



**SPECIMEN & MEDICAL PRODUCTS  
RESEALABLE ZIPPER & PACKAGING  
CUSTOM FLEXIBLES**

**800 Industrial Park Road  
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### **EBOLA & ENTEROVIRUS SOLUTIONS**

Com-Pac International has manufactured Laboratory specimen handling, storage and shipping products for over 25 years. Due to the recent Ebola and Enterovirus outbreaks, Com-Pac has added several new specimen handling products designed specifically around the recently provided guidance from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) relating to packaging and shipping these viruses. We have attached the two documents from the CDC which provide this guidance.

Specifically, Ebola specimens must be shipped as an **“Infectious Substance, Affecting Humans, Category A,”** and is assigned **UN 2814**. Further, the CDC has specified that specimens should be shipped either frozen or refrigerated at 2°C - 8°C.

Enterovirus specimens should be shipped as a **“Biological Substance, Category B,”** and is assigned **UN 3373**. The CDC has specified that these specimens should be shipped frozen on dry ice.

The above Categories (either A or B) which have been assigned to these substances determines the packaging requirements for each type and is regulated by the Department of Transportation (DOT in the U.S. and the International Air Transport Association (IATA) internationally. You and your employer can be subject to fines and penalties if the packaging regulations are not followed.

All of Com-Pac's shippers designated for use with Category A and Category B specimens have been tested and certified to comply with the UN 6.2 Dangerous Goods Regulations, 49 CFR D.O.T. regulations for air and ground shipments and IATA Packaging Instructions 620 and 650. Each of our shippers comes complete with all required absorbents, labels and labeling instructions, and shipping declarations.

Com-Pac's new **INFECON® 6200** is comprised of a ½ liter UN certified vessel, bubble wrap, and a carton with the required UN markings to contain the vessel. This vessel will hold up to 6 standard blood tubes. The vessel in its carton is to be placed in the overpack cooler which is also provided, with refrigerated gel packs or dry ice if you are shipping Ebola, or dry ice if you are shipping Enterovirus.

The **INFECON® 6300** is identical to the 6200 except the UN certified vessel has a 1 liter capacity and will hold up to 20 standard blood tubes.

It is important to follow all required labeling instructions, but particular attention should be given to the following:

- When shipping Ebola (a Category A specimen), the Infectious Substance label must be affixed to the outside of the cooler, whether or not you are shipping on dry ice or with gel packs;
- If you are shipping Ebola on dry ice, you must additionally affix the dry ice label to the outside of the cooler;
- When shipping Enterovirus (a Category B specimen), you must not affix the Infectious Substance label to the cooler, But you must affix the dry ice label to the cooler.

It should also be noted on the attached Ebola Guidance Sheet that the CDC reminds healthcare workers that **29 CFR 1910.1030** “requires that specimens should be placed in a durable, leak-proof secondary container for transport in a facility.” The typical bio-hazard bag is not guaranteed leak-proof. However, Com-Pac's line of **Bitran®** and **Infecon®** resealable specimen bags have been independently tested under regulations specifying the definition of “leak-proof” and comply with all such requirements.

On page 2 of the attached brochure, you will find information on each of these specimen bag lines, as well as the new **Bitran® Bubble Pouch Bags** which combine the leak-proof capability of our Bitran® Bags with a compartmented bubble pouch for safe and convenient handling of specimens within the facility. We have also provided several helpful links to websites which address regulations on specimen handling and shipping.

Remember that all of the components of our shippers may be purchased separately for refurbishment and re-use. We also specialize in custom bag sizes, printing, sequential barcoding and offer hundreds of other specimen handling and shipping products. All of our products are manufactured in Carbondale, Illinois USA.

# Ebola & Enterovirus Shipping Solutions



The World Health Organization, CDC and DOT have determined the following:

*“Ebola Virus Disease specimens **MUST** be shipped as INFECTIOUS SUBSTANCE, AFFECTING HUMANS, CATEGORY A (UN 2814).” Recommended shipping temperature: 2°C - 8°C.*

*“Enterovirus D68 (EV-D68) specimens may be shipped as BIOLOGICAL SUBSTANCE, CATEGORY B (UN 3373).” Recommended shipping temperature: -70°C.*

**Combination Shippers Designed Specifically For Use With Ebola or Enterovirus  
(use refrigerated gel packs for Ebola and dry ice for Enterovirus)**



**INFECON® 6200 (½ Liter Vessel)**  
Combines INF-2000 with INF-6000  
72 Hours @ -70°C with 22 lbs. Dry Ice  
72 Hours @ 5°C with Gel Packs  
Cat. No. INF-6200



**INFECON® 6300 (1 Liter Vessel)**  
Combines INF-3000 with INF-6000  
72 Hours @ -70°C with 22 lbs. Dry Ice  
72 Hours @ 5°C with Gel Packs  
Cat. No. INF-6300

**Separate Shippers For Use With or Without Gel Packs or Dry Ice**



**INFECON® 2000**  
½ Liter Vessel - Up To 6 Standard Tubes  
Cat. No. INF-2000



**INFECON® 3000**  
1 Liter Vessel - Up To 20 Standard Tubes  
Cat. No. INF-3000



**INFECON® 5000**  
Dry Ice or Gel Pack Shipper  
½ Liter Vessel - 60 Hrs With 5.6 lbs. Dry Ice  
Cat. No. INF-5000



**INFECON® 5500**  
Dry Ice or Gel Pack Shipper  
1 Liter Vessel - 100 Hrs. With 16 lbs. Dry Ice  
Cat. No. INF-5500



**INFECON® 6000**  
Overpack Cooler & Labels Only  
76 Hours With 22 lbs. Dry Ice  
Cat. No. INF-6000  
(Cat. A when used with INF-2000 or INF-3000)



**INFECON® DIAGNOSTIC MAILER**  
6 Compartment Bubble Pouch  
9" x 12" Liquid-Tight Infecan Bag  
250 mil Absorbent  
Cat. No. DIA-1000

## Com-Pac Shippers - Compliance, Convenience, Cost Effectiveness

- ✓ Items Designated "For Category A and B Specimens" are UN 6.2 Certified, Meet 49 CFR D.O.T. Regulations for Air & Ground Shipments, and Meet ICAO/IATA Packing Instructions 620 (Cat. A) and 650 (Cat. B).
- ✓ Items Designated "For Category B Specimens Only" Meet ICAO/IATA Packing Instruction 650.
- ✓ Items Include All Accessories, Absorbents, Labels, Labeling Instructions and Shipping Declarations.
- ✓ Components Such As Boxes, Vessels, Labels and Absorbents May Be Purchased Separately for Refurbishment and Reuse.

## Check-Out Our Other Specimen Transport and Storage Products



### **BITRAN® LEAKPROOF SPECIMEN BAGS**

3 Mil PE with No Printing  
Leakproof Resealable Zipper  
Cat. No. Based on Size



### **INFECON® LEAKPROOF SPECIMEN BAGS**

3 Mil PE with Document Pouch  
Leakproof Resealable Zipper  
Biohazard Logo  
Cat. No. Based on Size



### **INSPEX® TAMPER-EVIDENT ADHESIVE SPECIMEN BAGS**

3 Mil PE with Biohazard Logo  
Cat. No. 8022-XP 6.5" x 12"



### **BITRAN® BUBBLE POUCH BAG**

Liquid-Tight Bitran Zipper Bag  
With Document Pouch  
6 Compartment Bubble Pouch  
Cat. No. DA-1718 7" X 8"  
Cat. No. DA-1912 9" X 12"



### **SAF-T-ZIP® SPECIMEN BAGS**

6" X 9" 2.8 Mil PE Secondary Bag  
Document Pouch, Resealable  
Zipper & Biohazard Logo  
Cat. No. Based on Zipper Color



### **INSPEX® 95 kPa SPECIMEN BAG**

6" X 9" Super-Tough Material  
Tamper-Evident Adhesive Closure  
Cat. No. XP-95-0609

## Links to Helpful Websites on Specimen Packaging & Shipping

Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease:

<http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>

<http://www.cdc.gov/vhf/ebola/pdf/ebola-lab-guidance.pdf>

Diagram of a "Category A" Infectious Substance Shipper and "Category B" Biological Substance Shipper:

[Category A Shipper](#)

[Category B Shipper](#)

CDC Guidance for Collection, Storage and Shipment of Enterovirus:

<http://www.cdc.gov/non-polio-enterovirus/lab-testing/specimen-collection.html>

World Health Organization Guidance on Regulations for Transport of Infectious Substances 2013-2014:

[http://www.who.int/ihr/publications/who\\_hse\\_ihr\\_2012.12/en/](http://www.who.int/ihr/publications/who_hse_ihr_2012.12/en/)

International Air Transport Assn. (IATA) Dangerous Goods Regulations for Infectious Substances:

[https://www.iata.org/whatwedo/cargo/dgr/Documents/DGR52\\_InfectiousSubstances\(DGR362\).pdf](https://www.iata.org/whatwedo/cargo/dgr/Documents/DGR52_InfectiousSubstances(DGR362).pdf)

U.S. Dept. of Transportation Guidance for Transporting Ebola:

<http://phmsa.dot.gov/portal/site/PHMSA/menuitem.6f23687cf7b00b0f22e4c6962d9c8789/?vgnextoid=4d1800e36b978410VgnVCM100000d2c97898RCRD&vgnnextchannel=d248724dd7d6c010VgnVCM10000080e8a8c0RCRD&vgnnextfmt=print>



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# INTERIM GUIDANCE FOR Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease

## NOTIFICATION & CONSULTATION

Hospitals should follow their state and/or local health department procedures for notification and consultation for Ebola testing requests before contacting CDC.

CDC cannot accept any specimens without prior consultation.

FOR CONSULTATION, CALL THE CDC  
EMERGENCY OPERATIONS CENTER AT

**770-488-7100**



## WHEN SPECIMENS SHOULD BE COLLECTED FOR EBOLA TESTING



**Ebola virus is detected in blood** only after the onset of symptoms, usually fever. It may take up to 3 days after symptoms appear for the virus to reach detectable levels. Virus is generally detectable by real-time RT-PCR from 3-10 days after symptoms appear.



**Ideally, specimens should be taken** when a symptomatic patient reports to a healthcare facility and is suspected of having an Ebola exposure. However, if the onset of symptoms is <3 days, a later specimen may be needed to completely rule-out Ebola virus, if the first specimen tests negative.

## PREFERRED SPECIMENS FOR EBOLA TESTING

A minimum volume of 4 milliliters of whole blood preserved with EDTA is preferred but whole blood preserved with sodium polyanethol sulfonate (SPS), citrate, or with clot activator can be submitted for Ebola testing.

Specimens should be shipped at 2-8°C or frozen on cold-packs to CDC. Do not submit specimens to CDC in glass containers. Do not submit specimens preserved in heparin tubes.



**2-8°C**

Specimens other than blood may be submitted upon consult with CDC.

Standard labeling should be applied for each specimen. The requested test needs to be identified only on the requisition and CDC specimen submission forms.



## DIAGNOSTIC TESTING FOR EBOLA PERFORMED AT CDC

Several diagnostic tests are available for detection of Ebola virus disease. Acute infections will be confirmed using a real-time RT-PCR assay (CDC test directory code CDC -10309 Ebola Identification) in a CLIA-accredited laboratory. Virus isolation may also be attempted. Serologic testing for IgM and IgG antibodies will be completed for certain specimens and to monitor the immune response in confirmed Ebola virus disease patients (#CDC-10310 Ebola Serology).

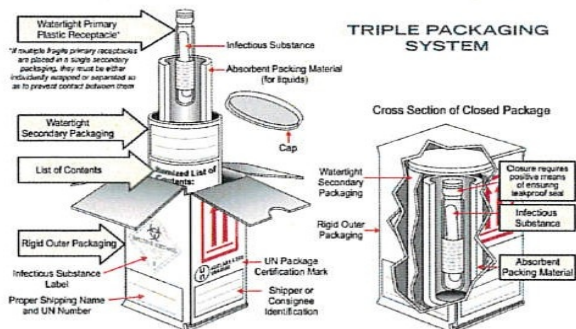
Lassa fever is also endemic in certain areas of West Africa and may show symptoms similar to early Ebola virus disease. Diagnostic tests available at CDC include but are not limited to RT-PCR, antigen detection, and IgM serology, all of which may be utilized to rule out Lassa fever in patients who test negative for Ebola virus disease.

## TRANSPORTING SPECIMENS WITHIN THE HOSPITAL / INSTITUTION



In compliance with 29 CFR 1910.1030, specimens should be placed in a durable, leak-proof secondary container for transport within a facility. To reduce the risk of breakage or leaks, do not use any pneumatic tube system for transporting suspected Ebola virus disease specimens.

## PACKAGING & SHIPPING CLINICAL SPECIMENS TO CDC



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

Specimens for shipment should be packaged following the basic triple packaging system which consists of a primary container (a sealable specimen bag) wrapped with absorbent material, secondary container (watertight, leak-proof), and an outer shipping package.

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## Non-Polio Enterovirus

### Non-Polio Enterovirus Home

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#### Related Links

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## Specimen Collection, Storage, & Shipment

Refer to this table when you collect, store and ship specimens. Before sending specimens to CDC, please contact [wnix@cdc.gov](mailto:wnix@cdc.gov) or [soberste@cdc.gov](mailto:soberste@cdc.gov).

Note that CDC will use real-time PCR for generic testing and nested PCR for typing.

Specimen Type	Minimum Amount	Collection	Storage	Shipping	Comments
<b>Respiratory - NP/OP swab</b>	1ml	Store in viral transport medium	Freeze at -20°C	Ship on dry ice	
<b>Respiratory - NP/OP wash or aspirate</b>	1ml	Collect in sterile container, no special medium required	Freeze at -20°C	Ship on dry ice	
<b>Stool</b>	≥1gram	Collect in sterile container, no special medium required	Freeze at -20°C	Ship on dry ice	Virus present for longer than other specimen types
<b>Rectal swab</b>	≥1gram	Store in viral transport medium	Freeze at -20°C	Ship on dry ice	
<b>Cerebrospinal fluid (CSF)</b>	≥150 ul	Collect in sterile container, no special medium required. Collect within 0-4 days of symptom onset (earlier the better)	Freeze at -20°C	Ship on dry ice	
<b>Serum</b>					Not recommended
<b>Fresh-frozen tissue</b>	N/A	Place directly on dry ice or liquid nitrogen	Freeze at -70°C	Ship on dry ice	Preferred to formalin-fixed/paraffin embedded tissue
<b>Formalin-fixed or formalin-fixed, paraffin-embedded tissue</b>	N/A	Avoid prolonged fixation—can fix in formalin then transfer to 100% ethanol	Room temperature	Ship at room temperature with paraffin blocks in carriers to prevent breakage	Acceptable, but lower sensitivity than fresh-frozen tissue

[Print page](#)

#### Contact Us:

Centers for Disease Control and Prevention  
1600 Clifton Rd  
Atlanta, GA 30333

800-CDC-INFO  
(800-232-4636)  
TTY: (888) 232-6348  
[Contact CDC-INFO](#)

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