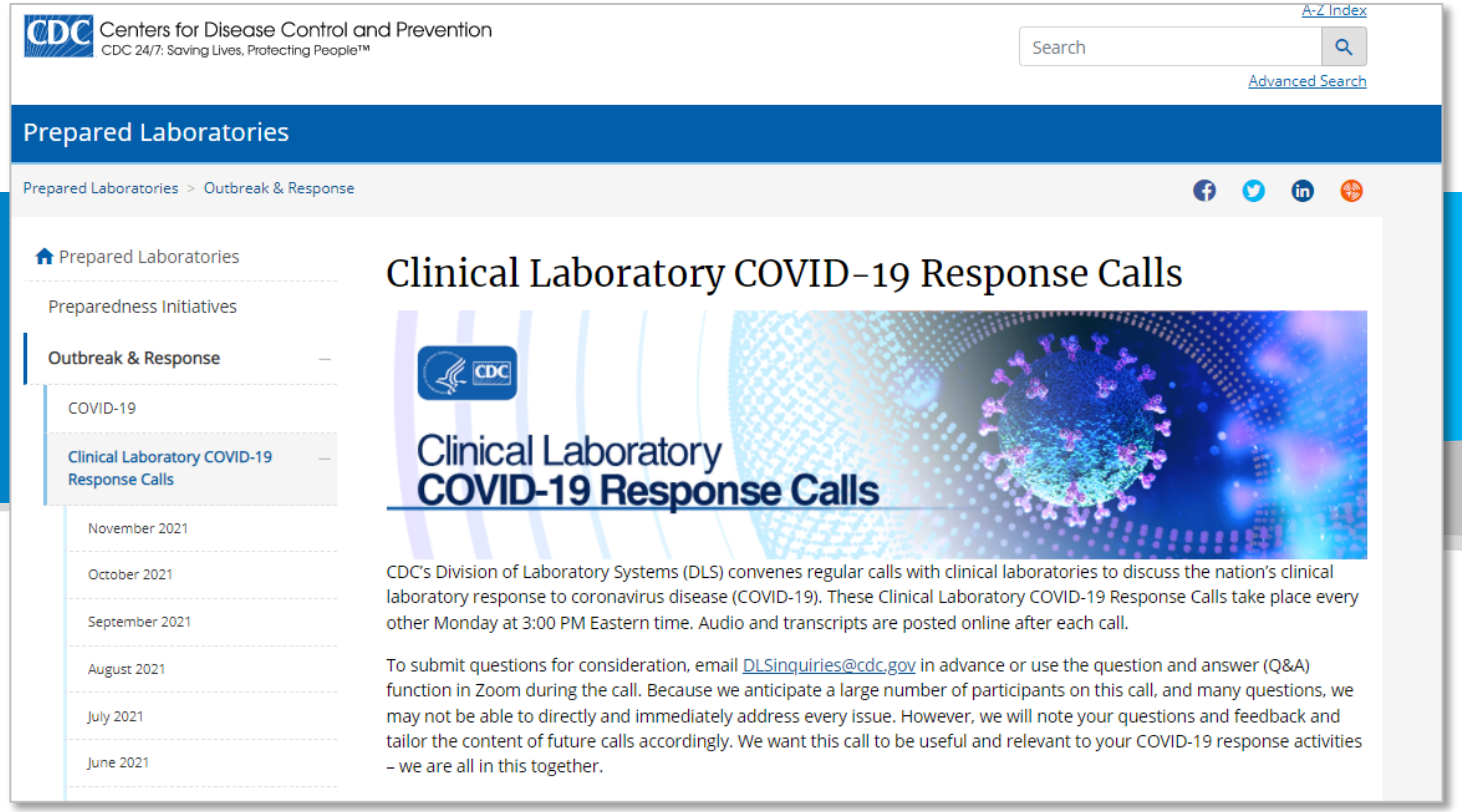
Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

CDC Preparedness Portal

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

Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal



CDC OneLab

The **CDC OneLab Network** is a collaborative **network of clinical, public health, and CDC laboratory education and training professionals.** It is an extension of the OneLab™ Initiative, the goal of which is to meet laboratory learners' most urgent COVID-19 laboratory education and training needs and collectively support rapid, large-scale responses.

Join the Network Here

OneLab™

A Unified Response to Training Needs

1,978 Members

1,300+ unique organizations

20+ eLearnings and Resources

Courses and job aids aligned to training needs identified in large scale needs assessment

8 Educational Events

Topics included validation and verification, crisis leadership, and supply chain lessons learned

Laboratory Learning Hub
Coming Soon

COVID-19 Laboratory training hub (OneLab REACH™) for CDC-developed courses

Next Scheduled CLCR Call

The next call will be on **Monday, January 10**

from **3:00 PM to 4:00 PM ET**

We Want to Hear from You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

How to Ask a Question

- **Using the Zoom 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
- If you are a patient, please direct any questions to your healthcare provider

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

Potential Increase in Testing Demand

Henry Walke
CDC Center for Preparedness and Response (CPR)

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

SARS-CoV-2 Variants Update

John Barnes
CDC Laboratory and Testing Task Force for the COVID-19 Response

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

FDA Update

Tim Stenzel
US Food and Drug Administration (FDA)

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

U.S. 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/

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)

- **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 (*)

- **FDA MedWatch**
  https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

U.S. FOOD & DRUG ADMINISTRATION

LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests – Overview

MariBeth Gagnon, MS CT(ASCP)HTL
Health Scientist
Informatics and Data Science Branch (IDSB)
Division of Laboratory Systems (DLS)

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

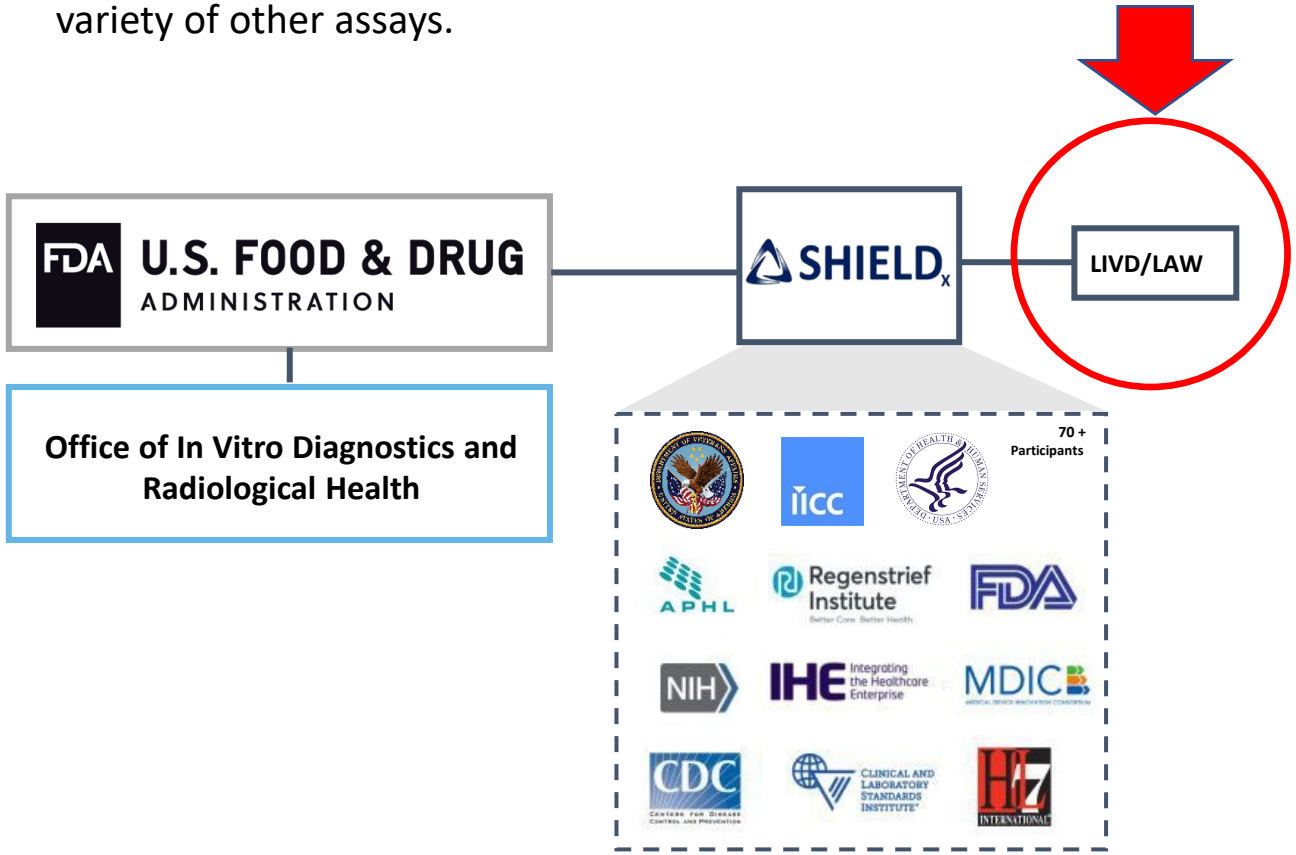
COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act

https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

- Test order code - LOINC
- Test performed code - LOINC
- Vendor result description - SNOMED-CT
- Vendor specimen description – SNOMED-CT
- Device Identifier
  - Equipment Unique Identification
  - Test kit name ID

FDA SHIELD

The Food and Drug Administration (FDA) **Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD)** is a public-private partnership that was assembled with a singular focus on improving the interoperability and utility of in-vitro diagnostic (IVD) test data. SHIELD provides the authoritative source of coding for COVID-19 testing and a wide variety of other assays.

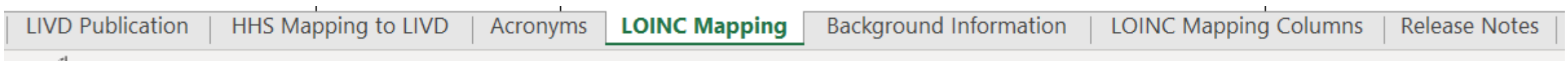


Benefits of FDA SHIELD

- **Eases the burden** for all stakeholder groups through a unified approach
- **Advances greater standards-based** information exchange across laboratories and healthcare institutions
- **Lays the foundation for improved semantic** interoperability by implementing infrastructure that directly harmonizes the process of how laboratory data standards are practically applied to IVD test data

LIVD Core Catalogue

- LIVD Publication
- HHS Mapping to LIVD
- Acronyms
- LOINC Mapping
- Background Information
- LOINC Mapping Columns
- Release Notes



SHIELD LIVD Core Team

- IVD Industry - Ed Heierman (Abbott)
- Regenstrief –David Baorto
- SNOMED-CT – John Snyder
- APHL – Riki Merrick and Jerry Sable
- FDA – Ryan Karsner
- CDC – MariBeth Gagnon and Jasmine Chaitram
- ONC – Andrew Northup

DLS website

https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests

On June 4, 2020, the Department of Health and Human Services (HHS) announced new laboratory data reporting guidance for COVID-19 testing. Using LOINC and SNOMED-CT to identify and report SARS-CoV-2 test results in electronic reporting systems will facilitate timely and quality data reporting to state and federal public health agencies. The following document (developed per the LIVD specification) provides LOINC and SNOMED mappings for SARS-CoV-2 diagnostic tests available in the United States. The LIVD mapping catalogue provides coding for these data elements: LOINC test order, LOINC test result, SNOMED-CT test description, SNOMED-CT specimen source, and Device Identifier.

Mapping tool: LIVD SARS-CoV-2 Test Codes.xlsx
LIVD publication date 2021-12-01.

LOINC Mapping Table

	A	B	C	D	E	F	H	M	O
1	Manufacturer	Model	Vendor Analyte Name	Vendor Specimen Description	Vendor Result Description	Test Performed LOINC Code	Test Ordered LOINC Code	Testkit Name ID	Equipment UID
182	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	FluB Result Interpretation	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) anterior nasal swab (697989009^Anterior nares swab^SCT)	Influenza B detected (260373001^Detected^SCT) Influenza B not detected (260415000^Not Detected^SCT)	92141-1	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories, Inc.	CFX96 Touch Real-Time PCR System_B
183	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	SC2 Result Interpretation	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) anterior nasal swab (697989009^Anterior nares swab^SCT)	SARS-CoV-2 detected (260373001^Detected^SCT) SARS-CoV-2 not detected (260415000^Not Detected^SCT)	94533-7	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories, Inc.	CFX96 Touch Real-Time PCR System_B
184	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	FluA Result Interpretation	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) anterior nasal swab (697989009^Anterior nares swab^SCT)	Influenza A detected (260373001^Detected^SCT) Influenza A not detected (260415000^Not Detected^SCT)	92142-9	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories, Inc.	CFX96 DX Real-Time PCR System ORM
185	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	FluB Result Interpretation	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) anterior nasal swab (697989009^Anterior nares swab^SCT)	Influenza B detected (260373001^Detected^SCT) Influenza B not detected (260415000^Not Detected^SCT)	92141-1	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories, Inc.	CFX96 DX Real-Time PCR System ORM
186	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	SC2 Result Interpretation	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) anterior nasal swab (697989009^Anterior nares swab^SCT)	SARS-CoV-2 detected (260373001^Detected^SCT) SARS-CoV-2 not detected (260415000^Not Detected^SCT)	94533-7	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories, Inc.	CFX96 DX Real-Time PCR System ORM
187	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	FluA Result Interpretation	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) anterior nasal swab (697989009^Anterior nares swab^SCT)	Influenza A detected (260373001^Detected^SCT) Influenza A not detected (260415000^Not Detected^SCT)	92142-9	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories, Inc.	C1000 Dx Thermal Cycler_BioRad
	Bio-Rad Laboratories,	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay	FluB Result	nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT)	Influenza B detected (260373001^Detected^SCT)	92141-1	95422-2	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit_Bio-Rad Laboratories,	C1000 Dx Thermal Cycler_BioRad

LIVD Publication | HHS Mapping to LIVD | Acronyms | **LOINC Mapping** | Background Information | LOINC Mapping Columns | Release Notes

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.

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Thank You For Your Time!

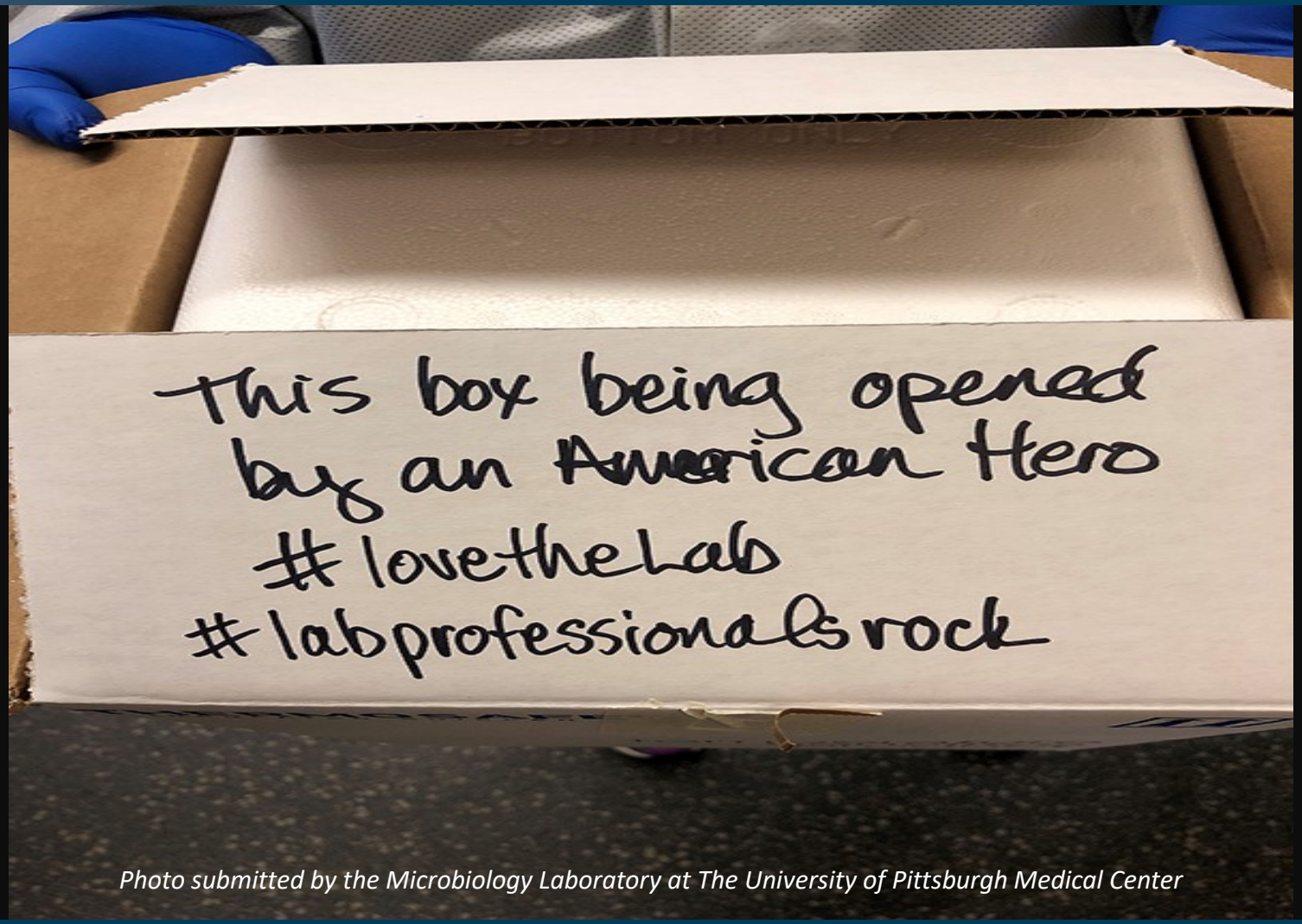

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center