

Division of Laboratory Systems



Packing and Shipping Suspected Ebola Specimens

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Agenda

- Introduction
 - *Today's Presenters*
 - *New and relevant OneLab™ Resources*
- Packing and Shipping Suspected Ebola Specimens
- Q&A
- Upcoming Events

Presenter



Julie Villanueva, PhD

Laboratory Preparedness and Response Branch Chief
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Presenter



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Team Lead

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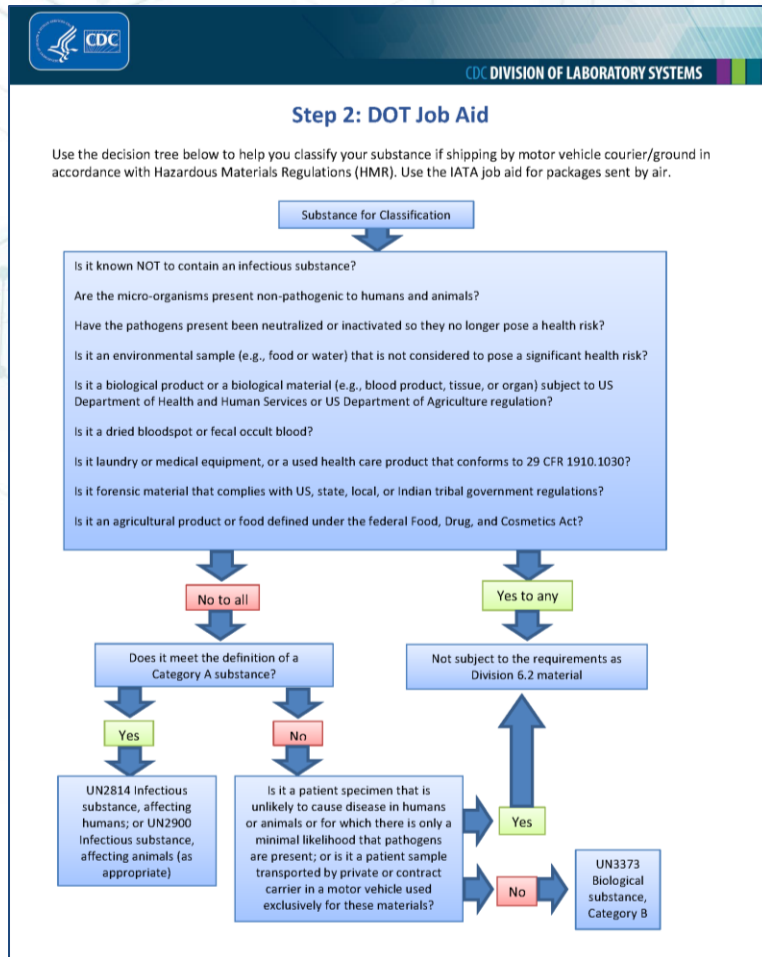
Presenter



Brian H. Harcourt, PhD

Biosafety Officer
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Job Aids for Specimen Shipping



Department of Transportation (DOT) Job Aid

Use [this job aid](#) to help classify your substance if shipping by motor vehicle courier/ground in accordance with Hazardous Materials Regulations (HMR).

International Air Transport Association (IATA) Job Aid

Use [this job aid](#) to help classify your substance if shipping by air in accordance with HMR.

Packing Category A and B and Exempt Human and Exempt Animal Specimens Job Aid

Use [this job aid](#) as a reference for packing the following:

- Category A Infectious Substance Packaging with and without dry ice
- Category B Infectious Substance Packaging with and without dry ice
- Exempt Human and Exempt Animal Specimens with and without dry ice

Labeling, Marking, and Documenting Requirements Job Aid

Use [the table in this job aid](#) as a reference for labeling, marking, and documenting requirements for the various classifications and modes of transport.



Packing and Shipping eLearning Course and Additional Resources



Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know

- The goal of [this course](#) is to provide training on packing and shipping Division 6.2 infectious substances and dry ice.

Specimen Storage and Shipping Guidance

- [This job aid](#) defines the criteria to properly ship biological specimens to CDC.

Packing and Shipping eLearning Course and Additional Resources

Updating Storage and Shipping Guidance for Submission to CDC

- Access [presentation and audio recording](#) of OneLab Network Event introducing updated storage and shipping guidance.

Introduction to Laboratory Risk Management (LRM)

- This [basic level eLearning course](#) provides details on applying risk management principles and briefly describes related practices to emphasize the importance of risk management in laboratory settings.

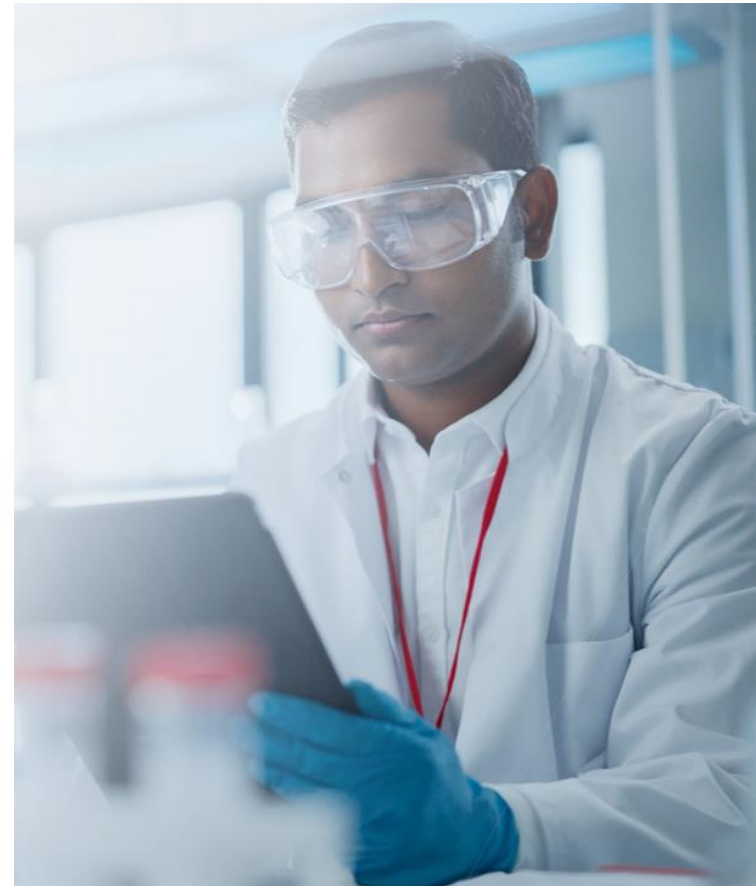
Ebola Laboratory Guidance

- [This job aid](#) provides guidance for collection, transport, and submission of specimens for Ebola virus testing in the United States.



Emergency Preparedness Response Guide for Laboratories

The [Emergency Preparedness Response Guide](#) covers available resources for biological, chemical, and radiological emergencies for laboratories to reference during an emergency. It can also help train new laboratory professionals hired to support emergency responses.



Objectives

By the end of this webinar, learners will be able to:

- Describe the background details of the Ebola virus disease (EVD) outbreak in Uganda caused by the Sudan virus (SUDV) (*Sudan ebolavirus*).
- Discuss the testing, packing, and shipping considerations for submission of suspected EVD specimens to the CDC (or other reference laboratories).



Webinar Outline

- Background on SUDV 2022 Outbreak in Uganda
- Domestic Preparedness Activities
- General Guidance for Laboratories Handling Specimens Suspected to Contain EVD
- Packing and Shipping



Background on SUDV 2022 Outbreak in Uganda

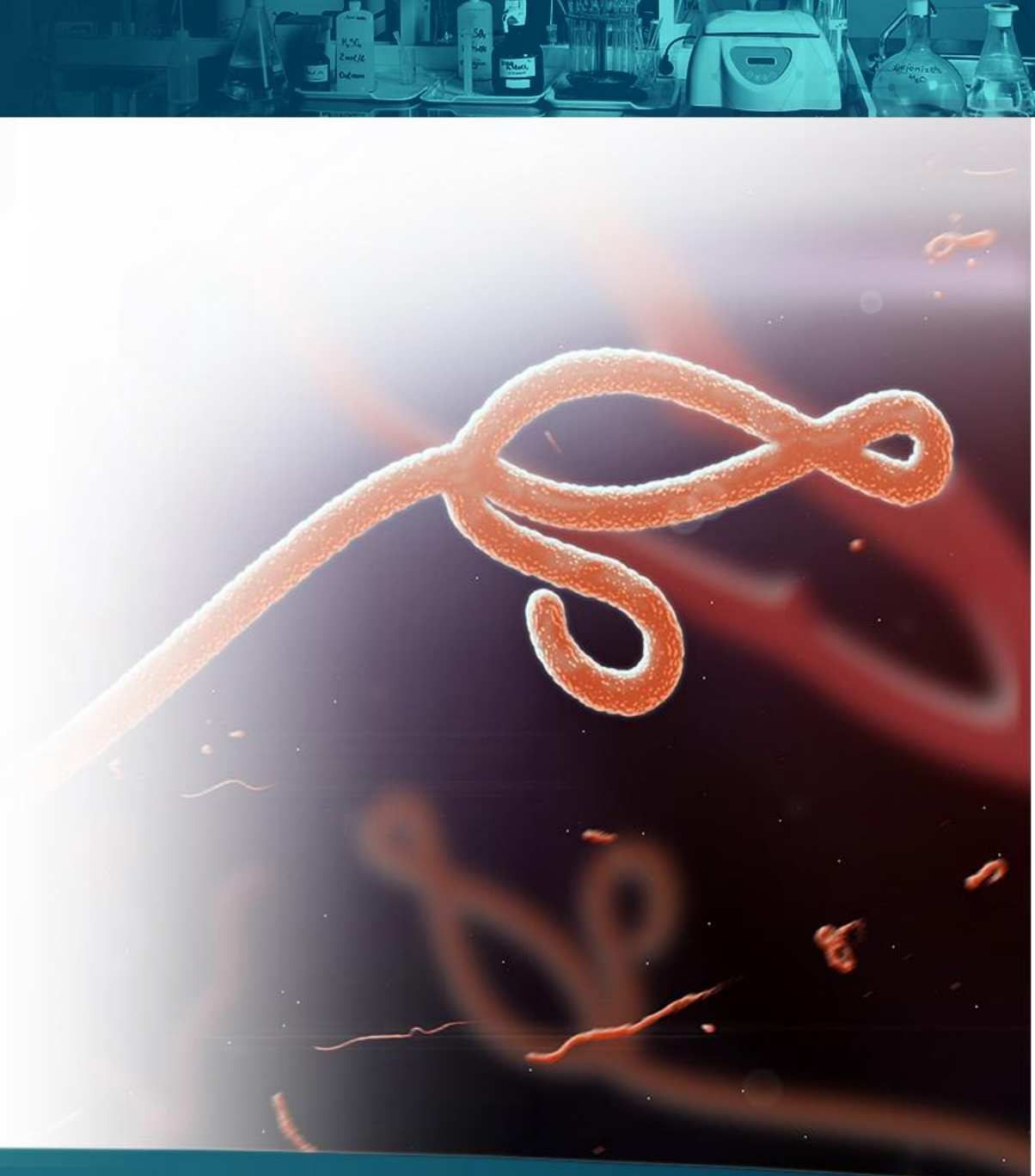


2022 SUDV Outbreak Epidemiology

An outbreak of SUDV (species *Sudan ebolavirus*) was declared by the Uganda Ministry of Health (MOH) on September 20, 2022, in Mubende District, Central Uganda.

The first confirmed case of Ebola Virus Disease (EVD) was a 25-year-old man who lived in the Mubende District.

The case was quickly identified as a suspect VHF. A sample was sent to the Uganda Virus Research Institute (UVRI) and confirmed by rRT-PCR on Sept 19th.



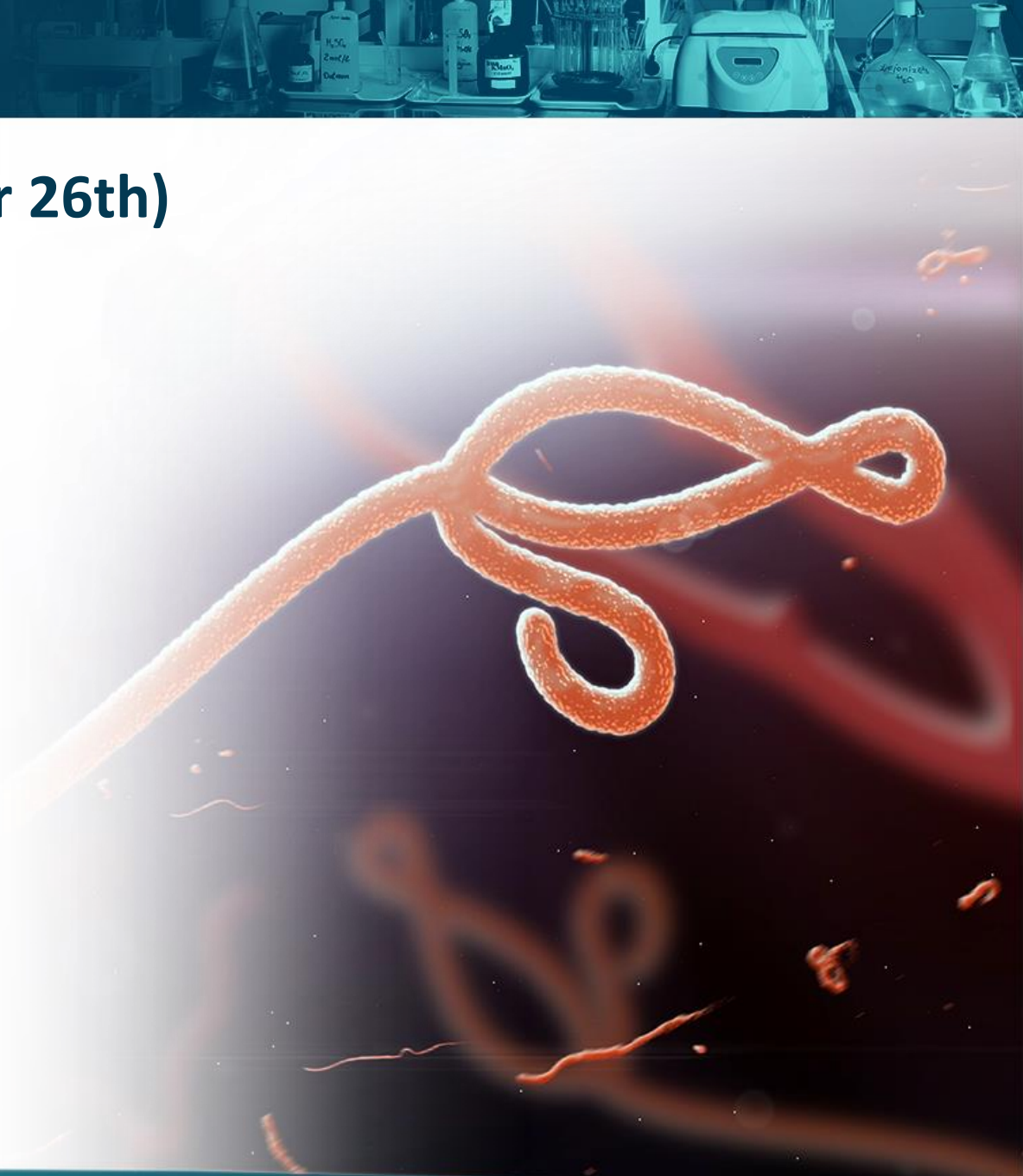
SUDV (*Sudan ebolavirus*) Genealogy and Transmission

- SUDV is a virological taxon included in the family *Filoviridae*, order *Mononegavirales*, genus *ebolaviruses*. Unlike Ebola Zaire, there is no vaccine available.
- SUDV is spread by human-to-human transmission via direct contact. It is not spread through airborne transmission.
- The incubation period can range from 2-21 days. Infected persons are not contagious until they become symptomatic.



Current Outbreak Update (as of October 26th)

- Total cases: 115 (95 confirmed, 20 probable)
- Total deaths: 52 (32 confirmed, 20 probable)
- Case-fatality proportion: 45.2%
- Total recoveries: 34
- Districts affected: 7 (Bunyangabu, Kagadi, Kassanda, Kyegegwa, Wakiso/Kampala, and Mubende)
- Total infections among Health Care Workers (HCWs): 15 (4 deaths)
- **Contact Tracing:**
 - 1844 active, 99% followed last 24 hours



Laboratory Data

- 867 samples received and tested by Uganda Virus Research Institute (UVRI)/CDC
- 84 samples PCR positive for Sudan virus
- 66 unique cases identified by Uganda Virus Research Institute (UVRI)
- 600+ samples tested in Mubende field laboratory
- 17 complete SUDV genomes sequenced
- 5 samples PCR positive for Crimean-Congo hemorrhagic fever (CCHF) (2 fatal)



Risk of SUDV Spread

- WHO assessed the risk of SUDV spread as low
- Uganda has experience in responding to EVD, including outbreaks of SUDV
- Exit screening of air passengers is being conducted in Uganda
- Risk of importation into the United State is currently assessed as low
- Low number of travelers and no direct flights to the United States
- Entry screening of Unites States-bound travelers from Uganda



Domestic Preparedness Activities



Domestic Preparedness Activities

- CDC has activated its emergency response structure
- Standing up multidisciplinary CDC Ebola Response Teams (CERT)
- Updating guidance on the management of patients with suspected SUDV
- Outlining a process to access experimental Sudan virus therapeutics



Incident
Commander

Domestic Preparedness Activities

- Expanding testing capabilities to 10 Regional Emerging Special Pathogens Treatment Centers and to 28 Laboratory Response Network (LRN) laboratories
- Preparing specialized high-level isolation units equipped with infrastructure, laboratory capabilities, and staff to care for patients with highly hazardous communicable diseases



Diagnostic Testing: SUDV

Biofire® FilmArray® NGDS Warrior Panel is an FDA 510(k)-cleared assay panel that detects:

- Sudan virus
- Ebola virus
- Tai forest virus
- Bundibugyo virus
- Reston virus



Diagnostic Testing: SUDV

- Presumptive testing for SUDV using the Biofire® FilmArray® NGDS Warrior Panel is available to date at:
 - 22 LRN laboratories throughout the United States
 - 4 Regional Emerging Special Pathogens Treatment Centers

Any presumptive positive Ebola test result must be confirmed at CDC



Diagnostic Testing Considerations

- A negative RT-PCR test result from a blood specimen collected from a symptomatic patient
 - < 72 hours after symptom onset does not rule out EVD infection
 - > 72 hours after symptom onset rules out EVD



Specimen Considerations for Laboratory Testing

EVD testing requires whole blood:

- At least 4 mL for an adult
- At least 1 mL for a child

Specimens must be:

- Collected in a plastic tube and preserved with ethylenediamine tetra-acetic acid (EDTA)
- Shipped from the state laboratory:
 - On cold packs (2-8 °C) to a designated LRN laboratory
 - On dry ice (-20°C) to CDC





General Guidance for Laboratories Handling Specimens Suspected to Contain EVD



Guidance for Transport and Shipment of Suspected EVD Specimens

October 19, 2022

- Before collecting specimens for EVD testing, clinical laboratories must first contact their state health department and CDC.
- State health departments and Laboratory Response Network (LRN) laboratories must consult CDC to determine whether testing for EVD is warranted.

[Lab Advisory: Guidance for Transport and Shipment of Specimens for Ebola Virus Testing \(cdc.gov\)](https://www.cdc.gov/lab-advisory/guidance-for-transport-and-shipment-of-specimens-for-ebola-virus-testing)

Guidance for Transport and Shipment of Suspected EVD Specimens

October 19, 2022

- Testing should be ordered and performed only for patients who meet the criteria for Person Under Investigation (PUI) for EVD.
- Most rule-out EVD cases will likely have other diseases especially if the patient has no high-risk exposures.
- In many instances, cases with similar symptoms have been related to Malaria.



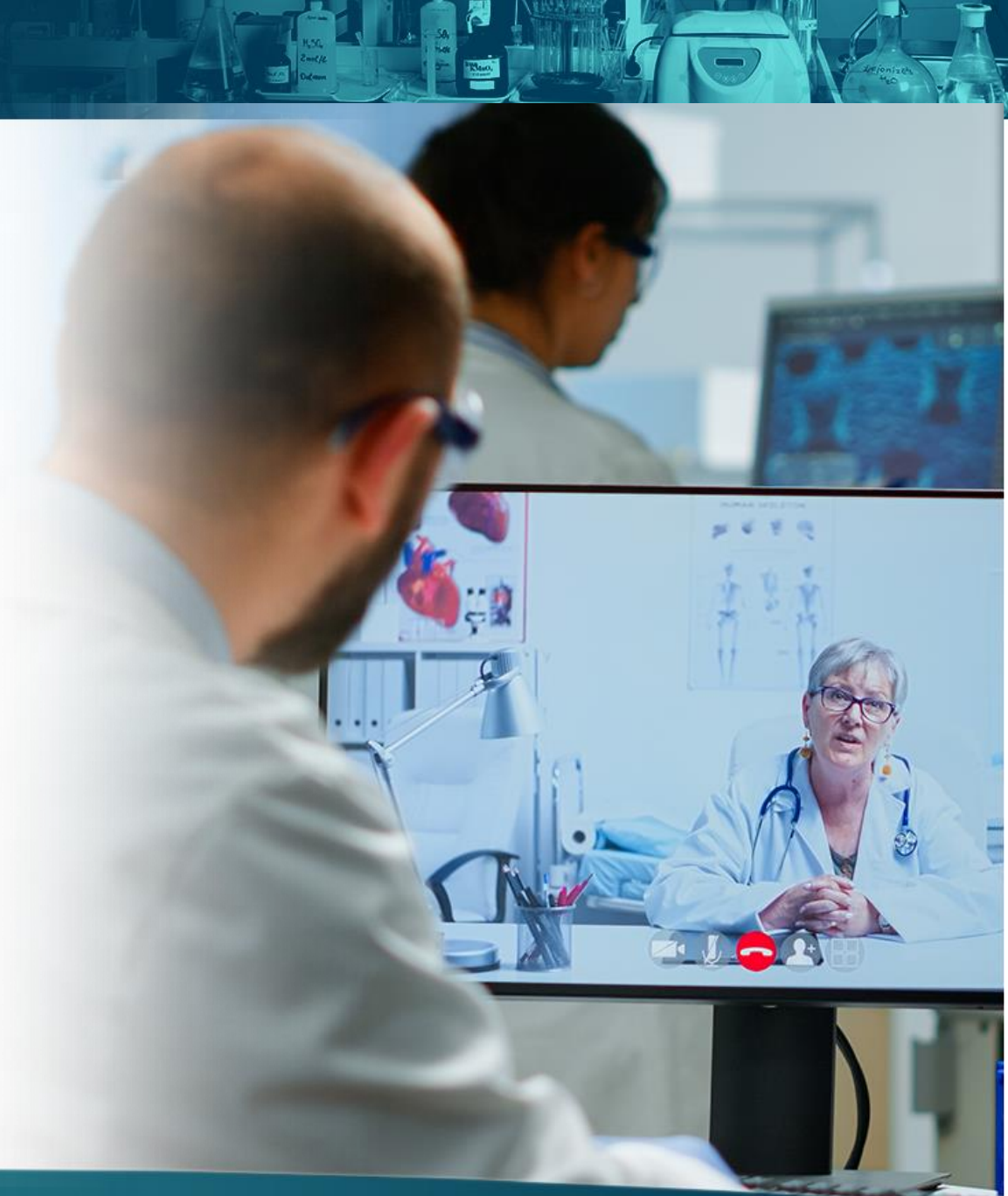
If Testing is Needed...

- CDC will provide guidance on specimen collection and shipping instructions to select public health laboratories that are members of the LRN.
- The designated public health laboratory can work directly with the clinical laboratory on procedures or specimen collection and shipping.



If Testing is Needed...

- Follow all 49 CFR 173.196 Category A infectious substances packaging and shipping requirements.
- These specimens are not considered select agents because they have not been identified to contain EVD.
- The APHIS/CDC Form 2: Request to Transfer Select Agents and Toxins does not need to be completed.



Risk Assessment and Mitigation Measures

Depend on:

- Procedures
- Hazards
- Path of the sample
- Training, competency level and certification of the personnel
- Laboratory equipment and facility
- Resources available

Follow U.S. Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standards.



Decontamination

- Perform routine cleaning and disinfection procedures using an EPA-registered List L: [Lab Advisory: Guidance for Transport and Shipment of Specimens for Ebola Virus Testing \(cdc.gov\)](#)
- Disinfect the areas where handling specimens, packing and packaging, and in the event of a specimen spill during the packaging and shipment process.



Decontamination

- Disinfection procedures should include continuous surface contact of at least 3 minutes using one of the disinfectants from the EPA registered L list.
- Follow the manufacturer's directions for concentration, to confirm contact time, care, and handling.



Waste Management

- Materials contaminated or suspected of being contaminated with EVD are regulated as a Category A infectious substance under the DOT HMR CFR, Parts 171-181.
- For procedural guidance on properly packaging EVD waste, see [Managing Solid Waste Contaminated with a Category A Infectious Substance \(dot.gov\)](https://www.dot.gov/operations/safety-and-security/emergency-preparedness-response-recovery/operational-safety/operational-safety-2017-01-17-managing-solid-waste-contaminated-with-a-category-a-infectious-substance).



Waste Management



- All waste disposal must comply with local, regional, state, national, and international regulations. See [State Universal Waste Programs in the United States | US EPA](#) for more information.
- Always discuss EVD waste disposal with your facility waste management contractor and the State Department of Public Health.



Packing and Shipping



EVD Classification for Shipments

- Specimens from PUIs or confirmed EVD cases should be packed and shipped as Category A infectious substances in accordance with the DOT's [Hazardous Materials Regulations \(HMR\) 49 CFR 171-180](#).
- All persons packing and shipping infectious substances must be trained and certified in compliance with DOT or the [International Air Transport Association](#) (IATA) requirements every two years.
- Specimens for shipment should be packed following the triple packaging system consisting of (1) a primary container (a sealable specimen container) wrapped with absorbent material, (2) a secondary container (watertight, leak-proof), and (3) an outer shipping package.

Packaging Considerations

- Must use UN-approved packaging noted with the UN specification mark to certify the box has passed the required drop test.
- Quantity limits and additional markings are based on the mode of transportation (passenger or cargo).
- No replacements or substitutions of packaging materials.



Packing Cold Specimens

- Ensure suspected EVD specimens are packed to maintain temperatures of 2-8°C.
- Within the secondary container, place sufficient ice packs to surround the sealed secondary packaging and provide further insulation.
- It is important to note that surrounding the secondary packaging on all sides with ice packs has been shown to improve the length of time the specimen remains frozen during transit.



Packing Frozen Specimens

- Ensure suspected EVD specimens are packed to maintain temperatures of $<-20^{\circ}\text{C}$.
- Within the secondary container, place sufficient dry ice to surround the sealed secondary packaging and provide further insulation.
- It is important to note that surrounding the secondary packaging on all sides with dry ice has been shown to improve the length of time the specimen remains frozen during transit.



Carrier Considerations for Transporting Category A Infectious Substances

FedEx accepts Category A packages

- Cannot use the FedEx clinical pack or clinical box.
- Must follow IATA Dangerous Goods Regulations/PI 620 packing instructions.

UPS accepts Category A packages

- Must follow the IATA Dangerous Goods Regulations/PI 620 packing instructions.

Additional private carriers may accept Category A packages. Check with your local carriers for more information.

USPS does not accept Category A packages.



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Q&A

Questions?



**Contact:
OneLab@cdc.gov**

Upcoming OneLab Network Events



When receiving samples from patients suspected to be infected with Ebola, what's the plan?

- Thursday, November 3, 2022, 12:00-1:00PM ET

Register Now!

https://cdc.zoomgov.com/webinar/register/WN_4bJGkNx-SrSEoFvT6OsBkQ



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

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