

Clinical Laboratory COVID-19 Response Call

Monday, July 20th, 2020 at 3:00 PM EDT

- **Welcome**
 - Jasmine Chaitram, Division of Laboratory Systems (DLS), CDC
- **Autopsies and Public Health Importance for COVID-19**
 - Roose Martines, Division of High-Consequence Pathogens and Pathology (DHCPP), CDC
 - Sarah Reagan-Steiner, Division of High-Consequence Pathogens and Pathology (DHCPP), CDC
- **COVID-19 Samples: Packaging and Shipping Issues**
 - Stuart Streck, U.S. Department of Transportation (DOT)
- **FDA Update**
 - Tim Stenzel and Sara Brenner, FDA
- **Laboratory Reporting Update**
 - Sara Brenner, FDA
 - Reynolds Salerno, Division of Laboratory Systems (DLS), CDC

Schedule for Clinical Laboratory COVID-19 Response Calls

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



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/>
- **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>

We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

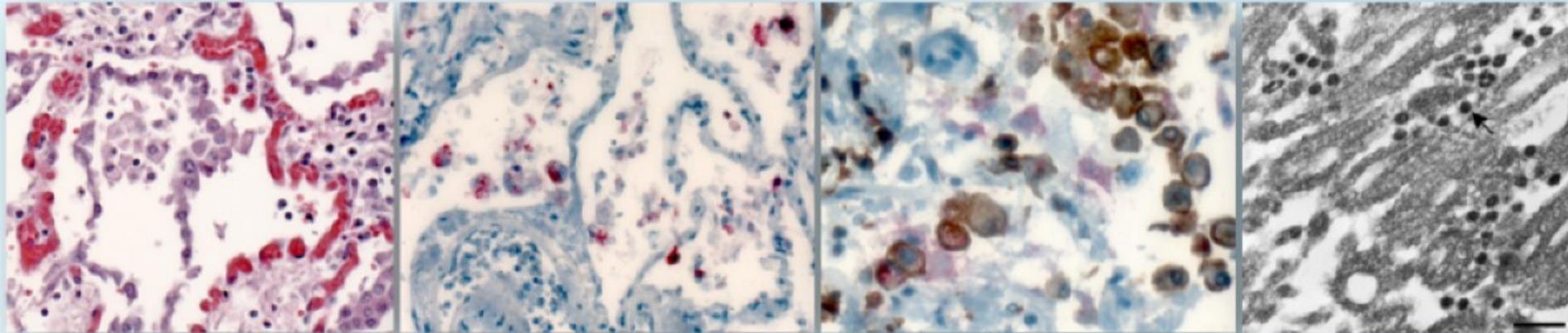


To Ask a Question?

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



INFECTIOUS DISEASE PATHOLOGY BRANCH

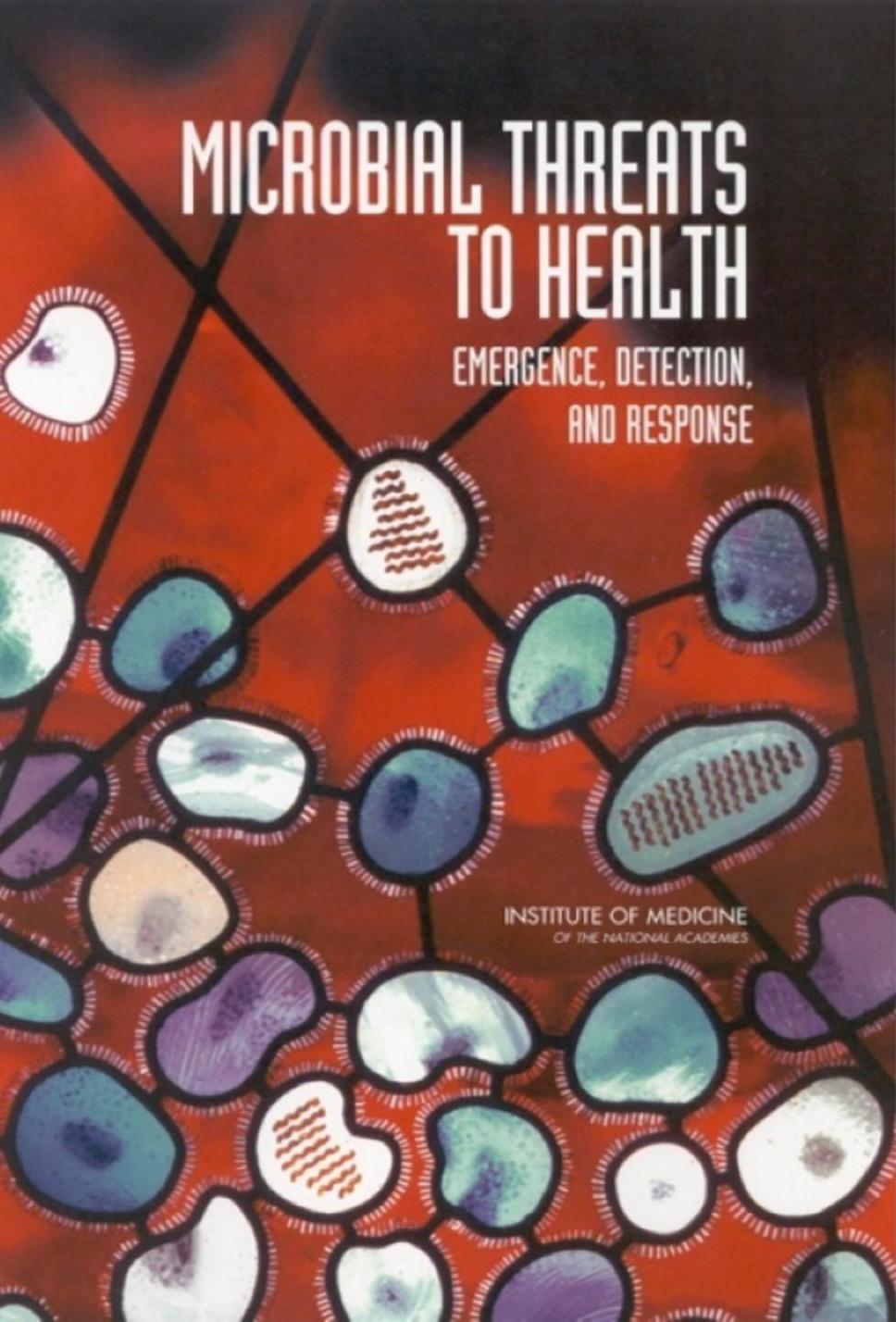


Roosecelis Brasil Martines, MD, PhD

Immunohistochemistry, Electron Microscopy and Microbiology Laboratory Team Leader

Outline

- Autopsy surveillance
- Currently known about autopsy and pathological findings of COVID-19
- Summary recommendations
- COVID-19 guideline



MICROBIAL THREATS TO HEALTH

EMERGENCE, DETECTION,
AND RESPONSE

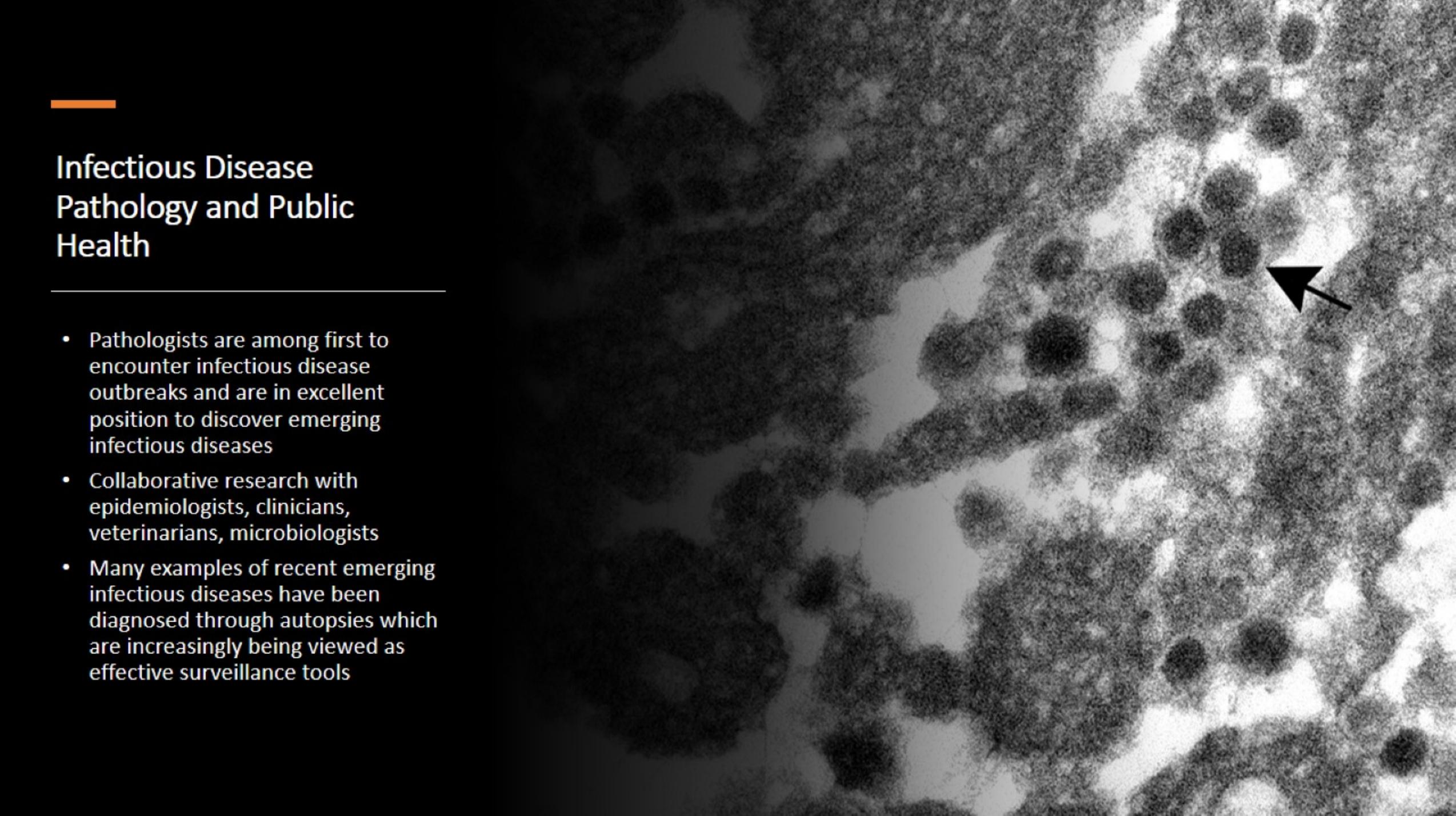
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

2003

- “A robust public health system—in its science, capacity, practice, and through its collaborations with clinical and veterinary medicine, academia, industry and other public and private partners—is the best defense against any microbial threat.”

Outline

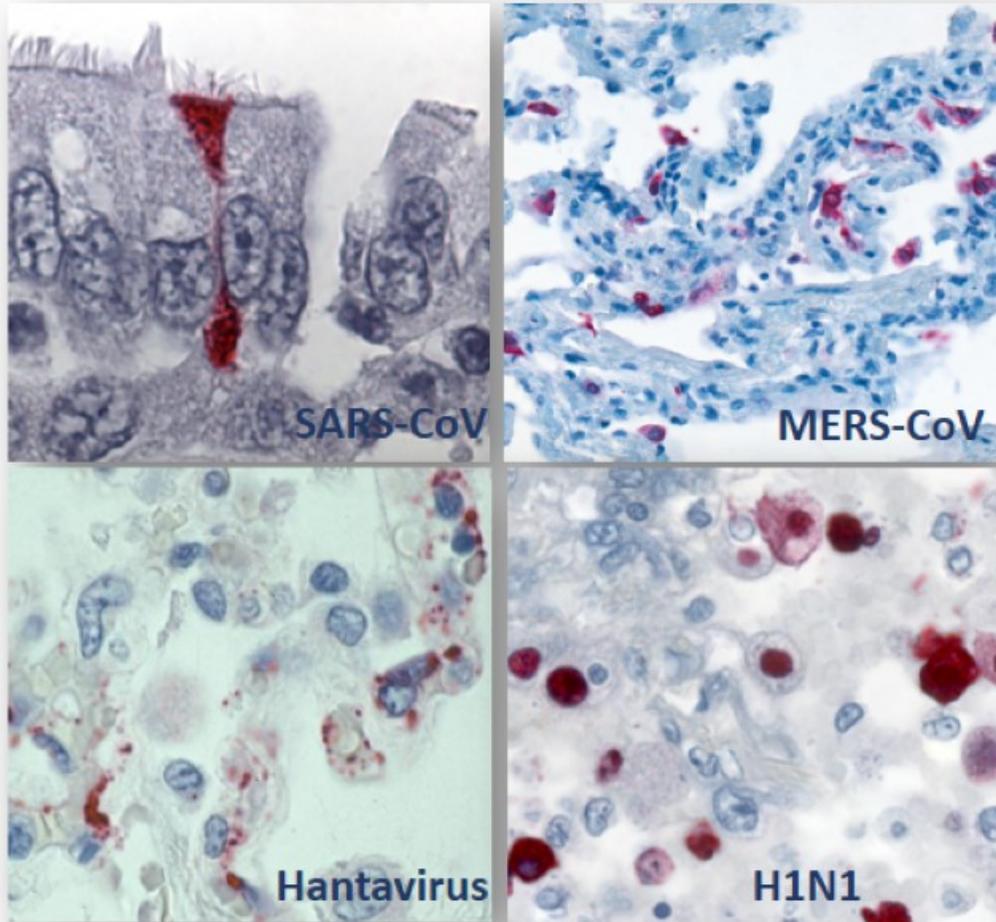
- Autopsy surveillance
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A grayscale electron micrograph of a cell. The image shows a complex internal structure with various organelles and numerous small, dark, circular particles. A black arrow points to one of these particles, which is likely a virus or a similar infectious agent. The background is a dense, granular texture representing the cytoplasm and other cellular components.

Infectious Disease Pathology and Public Health

- Pathologists are among first to encounter infectious disease outbreaks and are in excellent position to discover emerging infectious diseases
- Collaborative research with epidemiologists, clinicians, veterinarians, microbiologists
- Many examples of recent emerging infectious diseases have been diagnosed through autopsies which are increasingly being viewed as effective surveillance tools

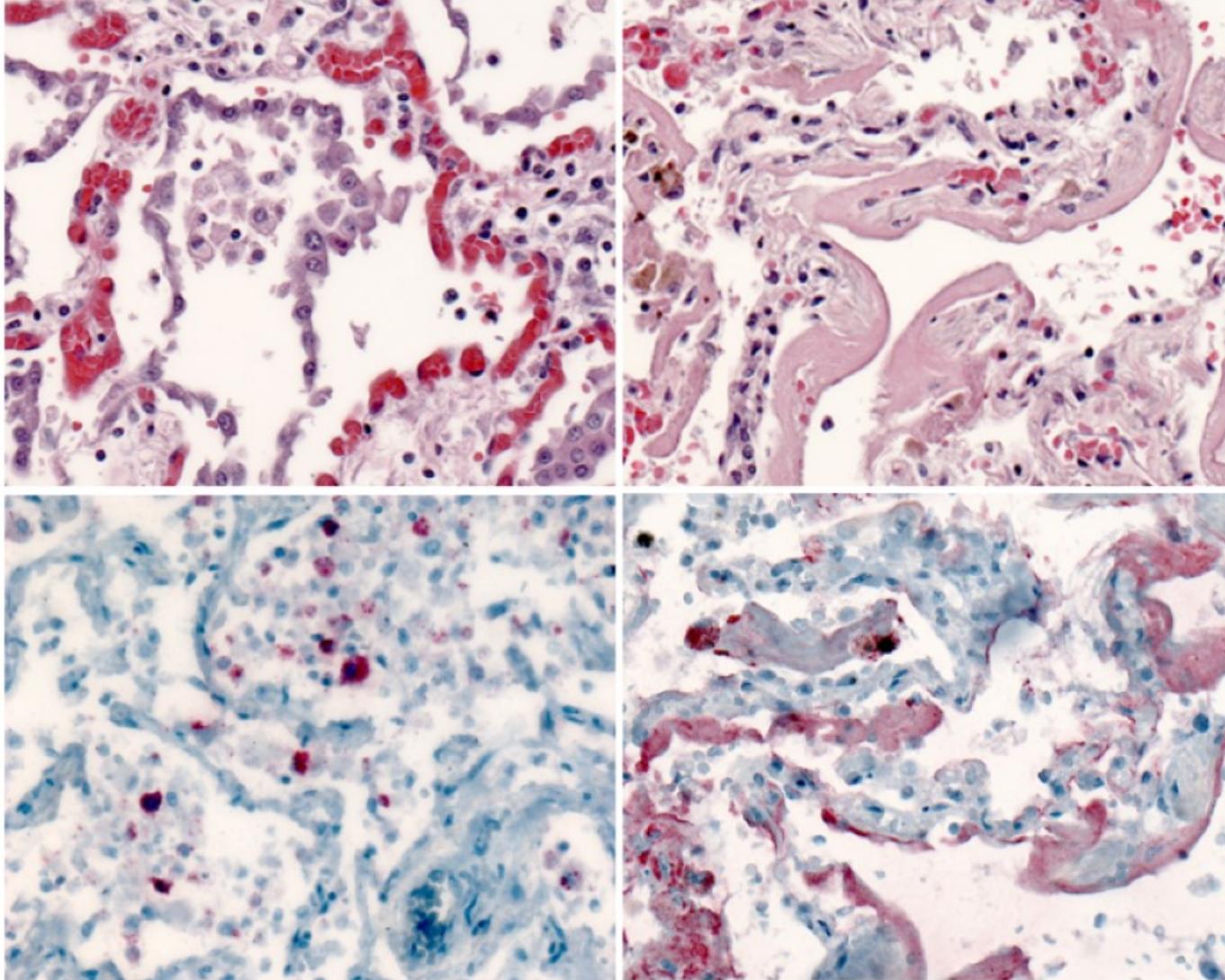
Autopsy Surveillance



- Autopsy is important to identify clinically unsuspected disease processes
- Correlate premortem clinical diagnosis with postmortem findings
- Elucidate the pathogenesis of new diseases
- The pathologist should approach the autopsy with a well-constructed differential diagnosis that provides the framework for appropriate selection of diagnostic specimens and tests
- Animals increasingly are being recognized as potential vectors for infectious diseases affecting humans

Enhancing collaboration between public health and pathology experts

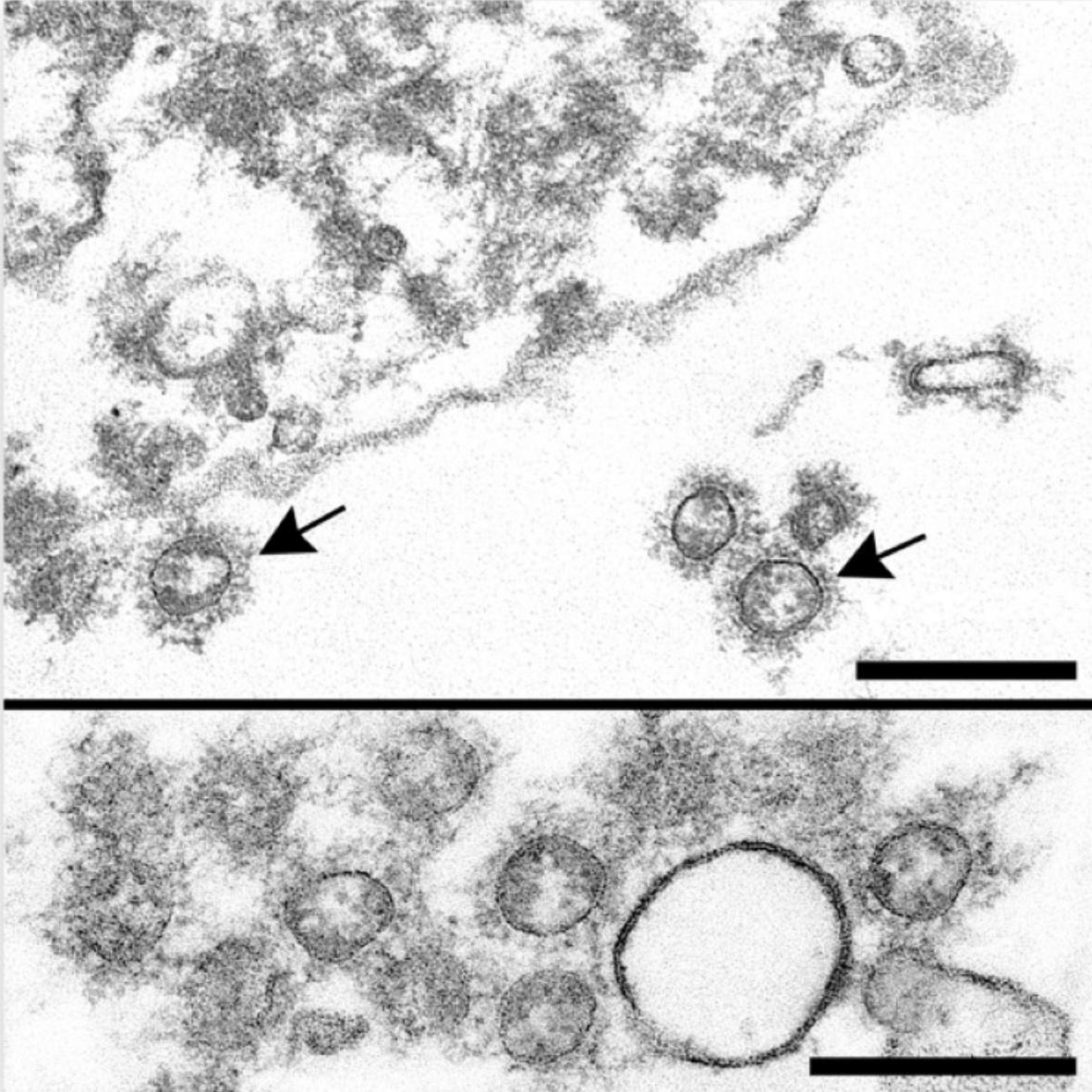
Autopsy – COVID-19



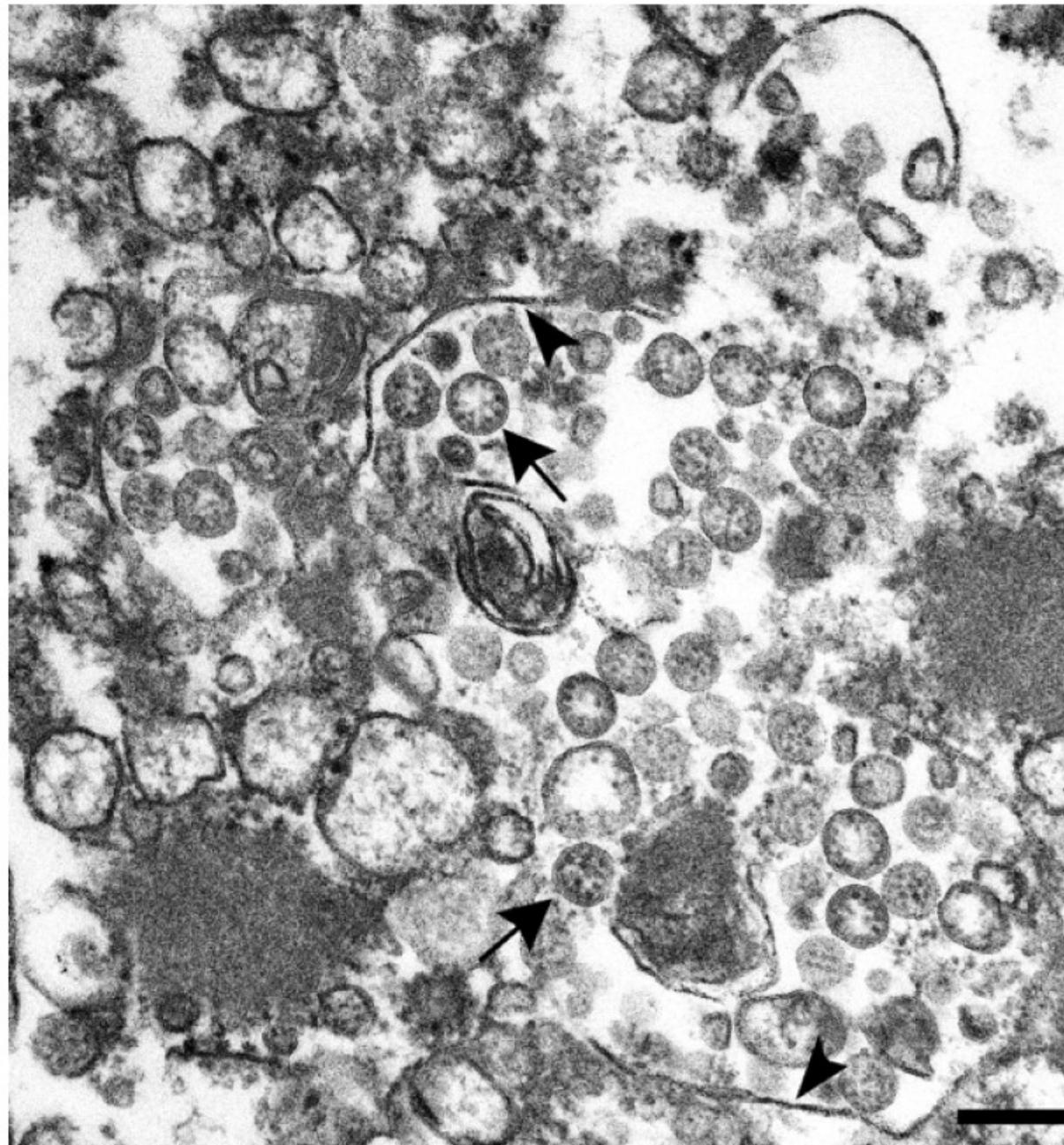
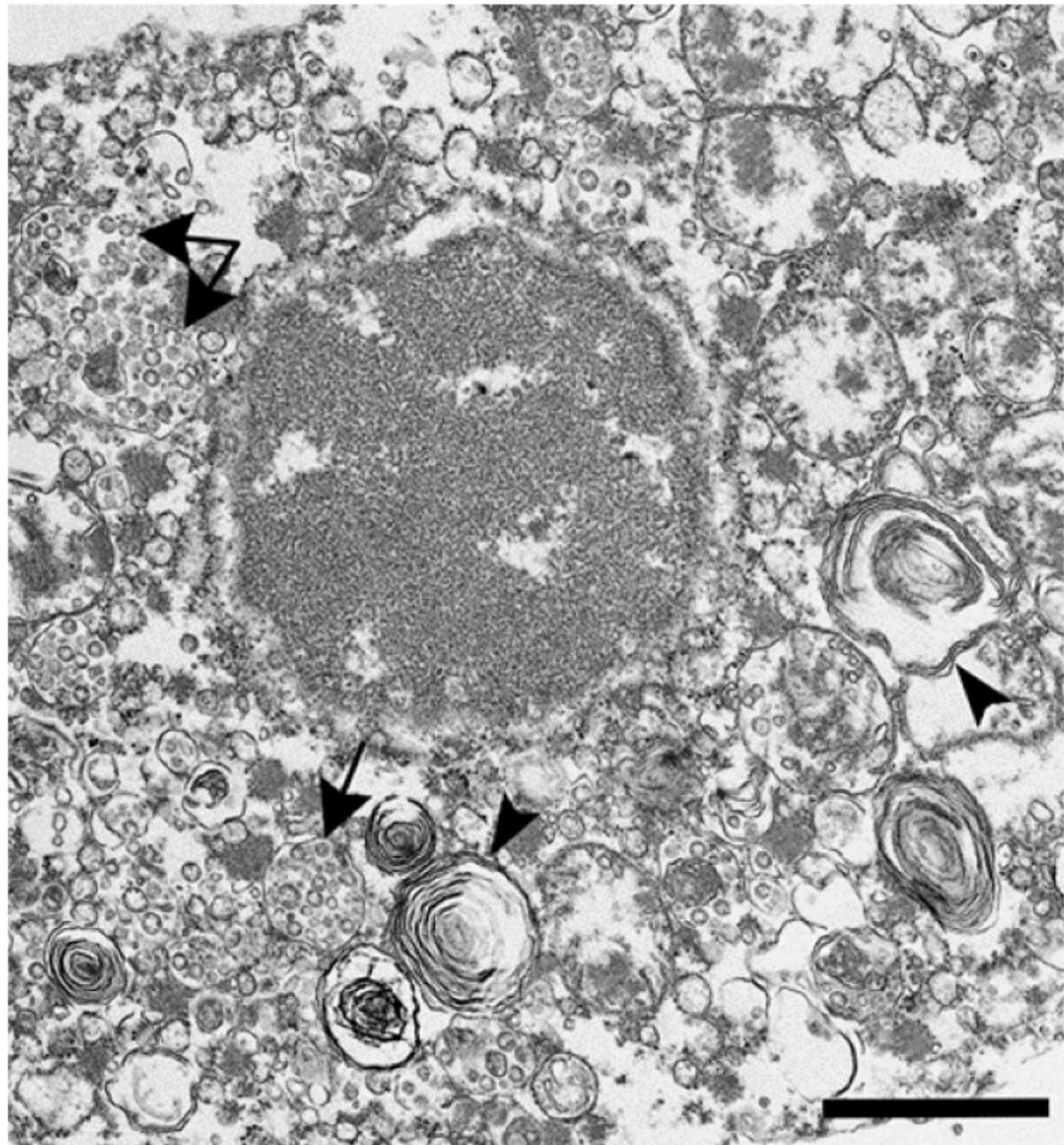
Autopsy case reports and case series have provided useful information regarding the pathogenesis of COVID-19

- SARS-CoV-2 infected epithelium of the upper and lower airways with diffuse alveolar damage
- SARS-CoV-2 was detectable by immunohistochemistry and electron microscopy in conducting airways, pneumocytes, alveolar macrophages, and a hilar lymph node but was not identified in other extrapulmonary tissues.

Electron Microscopy



- Identification of viruses is not always straight forward.
- Consideration should be given to the mechanism of virus production, including the location inside of cells, as well as the appearance (size, shape, internal pattern of the nucleocapsid, and surface spikes).
- Care should be taken to prevent mistaking cell organelles for viral particles



Summary recommendations - Autopsy



Infectious agent to be transmitted from a patient to autopsy room personnel and cause disease:

- 1- The deceased patient must harbor an infectious agent that has remained viable after death
- 2- route of transmission - aerosolized agents, direct skin/mucosa contact with an infectious agent or accidental inoculation of an infectious agent
- 3 - Autopsy room personnel must be susceptible to the infectious agent and manifest disease

Coronavirus Disease 2019 (COVID-19)

Your Health Community, Work & School **Healthcare Workers & Labs** Health Depts Cases & Data More

Healthcare Workers

- Testing
- Clinical Care
- Infection Control**
 - Infection Control Guidance
 - Using PPE
 - Hand Hygiene
 - Alternate Care Sites
 - Assisted Living Facilities
 - Blood & Plasma Facilities
 - Dental Settings
 - Dialysis Facilities
 - Nursing Homes & Long-Term Care Facilities
 - Pharmacies
 - Postmortem Guidance**
- Optimize PPE Supply
- Potential Exposure at Work
- First Responder Guidance
- Healthcare Facility Tools
- Pandemic Planning Scenarios
- Guidance for U.S. Facilities
- Operational Considerations for Non-US Settings
- Training for Healthcare Professionals
- FAQs
- Guidance Documents
- Communication Resources

HEALTHCARE WORKERS

Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19

Interim Guidance

Updated June 4, 2020

Print Page



On This Page

Background	Submission of Specimens for COVID-19 Testing
Recommended Postmortem Specimens	Submission of Fixed Autopsy Tissue Specimens to CDC
Recommended Biosafety and Infection Control Practices	Cleaning and Waste Disposal Recommendations
Collection of Postmortem Specimens	Transportation of Human Remains

Summary of Recent Changes:

- Criteria for fixed autopsy tissue specimen submission to CDC's Infectious Diseases Pathology Branch (IDPB) for COVID-19 testing
- These changes were made **June 15, 2020**.

CDC guidance for COVID-19 may be adapted by state and local health departments to respond to rapidly changing local circumstances.

Background

Medical examiners, coroners, and pathologists should **immediately** notify their [local](#) or [state](#) health department in the event of the identification of a deceased person with known or suspected COVID-19.

State and local health departments can contact CDC's Emergency Operations Center (EOC) at 770-488-7100 for urgent consultation if an autopsy is being considered for a deceased person with known or suspected COVID-19 or if submission of autopsy tissue specimens or postmortem swabs to CDC for COVID-19 testing is desired. The EOC will assist local/state health departments to collect, store, and ship specimens appropriately to CDC, including during afterhours or on weekends/holidays.

This interim guidance is based on what is currently known about [coronavirus disease 2019 \(COVID-19\)](#).

Current knowledge supports that spread of SARS-CoV-2 (the virus that causes COVID-19) usually happens when a person is in close contact (i.e., within about 6 feet) via respiratory droplets produced when an infected person coughs, sneezes, or talks. This route of transmission is not a concern when handling human remains or performing postmortem procedures. It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes. This is not thought to be the main way the virus spreads, but we are still

- Recommended postmortem autopsy tissue and swab specimens
- Biosafety and infection control practices
- Submission of postmortem fixed tissue specimens to CDC
 - Criteria for specimen acceptance
 - Specimen submission procedures
- Cleaning and waste disposal
- Transportation of human remains
- Links to other resources regarding the postmortem setting

CDC Guidance on Postmortem Specimen Collection

- **If an autopsy is performed:**
 - Collection of Nasopharyngeal Swab (NP swab) and if possible, lung swabs for COVID-19 testing
 - Separate swab specimens for testing of other respiratory pathogens and other postmortem testing, as indicated
 - Formalin-fixed autopsy tissues from lung, upper airway
 - 3 blocks of lung, 2 from upper airway
- CDC's Infectious Diseases Pathology Branch (IDPB) can perform testing for SARS-CoV-2 on fixed autopsy tissue specimens that meet specified criteria on Guidance website. Coordinate through your State Health Department.
- For questions, contact pathology@cdc.gov

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html>

COVID-19 Samples: Packaging and Shipping Issues

Stuart Streck

U.S. Department of Transportation



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

Shipping Category B Diagnostic Samples

Safety Advisory Notice on Transporting COVID-19 Diagnostic Samples



Background



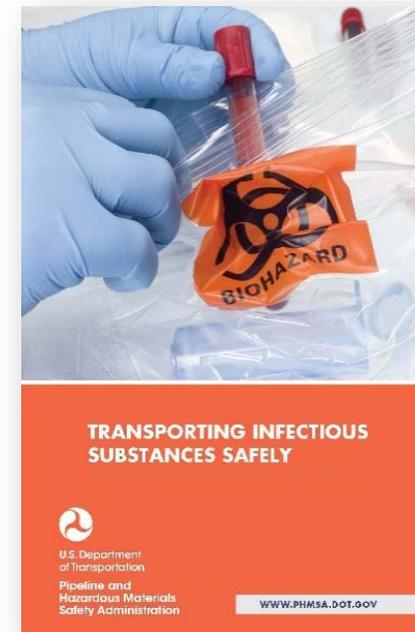
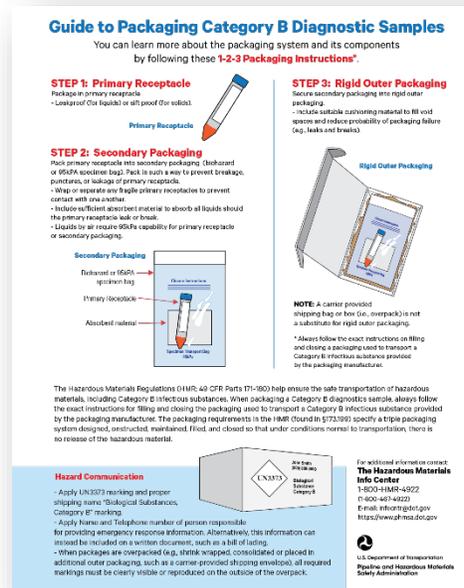
Overpack



Regulatory reference: 49 CFR, 173.199



Resource Materials



Publication:

- <https://www.phmsa.dot.gov/news/phmsa-safety-advisory-transportation-covid-19-diagnostic-samples>
- <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/Transporting%20Infectious%20Substances%20Safely.pdf>

Regulations: <https://www.ecfr.gov>



For additional information contact:

The Hazardous Materials Info Center

1-800-HMR-4922

(1-800-467-4922)

E-mail: infocntr@dot.gov

<https://www.phmsa.dot.gov>

Pipeline and Hazardous Materials Safety Administration Outreach, Engagement and Grants Division

East building, 2nd Floor

1200 New Jersey Ave., SE

Washington DC 20590

E-mail: training@dot.gov

202.366.4900

202.366.7342 (Fax)



FDA Update

Tim Stenzel and Sara Brenner
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

Spot Shortages of Testing Supplies: 24-Hour Support Available

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)

COVID-19 Laboratory Reporting Requirements

Sara Brenner, M.D., M.P.H.

Associate Director for Medical Affairs
Chief Medical Officer for In Vitro Diagnostics
Food and Drug Administration

HHS Data Strategy and Execution Workgroup
COVID-19 National Response Operations

Who needs to report?

All testing sites with a **Clinical Laboratory Improvement Amendments (CLIA) certificate** must report the results of the COVID-19 diagnostic and screening tests that they conduct to the appropriate state or local public health department.

Testing sites include

- Laboratories that perform clinical diagnostic testing under CLIA
- Non-laboratory COVID-19 testing locations
- Other facilities or locations offering point-of-care testing or in-home testing related to COVID-19

How to report?

Submit COVID-19 test result data one of three ways

1. Directly to state or local public health departments
2. Through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform)
3. Through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department



What to report?

- Patient name (Last name, First name, Middle Initial)
- Patient street address
- Patient phone number with area code
- Patient date of birth
- Patient age
- Patient race
- Patient ethnicity
- Patient sex
- Patient residence zip code
- Patient residence county
- Test ordered
- Test result
- Test Result date
- Accession # / Specimen ID
- Ordering provider name and NPI (as applicable)
- Ordering provider address
- Ordering provider phone number
- Ordering provider zip
- Performing facility name and CLIA number
- Performing facility zip code
- Specimen Source
- Date test ordered
- Date specimen collected

What information to include?

Healthcare providers will be required to provide laboratories with “ask on entry” questions

1. Do you currently work in a healthcare setting with direct patient contact?
2. Do you currently have one or more of the following symptoms?
 - Fever or chills
 - Cough
 - Shortness of breath or difficulty breathing
 - Fatigue
 - Muscle or body aches
 - Headache
 - New loss of taste or smell
 - Sore throat
 - Congestion or runny nose
 - Nausea or vomiting
 - Diarrhea
3. (Optional) [If yes to question #2] When did your symptoms start?
4. [If the individual is female] Are you currently pregnant?
5. Do you currently reside in a congregate (group) care setting, such as, but not limited to
 - a nursing home,
 - a residential care location for people with intellectual and developmental disabilities,
 - a psychiatric treatment facility,
 - a group home,
 - a dormitory,
 - a board and care home,
 - a homeless shelter, or
 - foster care setting.
6. [Optional] Have you had a COVID-19 test?
7. Is the individual hospitalized with confirmed or suspected COVID-19?
8. [If yes to question #7] Is the individual in an intensive care unit?



More resources

HHS Laboratory Reporting Guidance

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

HHS Laboratory Reporting FAQ

<https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf>

CDC Laboratory Reporting Website

<https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>



Need Help?

Electronic Laboratory Reporting

Laboratories that are not currently reporting electronically to their state or local health department and want assistance can contact CDC at eocevent405@cdc.gov

Additional Questions
DLSinquiries@cdc.gov

COVID-19 Clinical Trial Reporting FAQs

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems



New FAQs Posted on July 18, 2020

For a clinical research trial approved by the Institutional Review Board (IRB), are laboratories required to report laboratory testing data from CLIA-certified COVID-19 testing (nucleic acid, antigen, or antibody) if the specimens are de-identified and results *are not* returned to the ordering clinician?

In general, no. Laboratories are not responsible for reporting these data. However, state health department rules and regulations apply and may differ from this general guidance.

For an IRB-approved clinical research trial, what are the requirements for reporting laboratory testing data from CLIA-certified COVID-19 testing (nucleic acid, antigen, or antibody) if the specimens are de-identified and results *are* being returned to the ordering clinician for patient care?

The reporting requirements differ for laboratories and research clinicians:

Laboratories

- Laboratories are not responsible for reporting these data since laboratories do not have the patient-identifying information required for compliance with reporting requirements. However, state health department rules and regulations apply and may differ from this general guidance.

For an IRB-approved clinical research trial, what are the requirements for reporting laboratory testing data from CLIA-certified COVID-19 testing (nucleic acid, antigen, or antibody) if the specimens are de-identified and results *are* being returned to the ordering clinician for patient care?

Research Clinicians

- In clinical trials, research clinicians who are responsible for clinical care of trial participants are responsible for linking de-identified specimen test results to participant demographic information and are required to report the positive results daily to the appropriate state or local public health department based on the patient's residence. Demographic information required for reporting is detailed in HHS's [June 4, 2020 guidance](#).
- Research clinicians are not required to report negative test results. However, state health department rules and regulations apply and may differ from this general guidance.
- If a clinician receives COVID-19 test results from duplicate specimens that were collected in the same manner and tested with different test methods (e.g., different platforms) or in different CLIA laboratories, the clinician should not report both results. In the case of two positive test results, the clinician should report the result that is provided first. In the case of discrepant test results, the clinician should report the positive result. However, state health department rules and regulations apply and may differ from this general guidance.
- If the clinician requests COVID-19 testing for study participants independent of research activities or for clinical management, results should be reported to the appropriate state or local public health department.

CDC Social Media



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

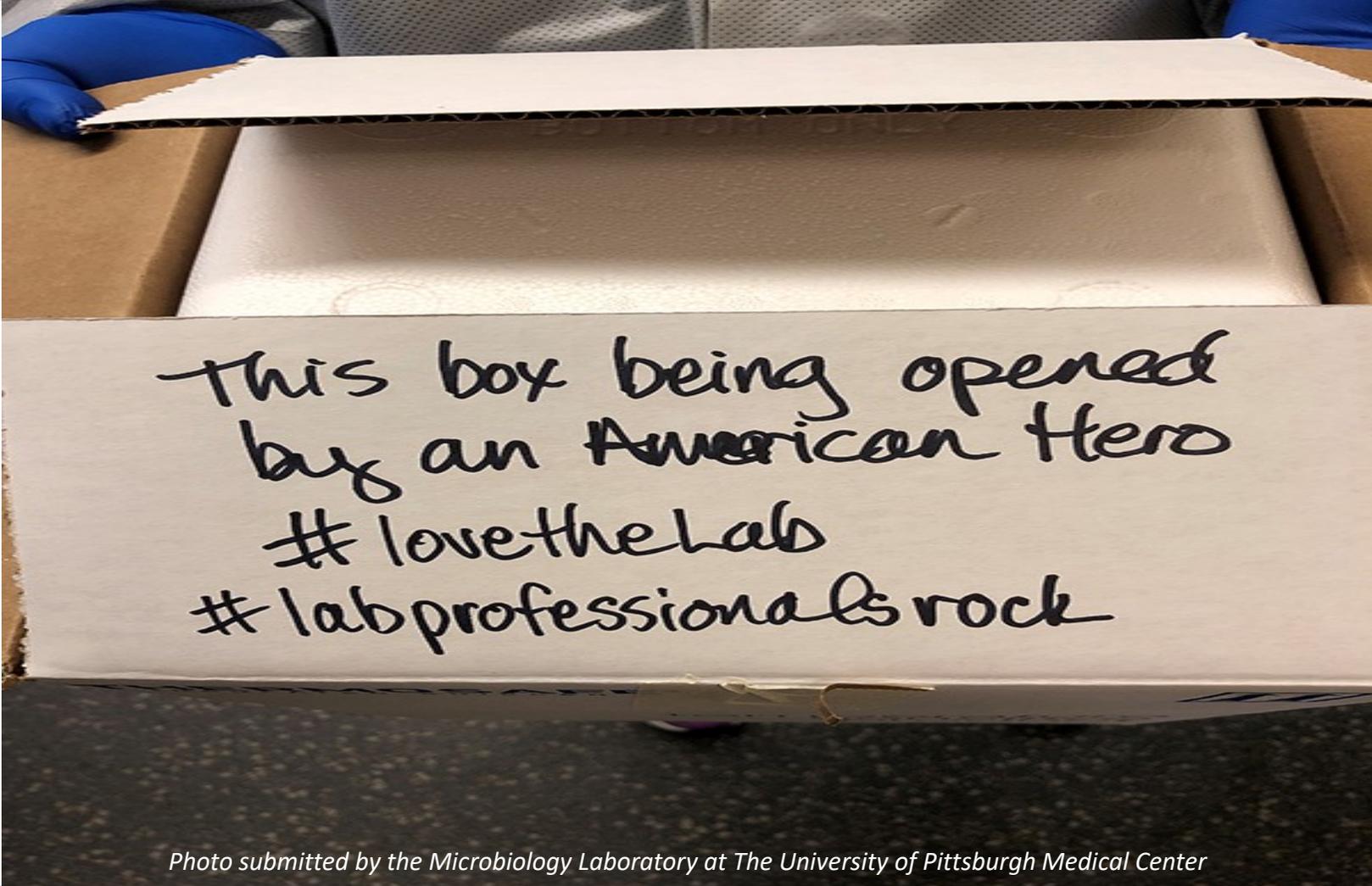


<https://twitter.com/cdcgov>



<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