Laboratory Outreach Communication System (LOCS) Call

Monday, October 17, 2022, at 3:00PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems
- **Ebola Update**
  - Joel Montgomery, CDC Division of High-Consequence Pathogens and Pathology
- **Packing and Shipping for Ebola Specimens**
  - Sabrina DeBose, CDC Division of Laboratory Systems
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, CDC Division of Viral Diseases
- **Monkeypox Update**
  - Serena Carroll, CDC Monkeypox Response
- **2022 US Monkeypox Outbreak & FSAP Regulations**
  - Denise Gangadharan and Lori Bane, CDC Division of Select Agents and Toxins

About 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.

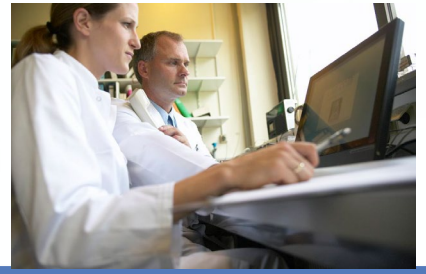
Four Goal Areas

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

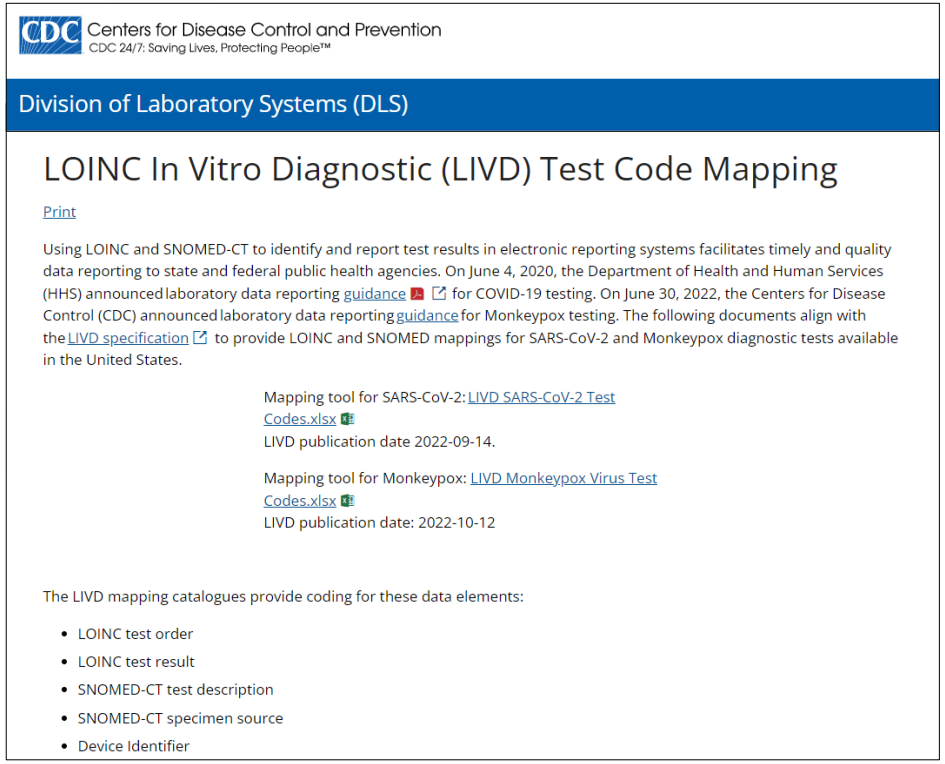
CLIAC 2022 Fall Meeting

- Register on CDC's CLIAC website: https://www.cdc.gov/cliac/upcoming-meeting.html
- Send oral and written comments to CLIAC@cdc.gov by November 4, 2022
- Meeting topics include:
  - CLIAC workgroup reports
  - Public health and clinical laboratory workforce challenges
  - Monkeypox response updates

CDC Publishes New LIVD Test Code Mapping added for Monkeypox Virus Test Results

- The guide supports use of harmonized LOINC and SNOMED Clinical Terms (CT) codes to help improve accuracy and standardization of Monkeypox virus test reporting

- This LIVD specification, which maps all Monkeypox virus diagnostic tests that have received FDA EUAs, was jointly developed by FDA, CDC, IVD Industry Connectivity Consortium, Regenstrief Institute, and APHL



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Division of Laboratory Systems (DLS)

LOINC In Vitro Diagnostic (LIVD) Test Code Mapping

Print

Using LOINC and SNOMED-CT to identify and report test results in electronic reporting systems facilitates timely and quality data reporting to state and federal public health agencies. On June 4, 2020, the Department of Health and Human Services (HHS) announced laboratory data reporting guidance for COVID-19 testing. On June 30, 2022, the Centers for Disease Control (CDC) announced laboratory data reporting guidance for Monkeypox testing. The following documents align with the LIVD specification to provide LOINC and SNOMED mappings for SARS-CoV-2 and Monkeypox diagnostic tests available in the United States.

Mapping tool for SARS-CoV-2: LIVD SARS-CoV-2 Test Codes.xlsx
LIVD publication date 2022-09-14.

Mapping tool for Monkeypox: LIVD Monkeypox Virus Test Codes.xlsx
LIVD publication date: 2022-10-12

The LIVD mapping catalogues provide coding for these data elements:

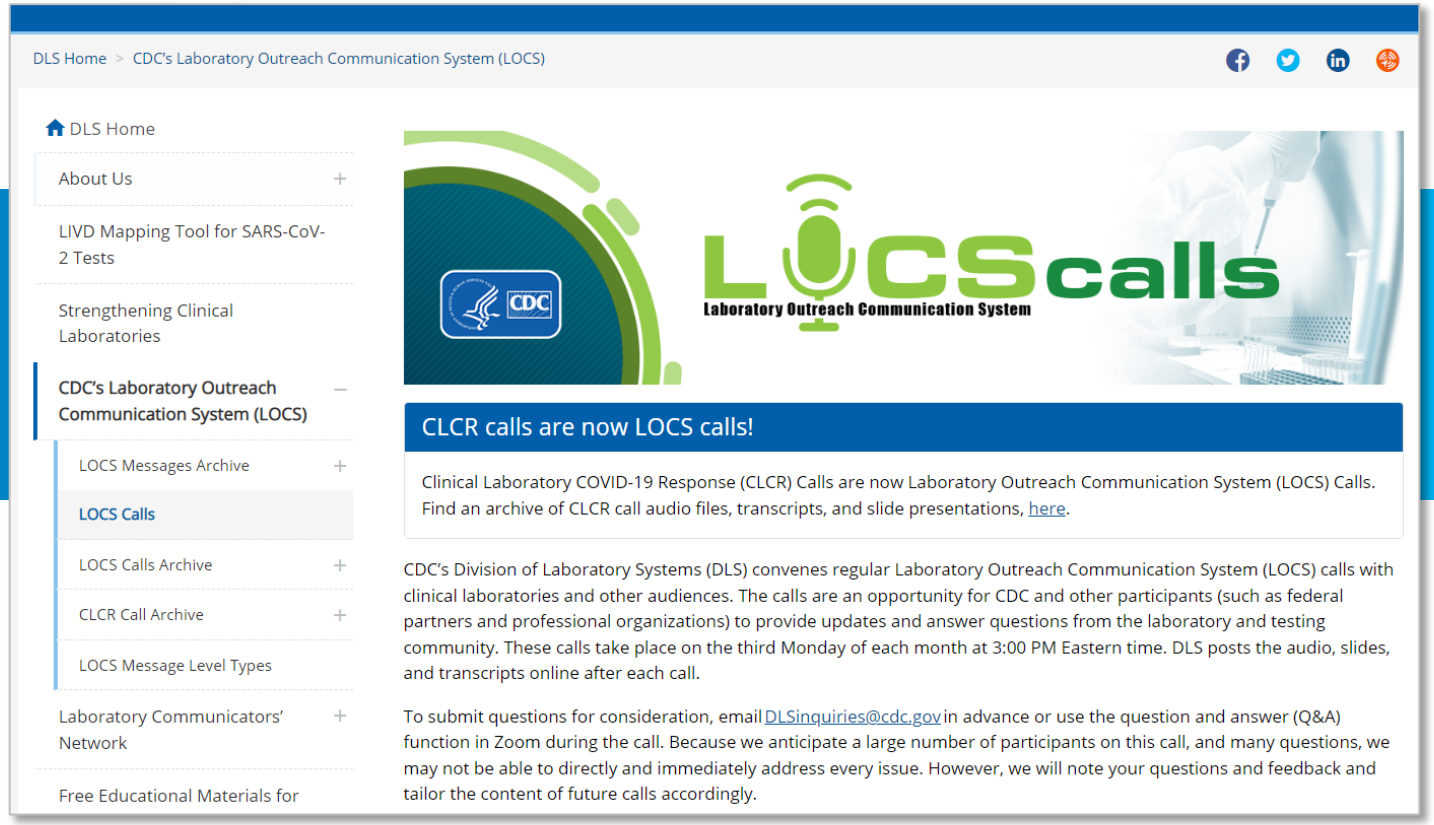
- LOINC test order
- LOINC test result
- SNOMED-CT test description
- SNOMED-CT specimen source
- Device Identifier

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

LOCS Calls

https://www.cdc.gov/locs/calls

Find LOCS Call information, transcripts, and audio recordings on this page



Next Scheduled Call

Monday, November 21

@ 3 PM to 4 PM ET

We Want to Hear From You!

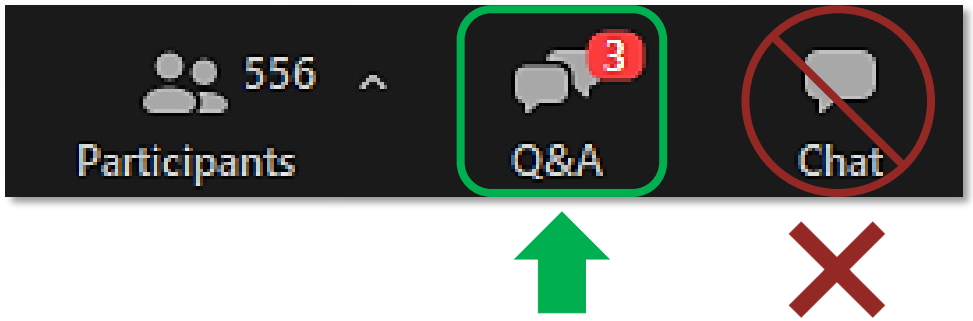
Training and Workforce Development

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.

Ebola Update

Joel Montgomery
Division of High-Consequence Pathogens and Pathology, CDC

Packing and Shipping for Ebola Specimens

CDR Sabrina DeBose
Division of Laboratory Systems, CDC

Division of Laboratory Systems

- CDC Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing: https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html
- US DOT - Transporting Infectious Substances Safely: https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Transporting-Infectious-Substances-Safely.pdf
- § 173.196 Category A infectious substances: https://www.ecfr.gov/current/title-49/subtitle-B/chapter-I/subchapter-C/part-173/subpart-E/section-173.196
- Select Agents FAQ for APHIS/CDC Form 2 Transfers: https://www.selectagents.gov/compliance/faq/transfers.htm
- CDC Screening Patients for Ebola Virus Disease: https://www.cdc.gov/vhf/ebola/clinicians/evaluating-patients/index.html
- CDC Laboratory Response Network: https://emergency.cdc.gov/lrn/index.asp

Division of Laboratory Systems

OneLab NETWORK™

ONELAB NETWORK PRESENTS:

Packing and Shipping Suspected Ebola Specimens

October 27, 2022 1-2pm ET

Registration Link: https://bit.ly/3CounIO

SARS-CoV-2 Variants Update

Natalie Thornburg
Division of Viral Diseases, CDC

Monkeypox Update

Serena Carroll
Monkeypox Response, CDC

2022 U.S. Monkeypox Outbreak & FSAP Regulations

LOCS Call

Denise Gangadharan, PhD

Associate Director for Science

Lori Bane, MS

Deputy Director

Division of Select Agent and Toxins

10/17/2022

Monkeypox Regulatory language

- §73.3 HHS select agents and toxins

  (b) HHS select agents and toxins:

  Monkeypox virus

  (d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

  12) Any South American genotypes of Eastern Equine Encephalitis Virus and **any West African Clade of monkeypox virus provided that the individual or entity can identify that the agent is within the exclusion category.**

SA Gram clarifying the regulatory status of materials

- Currently, there are two clades of monkeypox virus:
  - Congo Basin clade (Clade I) and West African clade (Clades IIa and IIb).
  - Up to this point in the 2022 U.S. Monkeypox Outbreak, laboratory testing has indicated that the current outbreak is associated with the Clade IIb of the monkeypox virus.
- Monkeypox virus is regulated as an HHS-only select agent [42 CFR 73.3(b)] and entities that possess, use, or transfer this agent must comply with the HHS Select Agent and Toxin Regulations [42 CFR 73] (“the regulations”) unless there is an applicable exemption or exclusion, such as the following:

SA Gram clarifying the regulatory status of materials: Exclusion

- West African Clade Exclusion (Clade IIa or IIb): The regulations provide that “any West African Clade of monkeypox virus [is excluded from the requirements of the regulations] provided that the individual or entity can identify that the agent is within the exclusion category.” 42 CFR 73.3(d)(12).
- This exclusion would apply to material that has been identified as being or containing West African Clade (Clade II) monkeypox virus.

SA Gram clarifying the regulatory status of materials: Exemption

- **Diagnostic Specimen Exemption:** The regulations provide that clinical or diagnostic laboratories or other entities that possess, use or transfer an HHS select agent contained in a specimen presented for diagnosis or verification will be exempt from the requirements of the regulations for such agent if the entity,
  1) reports the identification of the agent to the Federal Select Agent Program (FSAP) and other authorities as required by law,
  2) secures the select agent after identification, and
  3) transfers or destroys the material, in accordance with 42 CFR 73.5(a).

- This exemption would apply to material that has been identified as being or containing monkeypox virus, but the clade has not been determined or the clade has been determined to be Congo Basin clade (Clade I).

SA Gram clarifying the regulatory status of materials

- An entity may retain this material if registered with FSAP and approved to possess monkeypox virus.

- FSAP regulates material that has been identified as being or containing a select agent or toxin. Therefore, confirmed identifications of Orthopoxvirus that are presumptive identifications of monkeypox virus, are not considered select agents by FSAP until identified to be monkeypox virus or another select agent.

Regulatory status of material

Test result	Subject to the select agent requirements?
Non-variola *Orthopoxvirus*	No
Monkeypox virus clade undetermined	Yes
Monkeypox virus Clade I (Congo Basin clade)	Yes
Monkeypox virus clade II (West African clade)	No

Select Agent Reporting

Select agent less stringent reporting (Form 4)

- The HHS Select Agent and Toxin Regulations require entities, unless directed otherwise, to report the identification of a select agent or toxin to the Division of Select Agents and Toxins (DSAT) within seven days of identification by submitting an *APHIS/CDC Form 4 (Report of the Identification of a Select Agent or Toxin)*. Monkeypox virus is a select agent. *See* 42 CFR Part 73.
- In accordance with the HHS Select Agent and Toxin Regulations, 42 C.F.R. § 73.5 (a)(4)(iii), DSAT has authorized less stringent reporting requirements for the identification of monkeypox virus due to the 2022 Monkeypox Outbreak.

Select agent less stringent reporting (Form 4)

- Until the conclusion of the monkeypox virus outbreak as determined by the Centers for Disease Control and Prevention, clinical and diagnostic labs and other entities that possess HHS select agents and toxins may submit one consolidated report, using the APHIS/CDC Form 4, to report all identifications of monkeypox virus for a 180-day period.
- All monkeypox virus positive samples, not characterized to clade level or identified as Clade I of the monkeypox virus, can be submitted on a single APHIS/CDC Form 4 with an accompanied spreadsheet listing the different sample providers, as long as the form submission date is within 180 days of the earliest sample identification date.

Select agent less stringent reporting (Form 4)

- Please note, Clade II (West African Clade) monkeypox virus is excluded from the select agent regulatory requirements, including identification reporting.
  - Therefore, samples that have been identified to be or contain Clade II (West African Clade) monkeypox virus, do not need to be reported to DSAT.
  - However, each identification of monkeypox virus, clade undetermined, or Clade I (Congo Basin Clade) monkeypox virus must be reported to DSAT using an individual or consolidated APHIS/CDC Form 4 report.
- If an entity reports an identification of monkeypox virus, clade undetermined to DSAT and the sample is later determined to be the excluded Clade II (West African Clade) of monkeypox virus, the entity should update DSAT once the identification is known by sending an email to CDCForm4@cdc.gov.
- The entity should also update the identification to the recipient of the sample material if previously transferred.

Select agent reporting (Form 4) questions

Scenario: Laboratory A identifies a diagnostic specimen as positive for Non-variola orthopoxvirus by PCR. Laboratory A sends the specimen to Laboratory B for further characterization. Laboratory B identifies the specimen as monkeypox virus but does not determine the clade.

Which laboratory is responsible for reporting the identification of monkeypox virus with undetermined clade?

- *Each entity (Laboratory A) that identifies monkeypox virus, clade undetermined or monkeypox virus Clade I is required to complete and submit an APHIS/CDC Form 4A-AB (Report of the Identification of a Select Agent or Toxin) and Laboratory B would complete APHIS/CDC Form 4A-CD reporting the possession of the sample containing the select agent.*
- *If an entity received samples from multiple locations/sample providers, the entity must submit a separate APHIS/CDC Form 4 for each location/sample provider.*

Sections A-B of the Form 4 are for any clinical or diagnostic laboratory having identified a select agent or toxin contained in a specimen or sample presented for diagnosis, verification, or proficiency testing. Sections C-D of the Form 4 should be completed by the sample provider.

Once identified as monkeypox virus with undetermined clade, does the original sample from Laboratory A fall under the select agent regulations? If so, when?

- *Yes. Once a sample is identified as a select agent, the samples containing the identified a select agent must be treated as a select agent. Monkeypox virus is regulated as an HHS-only select agent [42 CFR 73.3(b)] and entities that possess, use, or transfer this agent must comply with the select agent regulations [42 CFR 73]. Only West African Clade (Clade II) monkeypox virus is excluded from the select agent regulatory requirements.*

Select Agent Waste

What are the select agent requirements for waste collected from patients that have been diagnosed with monkeypox virus, undetermined clade?

- *The select agent regulations provide that the following is excluded from the select agent regulations:*

  Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with state and Federal regulations within seven calendar days of the conclusion of patient care.

42 CFR 73.3(d)(11)

It is the policy of the Federal Select Agent Program (FSAP) that for an individual who has been admitted to a medical facility, that individual's "conclusion of patient care" and the point when "delivery of patient care by heath care professionals has concluded" is when that individual has been released from the medical facility where treatment was being provided.

www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301-851-2070

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Thank You For Your Time!

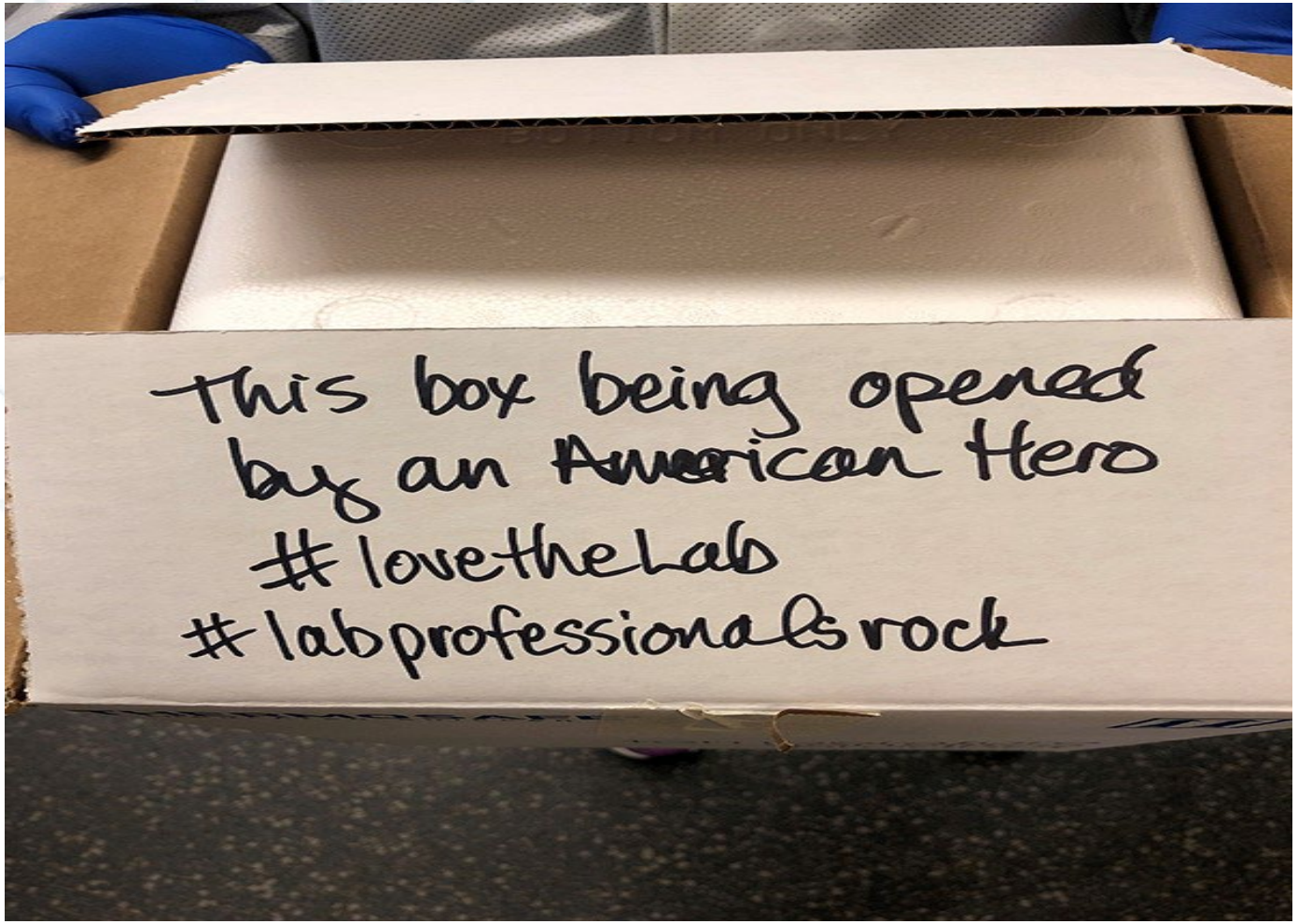

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center

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