Clinical Laboratory COVID-19 Response Call

Monday, May 18th, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Urgent Need for a Coherent National Testing Strategy for COVID-19**
  - Gary Procop, Chair, American Society for Clinical Pathology (ASCP) Commission on Science, Technology, Quality and Policy
- **COVID-19 Convalescent Plasma and the Transfusion Service**
  - Kerry O'Brien, Beth Israel Deaconess Medical Center
- **The Unexpected Impact of COVID-19 on the Blood Supply**
  - Kimberly Sanford, Virginia Commonwealth University
- **Laboratory Biosafety Update**
  - Bill Arndt, CDC Division of Laboratory Systems
- **FDA Update and Responses to Questions**
  - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)

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/
- 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
- IVD Industry Connectivity Consortium
  https://ivdconnectivity.org/livd/

Share Your Feedback!

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

Take the Survey Here:

https://www.surveymonkey.com/r/CLCR0518

Questions? Contact DLSinquiries@cdc.gov

We Want to Hear From You!

LabTrainingNeeds@cdc.gov

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.

STRONGERTOGETHER

Need for a Coherent National Diagnostic Test Strategy for COVID-19

Gary W. Procop, MD, MS, MASCP

Chair, ASCP Commission on Science, Technology, Quality and Policy

A Mission to Serve Patients and Be A Voice for Our Field

Call to Action

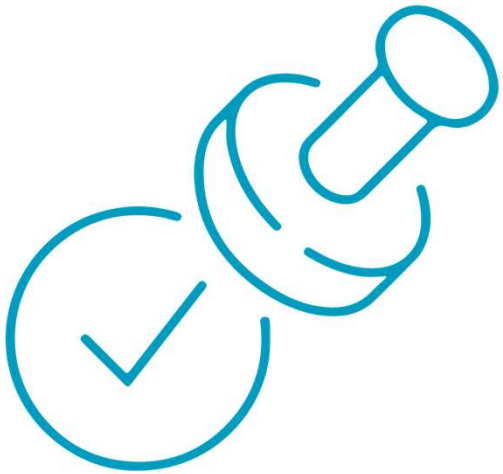
- ✓ **Flexibility to Expand Testing** (Granted)
- ✓ **Remote Read Pathology Slides** (Granted)
- ✓ **National Testing Strategy** (Elements Enacted)
- ✓ **Formation of National Task Force to Promote Reliable Testing** (Pending)

Rational Request

Stronger Representation of Laboratory Leadership Needed in Decision Making at Federal and State Level

Pandemic Response: Much Has Been Done in the Past 18 Weeks

- **Mobilization by public health community (Public Health Labs, CDC, FDA, HHS)**
- **Rapid response from diagnostic companies and clinical laboratories to ramp-up testing**
- **Appropriations and resource support – the White House, Congress and Governors**



Reliable Testing, Quality Improvement, Expedited Research

- **Evidence-based, best practices for reliable testing**
- **Optimal test use based on different performance characteristics**
  - pre-surgical screening, ambulatory, pre-admission, etc.
- **Ability to benchmark and compare**
- **Field new guidelines**
- **Rapid dissemination of research**

Building a Collation It's Like Baking a Cake

Ingredients

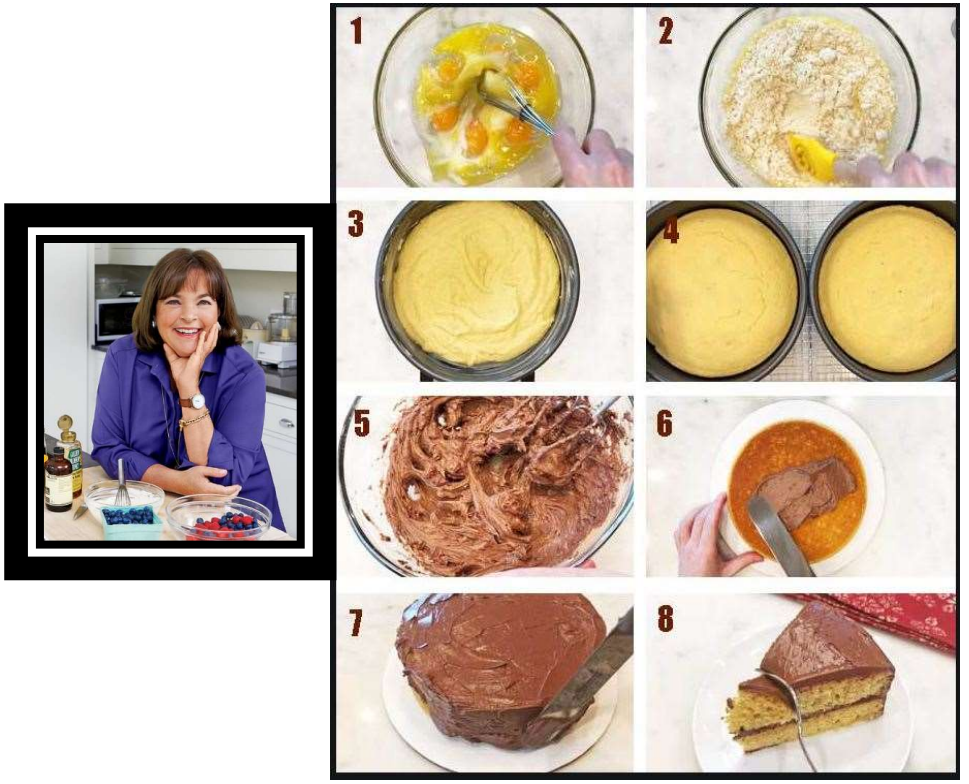
- ✓ **Experts from National Organizations**
  - AMP, ASCP, ASM, APHL, AACC, CAP…
  - Selfless, goal-oriented, team philosophy

Chef

- ✓ **Honest Broker**
  - ? CDC, FDA…

Worthwhile End Result (Cake!)

- ✓ **Evidence-Based National Guidance**
  - Innovations: Research & Development



Toward Optimal Test Utilization

Issues

- ✓ **What does it do?**
  - – Define it
    - • Scientific analyses
- ✓ **What can't it do?**
  - – Describe boundaries
- ✓ **How to use it?**
  - – Control it
    - • On-label use guidance
    - • Off-label hazards
    - • Best Practices

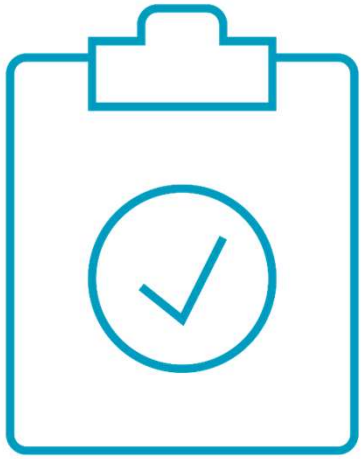
Assays

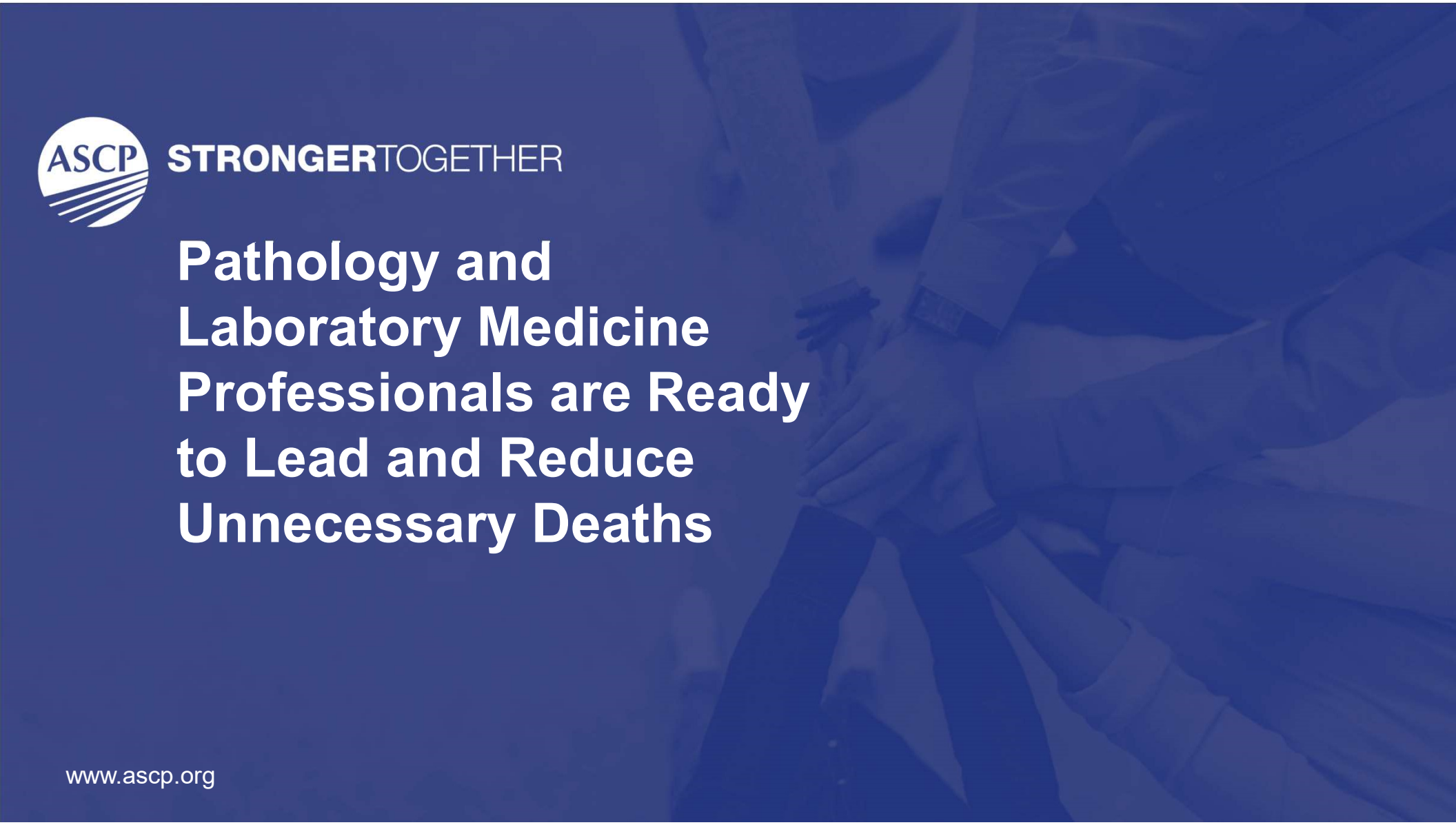
- ✓ **Direct Molecular Diagnostics**
  - – Highly Sensitive
  - – Not as Highly Sensitive
- ✓ **Serology**
  - – Qualitative
  - – Next:? Quantitative? Neutralizing
- ✓ **Antigen Detection Tests**
- ✓ **???**

Future State for COVID-19 Testing

A Coherent National Test Strategy Will:

- ✓ Promote reliable tests, right time, right patient
- ✓ Disseminate accurate scientific information about testing
- ✓ Develop best practices, and
- ✓ Provide logistical support for improved public health and patient care outcomes related to COVID-19




ASCP
STRONGERTOGETHER
Pathology and Laboratory Medicine Professionals are Ready to Lead and Reduce Unnecessary Deaths
www.ascp.org

COVID-19
Convalescent Plasma (CCP) and the Transfusion Service

Kerry O'Brien, MD
Medical Director Blood Bank
Beth Israel Deaconess Medical Center
Boston, MA

How can clinicians obtain CCP for their patients with COVID19?

Three options currently in the US:

- eIND – Emergency IND for one patient
- Expanded access program (EAP)
- Clinical trial

eIND – single patient emergency investigational new drug application to the FDA

- For a single patient and requires FDA approval, but no protocol is required
    - Can submit request to FDA by email or phone
- Individual physician applies for IND.
- Plasma sourced from FDA licensed blood establishment.

https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma

EAP

- Study design
  - Open-label expanded access
- Population
  - Severe or life-threatening COVID19
  - High risk of above
- No exclusion criteria
- Primary objective
  - Availability of CCP
- Secondary objective
  - Serious adverse events

Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19

Unique Protocol Identification Number: 20-003312

National Clinical Trial (NCT) Identified Number: 04338360

Principal Investigator: Michael Joyner, MD

IND 19832 Sponsor: Michael Joyner, MD

Funded by: BARDA

Version 5.0

4 May 2020

The Mayo Clinic IRB will serve as the IRB of record for all sites participating in this protocol. In accordance with 45 CFR 46.103(e), agreeing to participate in the trial via sign up on www.uscovidplasma.org will serve as documentation of each participating institution's reliance on Mayo's IRB. A separate IRB reliance agreement is not required.

https://www.uscovidplasma.org

EAP

- Collaboration between BARDA and Mayo Clinic
- Overseen by central IRB
- Rate-limiting step: Blood suppliers have to have enough inventory to supply any/all requests in the country

Research IND – Clinical trials

THE UNEXPECTED IMPACT OF COVID-19 ON THE BLOOD SUPPLY

Kimberly W. Sanford, M.D. MASCP

Medical Director, Transfusion Medicine

Virginia Commonwealth University

Richmond , VA

ASCP President Elect

BLOOD COLLECTIONS

- 80% of the US Blood Supply is collected by mobile blood drives
- Stay at home orders closed large business, universities and schools
- American Red Cross reported more than 4600 blood drives canceled resulting in the loss of 143,600 blood units
- March 15, 2020 Dr. Pampee Young, Chief Medical Officer of Biomedical Services at American Red Cross issued statement to medical directors of blood banks to reduce blood transfusions by > 25% immediately
- Elective surgeries and procedures canceled nationwide by recommendation from the U.S. Surgeon General, Dr. Jerome Adams
- FDA revised recommendations in several guidances for blood donor eligibility

TRANSFUSION CENTERS

- Emergency preparations
  - Planned for mass casualty incidents
  - Pandemic preparations focused on staffing related issues not long term blood shortages
- Response to COVID
  - Raised awareness to hospital administrators and surgical/trauma centers
  - Consolidation of blood units from remote locations
  - Strict enforcement of transfusion utilization guidelines
  - Encouraged and increased blood drives in hospitals and in the community
  - Blood Conservation Task Force
  - Emergency Management of Blood Supply Policies written
  - Bagging policies written to minimize contamination of blood components

PATIENT IMPACT

- Conference calls: surgeons, hematology/oncologists and cellular therapy providers to reduce blood usage immediately
- Reduced components dispensed for trauma patients
- Implemented Jehovah's Witness protocols for blood reduction
- Reviewed all patients with Sickle Cell Anemia (SCA) to prolong intervals between RBC exchange procedures or switch to simple transfusions
- Deferred cellular therapies for patients or suggested self isolation and testing patients whose treatment could not be deferred.
- Increased intervals for patients undergoing apheresis procedures for chronic medical conditions or alternative therapies

IMPACT TO TRANSFUSION SERVICES

- Ongoing reduction of blood donors, most importantly minority donors
  - Related to ongoing shelter in place orders, fear of donating and lack of large facilities to collect blood
- Daily management of local, regional and national shortages
- Elective surgeries and procedures continue to increase, taxing a recovering blood supply
- Convalescent Plasma
  - New product for blood banks, logistical issues due to EUA/EIND requirements, increasing demand on limited resource, prolonged delays, and lack of consistent antibody testing of transfused product

SUGGESTIONS FOR ACTION

- National awareness of blood shortage
- National call for donations, especially for minority donors, with assurance of donor safety
- Provide support to strengthen the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism
- Provide National support for implementation of FDA guidelines for donor reentry of deferred donors
- Provide National financial relief for blood collection centers
- National recommendations for antibody testing of convalescent plasma and accelerate publication of outcomes data
- Consider genotyping donors to build genotype library to assist with finding compatible blood for patients with multiple antibodies or SCA patients
- Consider a National Alloantibody Registry of patients to improve transfusion safety

Laboratory Biosafety Update

Bill Arndt
CDC Division of Laboratory Systems

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

CDC 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

FDA Update and Responses to Questions

Tim Stenzel and **Sara Brenner**
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)

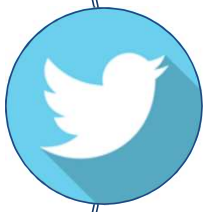
COVID-19 Diagnostic Development: CDRH-EUA-Templates@fda.hhs.gov

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!

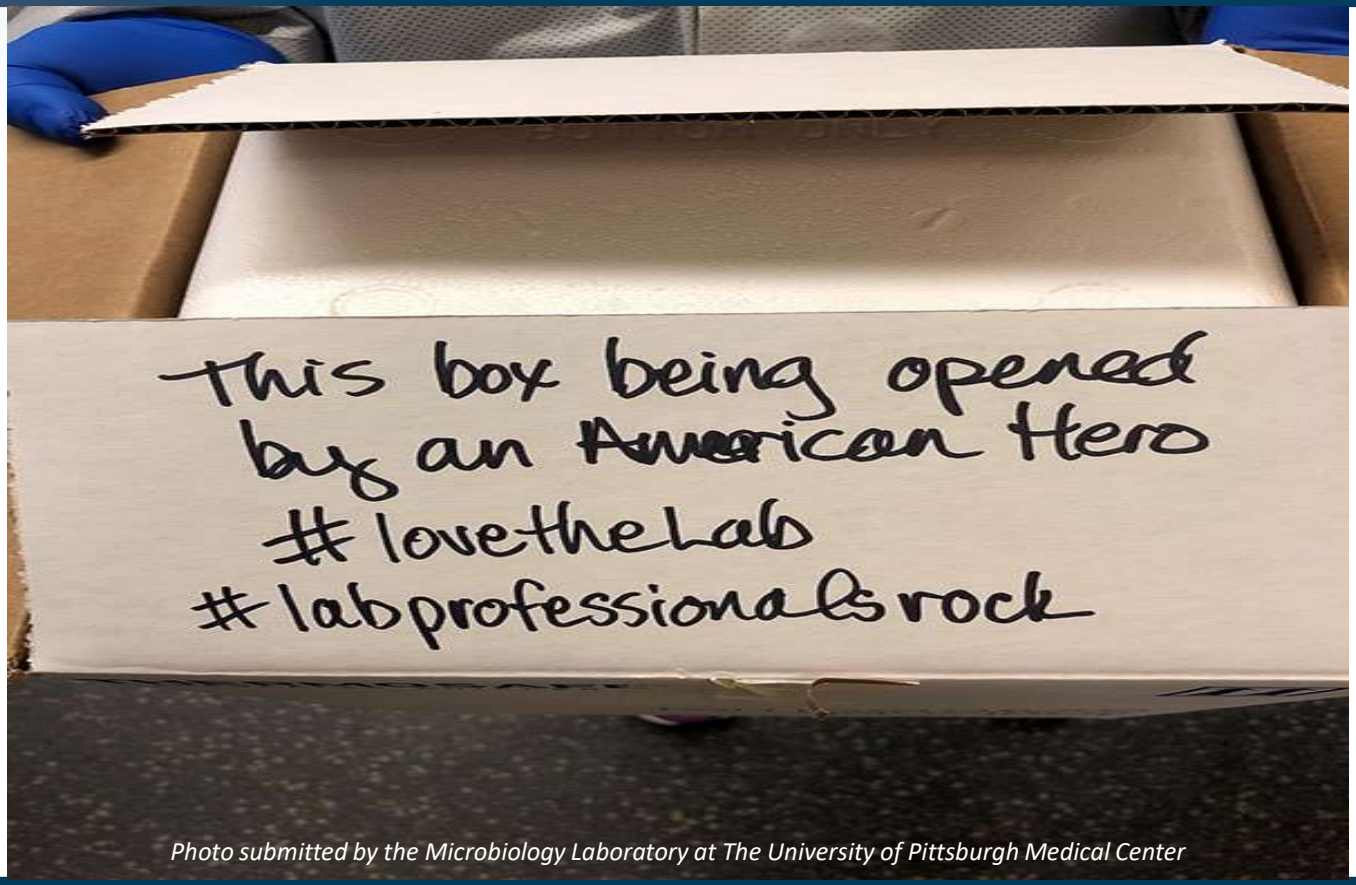


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center