

Florida Department of Health

Ebola Virus Disease (EVD) Laboratory Diagnosis

Focus Area: Collection, Packaging and Shipping of Laboratory Specimens

Guidance document number 2022-01

Ebola Virus Diagnostic Specimen Collection, Packaging and Shipping Guidance for Laboratories and County Health Departments

Version 6.0 November, 2022

Summary:

- Authorization: Contact your local County Health Department for authorization prior to
 collecting and shipping diagnostic specimens for Ebola Virus testing. <u>Specimens will not be</u>
 accepted without prior approval.
- **Specimen Collection:** Specimens should be collected following CDC's Guidance for Collection, Transport, and Submission of Specimens for Ebola Virus Testing. Adhere to the OSHA Blood-borne Pathogens Standards and wear appropriate personal protective equipment. Collect two lavender top EDTA tubes.
- Packaging-for Shipments by Commercial Carrier: All suspect Ebola diagnostic
 specimens must be packaged according to IATA Packaging Instructions 620 for Category A
 agents which requires specimens be packed in a triple packaging system: a positively
 sealed, leakproof primary container wrapped with absorbent material, secondary leakproof,
 pressure tested container and a UN certified rigid outer shipping package. A Shipper's
 Declaration is required. Please consult with your County Health Department regarding the
 need for same day shipping.
- Packaging-for Transport by Local Courier: As above, specimens must be packaged in a
 triple packaging system a positively sealed, leakproof primary container wrapped with
 absorbent material, secondary leakproof, pressure tested container and a rigid outer
 shipping package. Packages transported by local courier require a Shipper's Declaration.
 The Materials of Trade exception does not apply to Category A Infectious Substances.
- Packaging-for Transport by Regional Emergency Response Advisor (RERA): As
 above, specimens must be packaged in a triple packaging system a positively sealed,
 leakproof primary container wrapped with absorbent material, secondary leakproof, pressure
 tested container and a rigid outer shipping package. Packages transported by RERA require
 a Shipper's Declaration. (RERAs will be provided prefilled shipper's declarations that will
 need only minor additions before use.)
- Laboratory Requisition: Complete and attach DOH Form 1847 and indicate "Ebola RT-PCR" in the "Comment/Additional Information" section in the lower right-hand corner of the form. Also complete the CDC Infectious Disease (CDC Form 50.34) and Viral Special Pathogens Branch (https://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission-508.)

forms. All three forms should be included in the packaging between the secondary and outer package.

- **Checklist**: Ensure completion of the EVD Checklist prior to shipment and include a copy in the packaging between the secondary and outer package
- Ship To for testing at the Tampa BPHL:

Bureau of Public Health Laboratories-Tampa 3602 Spectrum Blvd Tampa, FL 33612

Attention: Justin Hubsmith

For Additional Information: Contact Justin Hubsmith at 813-459-4039 or 813-455-9105 or Lisa Tate at 813-459-4039 or 813-956-8853

Ship To for testing at the Jacksonville BPHL:

Bureau of Public Health Laboratories-Jacksonville 1217 N. Pearl Street Jacksonville, FL 32202 Attention: Phil Lee

For Additional Information: Contact Phil Lee at 904-791-1712 or 904-945-4415 or George Churchwell at 904-791-1781 or 904-637-9260 or Maria Pedrosa at 904-791-1756

Authorization

Contact your local County Health Department and refer to the DOH <u>Decision Algorithm to Assist with Testing and Monitoring of Patients with Suspected Ebola Virus Disease (EVD)</u> and the <u>Ebola Virus Diagnostic Specimen Submission Check List</u> prior to collecting any specimens from suspect Ebola cases. <u>Specimens will not be accepted or tested without prior authorization.</u>

Specimen Collection

- Specimen collection should be performed following standard precautions. Wear appropriate
 personal protective equipment (PPE) at all times while collecting and handling specimens.
 Current recommendations for specimen collection include full face shield or goggles, masks to
 cover all of nose and mouth, gloves, fluid resistant or impermeable gowns. Additional PPE may
 be required in certain situations.
- Collect whole blood specimens following the CDC Guidelines found at https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html
- Collect specimens in plastic lavender top EDTA blood specimen tubes. At least 4ml of blood should be collected per tube. For pediatric samples, a minimum of 1 ml whole blood should be collected in pediatric-sized collection tubes. <u>DO NOT collect samples in glass tubes or tubes</u> containing heparin, sodium polyanethol sulfonate, citrate or with a clot activator.
- If necessary, short-term storage or specimens before shipping should be at 4°C or frozen.

Packaging Requirements and Shipping Requirements

Specimens collected for EVD testing should be packaged and shipped without attempting to open collection tubes or aliquot specimens.

Shipping by Commercial Carrier

General Requirements

- The specimens must be packaged as as a Category A agent.
- Remember, to ship Category A substances you MUST have attended and been certified at a Category A training session within the last two years. Category A Infectious Substances require a Shipper's Declaration for Dangerous Goods.
- The Consignee section of the Shipper's Declaration for Dangerous Goods must include a name and phone number for the person responsible for the shipment.
- Proper shipping names must be indicated on the outside of the package; UN 2814 Infectious Substance, Affecting Humans.
- Technical names are not to be marked on the outside of the package.
- On the Shipper's Declaration for Dangerous Goods write "Suspected Category A Infectious Substance" in parentheses following the proper shipping name.
- The Additional Handling Information box on the Shipper's Declaration for Dangerous Goods must include an emergency telephone number.
- Enclose an itemized list of contents between the secondary packaging and the outer packaging. If you add the number of "items" in the box to your requisition that satisfies the requirement (e.g., add "2 lavender-top tubes" to the notes section).
- Package on cold packs.
- If consultation regarding same day shipping is needed, please contact the Bureau of Public Health Laboratories (BPHL).

Inner Packaging Requirements

- Primary receptacle(s) must be leakproof and positively sealed (tape, parafilm, etc).
- Secondary receptacle must be leakproof and 95 kPa pressure tested.
- Absorbent material must be placed between the primary receptacle(s) and secondary receptacle and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).
- An itemized list of the contents enclosed between the secondary receptacle and the outer packaging. Do not place paperwork within the secondary container.

Outer Packaging Requirements

- Package must be rigid.
- Package must be at least four inches in the smallest overall external dimension.
- Package must be properly labeled.
- Package must pass required testing and be marked with UN specification marking for CLASS 6.2.

Packaging Requirements-Transport by Local Courier

Package specimens in combination packaging according to 49 CFR 173.6(a)(4).

General Packaging Requirements

- Packaging must coincide with 29 CFR 1910.1030 and specimens should be packed in a triple packaging system: a positively sealed, leakproof primary container(s) wrapped with absorbent material, a secondary leakproof, pressure tested container and a UN certified rigid outer shipping package.
- Enclose an itemized list of contents between the secondary packaging and the outer packaging.
- Package on cold packs.

Inner Packaging Requirements

- Primary receptacle(s) must be leakproof and positively sealed. Place cushioning between multiple primaries to reduce risk of breakage. (The absorbent may be used for this purpose.)
- Secondary receptacle must be leakproof and pass a 95 kPa pressure test.
- Absorbent material must be placed between the primary receptacle(s) and secondary receptacle and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).

Outer Packaging Requirements

 Package must be rigid. A UN specification package must be used, marked and labeled per Category A regulations.

Transport by Florida Department of Health Regional Emergency Response Advisor (RERA):

Packaging requirements are the same as above for transport by local courier.

After authorization for specimen testing has been obtained, the Bureau of Public Health
Laboratories in collaboration with the hospital, the County Health Department, and/or the
Bureau of Preparedness and Response (BPR) may determine to have the Department's
RERAs transport the specimen to ensure rapid and safe delivery of samples to the
laboratory. In this case, Bureau of Public Health Laboratory staff will contact the RERA in
the region of the specimen origin using the following contact information.

Shayne Stewart Region 1

Mobile: 850-699-4228

Howell Batts Region 2

Mobile: 850-251-0750

Freda Vaughn Region 3

Mobile: 954-702-0691

Kaila Yeager Region 4

Mobile: 813-363-0074

David Crowe Region 5

Mobile: 321-689-9464

Levi Connelly Region 6

Mobile: 239-671-1207

Bill Senyshyn Region 7

Mobile: 954-702-0691

- The RERA verifies that the Ebola Virus Diagnostic Specimen Submission Check List has been completed by hospital before transporting sample. The RERA will not transport sample unless the Ebola Virus Diagnostic Submission Check List has been completed and signed by Infection Control Practitioner.
- The hospital representative relinquishing the sample to the RERA will sign a RERA Transportation and Tracking form indicating they are relinquishing the sample to the RERA.
- The hospital must sign a Shipper's Declaration before RERA transport. The RERAs will be
 provided prefilled Shipper's Declarations that can be used with minor additions to assist
 with this requirement. The Shipper's Declaration must be signed by a person trained and
 certified to ship Category A material. Copies must be kept for one year.
- The originating RERA will pick up the sample and notify the destination laboratory. The originating RERA will transport to the next RERA. Each preceding RERA is responsible for coordinating with the next RERA if multiple RERAs will be used to transport the sample to its final destination. If multiple RERAs are used, each RERA will sign off that they are now in possession of the package and will contact the destination laboratory to indicate status of package.

 The destination laboratory will sign the RERA's Transportation and Tracking form indicating that package has been delivered.

Laboratory Requisition

- Complete DOH Form 1847 for each specimen and indicate "Ebola RT-PCR" in the
 "Comment/Additional Information" section in the lower right-hand corner of the form. This form
 can be found at http://www.floridahealth.gov/programs-and-services/public-health-laboratories/forms-publications/ documents/DH1847.pdf.
- Also complete the CDC Infectious Disease Form (<u>CDC Form 50.34</u>) and the 2-page form (https://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission-508.pdf) for the Viral Special Pathogens Branch (https://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission-508.pdf).
- All three forms should be included in the packaging between the secondary and outer package.
- **Checklist:** Complete an EVD Checklist prior to shipment and include a copy in the packaging between the secondary and outer package along with the 3 forms listed above.

Ship Specimens To: the appropriate location of the Bureau of Public Health Laboratories, addresses are located on page 2.

Notification: On shipment of a specimen for a suspect EVD patient for EVD testing at BPHL, please notify <u>Justin Hubsmith or Lisa Tate with the Tampa BPHL</u> (see below for contact information) or <u>Phil Lee, George Churchwell or Maria Pedrosa with the Jacksonville BPHL</u> (see below for contact information).

Provide the shipping tracking number if being shipped commercially.

For Additional Information:

On Submitting Specimens for Ebola Testing: Contact your local County Health Department. Contacts for Laboratory Questions:

Tampa

Justin Hubsmith, Bureau of Public Health Laboratories at 813-233-2237 or 813-455-9105 Lisa Tate, Bureau of Public Health Laboratories at 813-233-2323 or 813-956-8853

Jacksonville

Phil Lee, Bureau of Public Health Laboratories at 904-791-1712 or 904-945-4415 George Churchwell, Bureau of Public Health Laboratories at 904-791-1781or 904-637-9260 Maria Pedrosa, Bureau of Public Health Laboratories at 904-791-1756 or 904-718-8744

Biosafety

Leah Kloss, Biosafety Officer, Bureau of Public Health Laboratories at 813-233-2278 or 813-407-7173

For more information on DOT Shipping regulations:

https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Transporting-Infectious-Substances-Safely.pdf

Infectious Substances Packaging & Shipping Training info:

BPHL sponsored classes: http://www.floridahealth.gov/programs-and-services/public-health-laboratories/educational-opportunities/packaging-and-shipping-training.html

CDC online training: https://www.cdc.gov/labtraining/training-courses/packing-shipping-division-6.2-materials.html

Specimen collection and handling: see the CDC guidance at http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

Updates and other CDC guidance is available at http://www.cdc.gov/vhf/ebola/