

Ebola Virus Disease Testing & Shipping Instructions

Important Contact your local Health Department Epidemiology representative for all suspect Ebola virus cases:

I. **Key Points**

- Department of Transportation classifies SUSPECT Ebola specimens as “Risk Group 4” agents.
 - **Risk Group 4 (RG4)** classification applies to those agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.
 - **Biosafety Level 4 (BSL4)** classification applies to a combination of laboratory practices/techniques, safety equipment and laboratory facilities that provide a level of containment adequate to work with dangerous and exotic agents that pose a high risk of life-threatening disease. This includes diseases transmitted via aerosol transmission and diseases for which there is no available vaccine or therapy available.
- DOT requires that “contracted” couriers only transport packages containing Risk Group 4 suspected or confirmed agents that are prepared by Category A certified individuals.
- Category A packages must include DOT-approved labeling, packaging materials and shipper’s declaration.
- DCLS is providing Category A/Risk Group 4 collection/shipping kits (See Section VII) to all area Health Districts for Ebola virus testing. These kits will be provided to facilities as needed.
- DCLS can also provide a kit directly to a facility if one cannot be obtained from the area Health District. The kit will only be issued once a suspect case has been approved for testing by VDH/CDC.
- **Please communicate to DCLS if your facility does not have staff certified to package and ship Category A specimens.**
- **A courier cannot be deployed to retrieve a Risk Group 4 specimen that has not been packaged properly by a person certified in packaging Category A specimens using defined DOT requirements.**

II. **PCR Testing** ****NOTE: Testing will not be performed without prior consultation with VDH and the CDC, a CDC-issued Patient Under Investigation (PUI) number, and CDC approval to test.**

- DCLS will perform real-time PCR testing for Ebola virus once testing has been approved by the CDC.
- Ebola virus can be detected in blood only after onset of symptoms, most notably fever; however, it may take up to 3 days post-onset of symptoms for the virus to reach detectable levels.
- The real-time PCR assay detects the presence of RNA for the Ebola Zaire virus.
 - **Negative test results** are considered final test results.
 - If fever or symptoms have been present for less than 72 hours, a repeat test may be required to rule out Ebola virus infection, after consultation with the CDC.
 - If Lassa Fever is being considered as a cause of illness, DCLS will refer a blood specimen to CDC for Lassa Fever testing.
 - **Positive test results** will be confirmed at CDC. DCLS will refer a blood specimen to CDC for confirmatory testing.

III. **Specimen Collection**

- Collect **2 lavender top** blood tubes (plastic tubes only) containing **whole blood** preserved with EDTA (**minimum volume of 4mL each**).
 - One specimen will be tested at DCLS.
 - DCLS will forward the second whole blood tube to CDC for confirmatory testing and additional viral testing, as needed and directed by the CDC.
- Collect blood in **plastic** tubes only. **Do not collect in glass tubes.**
- Do not centrifuge specimens.
- Specimens should be stored and shipped at 4°C.

IV. Submission Forms

- Complete and submit the DCLS Clinical Microbiology/Virology Request Form.
- Provide all patient information, including full address and medical history.
- Write “Ebola virus” as the disease suspected in the “Patient Medical History” section.
- Complete Shipper’s Declaration Form (must have red border)

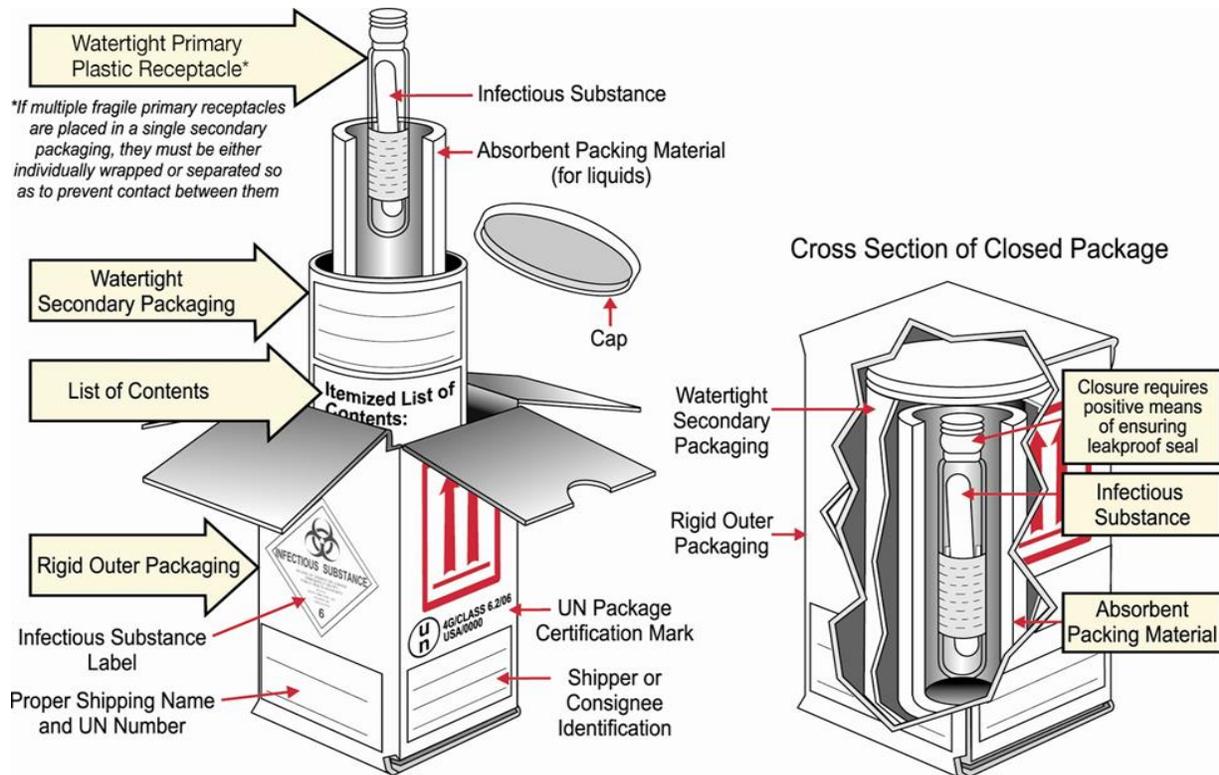
NOTE: The Shipper’s Declaration form must to be completed by a certified Category A shipper using compliance checking software. Forms can be found at: <https://www.iata.org/whatwedo/cargo/dgr/Documents/Shippers-Declaration-Column-Format-Fillable.pdf> or <https://www.saftpak.com/Support/Support.aspx> (individual Saf-T-Pak registration is required).

- Place 3 copies (**two must be printed in color**) of the printed shippers declaration in the plastic sleeve that is attached to the outermost insulated shipper.

V. Specimen Packaging

- Category A/Risk Group 4 collection/transport kits will be provided to all Health Districts. Specimens (blood tubes) should be packaged following the basic triple packaging system (**see diagram #1 below**):
 - Primary “shipping” receptacle (sealable specimen bag) wrapped with absorbent material
 - Secondary “shipping” receptacle (watertight, leak-proof, and puncture proof container)
 - Tertiary “shipping” receptacle (rigid outer shipping package)
- If multiple primary receptacles will be placed in a single secondary receptacle, they must be individually wrapped or separated to prevent contact between them.
- Submission form should be included in the package **outside** of the secondary receptacle.
- The shipping receptacle should have the appropriate DOT-approved labeling required for Category A packages (**see diagram #2 below**)

Diagram #1: Triple Packaging System for Category A Packages



ALL QUESTIONS AND INQUIRIES REGARDING LABORATORY TESTING SHOULD BE DIRECTED TO:

- **DCLS Emergency Mobile 24/7 Number: 804-335-4617**
- **Dr. LaToya Griffin-Thomas (DCLS Bioterrorism/Special Pathogens Response Coordinator): 804-385-8057**

VIII. REFERENCES:

1. DCLS website (Hot Topics Link): <https://dgs.virginia.gov/division-of-consolidated-laboratory-services/updates/hot-topics/>
2. CDC's Guidance for US Clinical Labs: <https://www.cdc.gov/vhf/ebola/laboratory-personnel/safe-specimen-management.html>
3. CDC's Guidance for Specimen Collection, Transport, and Submission for Specimens for Ebola Virus Testing: <https://www.cdc.gov/vhf/ebola/laboratory-personnel/shipping-specimens.html>
4. CDC Interim Guidance for Environment Infection Control in Hospitals for Ebola Virus: <http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html>