



INTERIM GUIDANCE FOR COLLECTION AND TRANSPORTATION OF CLINICAL SAMPLES FOR TESTING FOR EBOLA VIRUS DISEASE

November 10, 2014

This document provides information on the collection and transportation of clinical samples for testing for Ebola virus disease (EVD).

This information is based on currently available scientific evidence and expert opinion, and is subject to change as relevant new information becomes available. It should be read in conjunction with relevant national legislation, regulations and policies.

Ebola Virus Disease

CARPHA is working with the Pan American Health Organization (PAHO)/World Health Organization (WHO), CARPHA Member States, and other international organizations in response to an outbreak of Ebola virus disease (EVD) in West Africa, which was first reported in late March 2014. This is the largest outbreak of EVD ever documented and the first recorded in West Africa.

In light of the recent WHO declaration that Ebola Virus Disease is currently a Public Health Emergency of International Concern (PHEIC) ¹, CARPHA reminds all member states to strengthen existing biosafety protocols in keeping with international standards for handling all types of clinical specimens e.g. blood, other fluids or tissues as potentially infectious materials.

When to test for Ebola Virus in Persons Under Investigation for EVD

The decision to obtain a sample to test for Ebola Virus must be made in consultation with the latest guidance available in each country including the CARPHA EVD Risk Assessment algorithm and the following parties:

- National authorities (clinical team leader, Chief Medical Officer, International Health Regulations (IHR) National Focal Point)
- PAHO/WHO IHR Focal Point
- CARPHA (contact information **1- 868-472-9451 available 24/7**)
- Referral laboratory (CDC, USA or PHAC, Canada as chosen by Member State)

Ebola virus is detected in blood **only after** the onset of symptoms, of which fever is usually the first. 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**. Specimens ideally 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.

Screening of asymptomatic persons with no documented history of exposure to Ebola virus disease is **NOT** recommended^{2,3,4}.

How to collect the sample and transfer within the hospital

- **Sample requirement:** minimum of 4mL whole blood preserved with EDTA OR whole blood preserved with sodium polyanethol sulfonate (SPS), citrate, or with clot activator²
- **Use only plastic blood collection tubes**^{2,5}
- It is recommended that the **Health Care Worker who is attending to the patient** be responsible for collecting samples.
- Any person collecting specimens from a patient with suspected Ebola virus disease should wear appropriate **Personal Protective Equipment (PPE)**. This consists of gloves, water-resistant gowns, full face shield or goggles, N95 mask to cover all of mouth and nose and shoe covers (Appendix A). Additional PPE may be required in certain situations².
- **Don and doff the appropriate PPE using a buddy system and under supervision**^{3,6}
 - Video links for donning <http://www.youtube.com/watch?v=ynr9gIFcVd8> ;
<http://www.youtube.com/watch?v=T5knZceQ1xA>
 - Video links for doffing (removal) <http://www.youtube.com/watch?v=ls69Tib1PjU> ;
<http://www.youtube.com/watch?v=FtvkAOJOMUI>
- **Standard Operating Procedure**

Steps for sample collection and transfer within facility:

- 1) Use a pre-labelled tube which has the name, sex and date of birth of the patient, date of collection and is labelled 'Suspected EVD'.
- 2) Use universal precautions to take the sample from patient, and place into the appropriate plastic blood collection tube.
- 3) Dispose of needle and other items used for sample collection in appropriately labeled sharps and waste containers.
- 4) Remove outer pair of gloves and replace with new pair.
- 5) Wipe sample with a disinfectant wipe. Dispose of wipe and perform hand hygiene.

- 6) Wrap sample in absorbent material (e.g. paper towel/tissue) place within a 50 mL centrifuge tube and cap firmly.
- 7) Insert tube into a biohazard bag, seal and place the bag in a durable, leak-proof secondary container for transfer by a second person to an external location e.g. the laboratory to be appropriately packaged by a certified shipper³.
- 8) Remove outer pair of gloves and replace with a new pair to continue work as applicable.
- 9) Do not use any pneumatic tube system for transporting suspected EVD specimens.

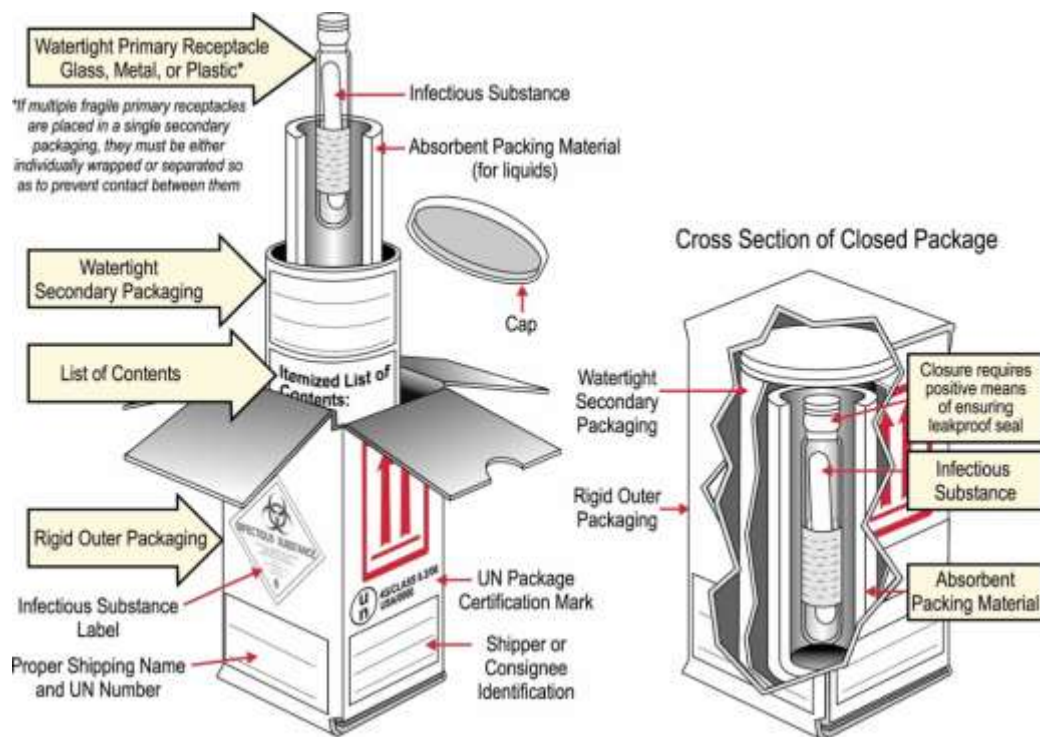
[Click here for a listing of PPE and links to PPE providers](#)

Preparation of Package for shipping to the referral laboratory

- 1) Store the sample at 4°C in an appropriately identified refrigerator if packaging is delayed.
- 2) The package must be prepared by a **certified** Category A, Infectious Substance Shipper using the triple packaging method shown in the diagram below and described in Packaging Instruction 620 for Category A, Infectious Substances^{7,8}.

A pre-labelled and pre-marked outer box should be readily available.

- 3) **Refrigeration:** ensure sufficient **frozen ice packs** are placed into the secondary container to maintain the cold chain and integrity of the sample. Mark outer box "**Refrigerate at 4°C**" or other similar marking.
- 4) Ensure all the **appropriate documentation** is completed i.e. courier airway bill (AWB), Dangerous Goods Declaration Form (DGD), CARICOM Invoice (where applicable). Enclose relevant import and/or export permits as required by national authorities and the referral laboratory.



Shipping to the referral laboratory

The sample will be shipped by the courier that has been previously identified by each Member State.

The shipment is to be addressed as follows:

CDC, USA

Centers for Disease Control and Prevention

ATTN STAT LAB: VSPB, UNIT #70

1600 Clifton Road NE

Atlanta, GA 30333

United States of America

Phone 770-488-7100

PHAC, CANADA

Please contact the Public Health Agency of Canada Health Portfolio Operations Centre (HPOC) at 1-800-545-7661 for specific details related to shipments.

CARPHA will continue to evaluate new information as it becomes available, and will update this guidance as needed.

REFERENCES

1. WHO Statement on the Meeting of the International Health Regulations Emergency Committee Regarding the 2014 Ebola Outbreak in West Africa <http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/>
2. Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease in the United States. Available from: <http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>
3. Interim Biosafety Guidelines for Laboratories Handling Specimens from Patients Under Investigation for Ebola Virus Disease. Available from: <http://www.phac-aspc.gc.ca/id-mi/vhf-fvh/ebola-biosafety-biosecure-eng.php>
4. Ebola Virus Pathogen Safety Data Sheet <http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/ebola-eng.php>
5. BD Vacutainer® Blood Collection Tube Product Ordering Information http://www.bd.com/vacutainer/products/venous/ordering_info_tubes.asp
6. Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing) <http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>
7. WHO Guidance on regulations for the Transport of Infectious Substances 2013-2014 http://www.who.int/ihr/publications/who_hse_ihr_2012.12/en/
8. CDC Packaging and Shipping Clinical Specimens Diagram <http://www.cdc.gov/vhf/ebola/hcp/packaging-diagram.html>

Appendix A: Types of Personal Protective Equipment (PPE) for use by the Health Care Worker and Laboratory Workers

a. Coveralls

https://us.vwr.com/store/catalog/product.jsp?catalog_number=10010-196

b. Impermeable gowns

[http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=766221&catalogId=29104&fromBrowse=1&matchedCatNo=19037084||19065278&highlightProductsItemsFlag=Y&endecaSearchQuery=browseproducts_gowns-frocks-and-smocks_62291219%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D\[\]&xrefPartType=From&savings=0.0&xrefEvent=1413398345117_7&searchType=&hasPromo=0#](http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=766221&catalogId=29104&fromBrowse=1&matchedCatNo=19037084||19065278&highlightProductsItemsFlag=Y&endecaSearchQuery=browseproducts_gowns-frocks-and-smocks_62291219%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D[]&xrefPartType=From&savings=0.0&xrefEvent=1413398345117_7&searchType=&hasPromo=0#)

c. Head covers

[http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=679278&catalogId=29104&matchedCatNo=0136175D&fromBrowse=1&endecaSearchQuery=browseproducts_bouffants-beard-covers-and-facemasks_62291209%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D\[\]&endecaSearchQuery=browseproducts_bouffants-beard-covers-and-facemasks_62291209%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D](http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=679278&catalogId=29104&matchedCatNo=0136175D&fromBrowse=1&endecaSearchQuery=browseproducts_bouffants-beard-covers-and-facemasks_62291209%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D[]&endecaSearchQuery=browseproducts_bouffants-beard-covers-and-facemasks_62291209%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D)

d. 1860/1860S Healthcare Particulate Respirator and Surgical Mask/ N 95 masks

[http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=731193&catalogId=29104&fromBrowse=1&matchedCatNo=18992||18991||19805850&highlightProductsItemsFlag=Y&endecaSearchQuery=browseproducts_respiratory-protection_62291335%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D\[3M+N95\]&xrefPartType=From&savings=0.0&xrefEvent=1413408923261_8&SWKeyList=\[3M%20N95\]&searchType=&hasPromo=0](http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=731193&catalogId=29104&fromBrowse=1&matchedCatNo=18992||18991||19805850&highlightProductsItemsFlag=Y&endecaSearchQuery=browseproducts_respiratory-protection_62291335%3F%23brpp%3D25%23searchType%3DPROD%23SWKeyList%3D[3M+N95]&xrefPartType=From&savings=0.0&xrefEvent=1413408923261_8&SWKeyList=[3M%20N95]&searchType=&hasPromo=0)

https://us.vwr.com/store/catalog/product.jsp?catalog_number=89138-046

e. Face shields

Available in WHO Sample Collection Kits Module 1 PPE Basic

[http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=720312&catalogId=29104&matchedCatNo=189992885||189992886&fromSearch=1&searchKey=face%20shield||shields||face||faces||shield||faceshield&highlightProductsItemsFlag=Y&endecaSearchQuery=%23store%3DRE_SC%23nav%3D0%23rpp%3D25%23offSet%3D0%23keyWord%3Dface%2Bshields%23searchType%3DPROD%23SWKeyList%3D\[\]&xrefPartType=From&savings=0.0&xrefEvent=1413926836542_5&searchType=PROD&hasPromo=0](http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=720312&catalogId=29104&matchedCatNo=189992885||189992886&fromSearch=1&searchKey=face%20shield||shields||face||faces||shield||faceshield&highlightProductsItemsFlag=Y&endecaSearchQuery=%23store%3DRE_SC%23nav%3D0%23rpp%3D25%23offSet%3D0%23keyWord%3Dface%2Bshields%23searchType%3DPROD%23SWKeyList%3D[]&xrefPartType=From&savings=0.0&xrefEvent=1413926836542_5&searchType=PROD&hasPromo=0)

f. Aprons

[http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=5528618&catalogId=29102&matchedCatNo=19181529&fromSearch=1&searchKey=apparel&highlightProductsItemsFlag=Y&endecaSearchQuery=%23store%3DSafety%23nav%3D10396600%23rpp%3D25%23keyWord%3Dapparel%23SWKeyList%3D\[\]&xrefPartType=From&savings=0.0&xrefEvent=1414417824304_0&searchType=&hasPromo=0#](http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=5528618&catalogId=29102&matchedCatNo=19181529&fromSearch=1&searchKey=apparel&highlightProductsItemsFlag=Y&endecaSearchQuery=%23store%3DSafety%23nav%3D10396600%23rpp%3D25%23keyWord%3Dapparel%23SWKeyList%3D[]&xrefPartType=From&savings=0.0&xrefEvent=1414417824304_0&searchType=&hasPromo=0#)

g. Shoe covers

[http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=4649081&catalogId=29104&fromBrowse=1&matchedCatNo=190881520||19048300&highlightProductsItemsFlag=Y&endecaSearchQuery=browseproducts_shoes-boots-and-covers_62291278%3F%23brpp%3D25%23offSet%3D25%23searchType%3DPROD%23SWKeyList%3D\[\]&xrefPartType=From&savings=0.0&xrefEvent=1413398522213_7&searchType=&hasPromo=0#](http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=4649081&catalogId=29104&fromBrowse=1&matchedCatNo=190881520||19048300&highlightProductsItemsFlag=Y&endecaSearchQuery=browseproducts_shoes-boots-and-covers_62291278%3F%23brpp%3D25%23offSet%3D25%23searchType%3DPROD%23SWKeyList%3D[]&xrefPartType=From&savings=0.0&xrefEvent=1413398522213_7&searchType=&hasPromo=0#)