GUIDANCE DOCUMENT FOR THE COLLECTION AND REFERRAL OF SPECIMENS FROM SUSPECTED EBOLA PATIENTS

USE

This guidance document should be used to explain the biosafety requirements for how to safely collect specimens from suspect Ebola patients and transport to CDC for testing. It is not intended to be a comprehensive or all-inclusive guide. Refer to the CDC and/or WVBPH website for additional information as needed.

BACKGROUND

CDC is working with the World Health Organization (WHO), the ministries of health 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. For the latest information on the outbreak, please see the 2014 Ebola Outbreak in West Africa highlights on the CDC website.

EVD is one of several known viral hemorrhagic fevers (VHF). It is a severe, often fatal disease in human and nonhuman primates. Ebola virus is spread by direct contact with the blood or body fluids (such as urine, saliva, feces, vomit and semen) of an infected person or by being exposed to objects that have been contaminated with infected blood or body fluids. The incubation period is usually 8–10 days (rarely ranging from 2 to 21 days). Patients can transmit the virus once symptoms appear and through the later stages of disease, as well as postmortem.

Clinical laboratories can safely handle specimens from these patients by strict adherence to precautions and practices specifically designed for bloodborne pathogens in the laboratory environment. However, Ebola has an apparent low infectious dose, the potential of high virus titers in the blood of ill patients, and can result in severe disease. Therefore, it is essential that laboratorians, supervisors, and other workers review laboratory safety procedures and guidelines to make sure to follow these biosafety recommendations.

Potentially infectious diagnostic specimens are routinely handled and tested in U.S. laboratories in a safe manner, by closely following the standard safety precautions below.

INITIAL CONSULTATION STEPS

1. In the event a suspect case of Ebola is identified in your area, the Division of Infectious Disease Epidemiology (DIDE) must be notified immediately. Facilities must call 304-558-5358, option 1 to speak with the epidemiologist-on-call for consult.

2. Once the patient has been determined by DIDE to be a credible case, please call the Office of Laboratory Services (OLS) Threat Preparedness Bioterrorism Response Section at 304-558-3530, extension 2301 for guidance on specimen collection, packaging, and shipping.
WHEN TO COLLECT

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. 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.

PREFERRED SPECIMENS

A minimum volume of 4mL whole blood in plastic collection tubes can be used to submit specimens for testing for Ebola virus. It is recommended to collect two tubes from each patient. Do not submit specimens in glass containers or in heparinized tubes. Whole blood preserved with EDTA is preferred but whole blood preserved with sodium polyanethol sulfonate (SPS), citrate, or with clot activator is acceptable. It is not necessary to separate and remove serum or plasma from the primary collection container. Specimens other than blood may be submitted upon consult if necessary. All specimens should be immediately stored or transported at 2-8°C or frozen on cold-packs. See Packing and Shipping Section below for transport information.

INFECTION CONTROL WHEN COLLECTING AND HANDLING SPECIMENS

All laboratorians and other healthcare personnel collecting or handling specimens must follow established standards compliant with the OSHA bloodborne pathogens standard, which includes blood and other potentially infectious materials. These standards include wearing appropriate personal protective equipment (PPE) and following all safety rules for all specimens regardless of whether they are identified as being infectious.

Recommendations for risk assessment to staff: Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible personnel to determine the potential for sprays, splashes, or aerosols generated from laboratory procedures. They should adjust, as needed, PPE requirements, practices, and safety equipment controls to protect the laboratorian’s skin, eyes, and mucous membranes.

Recommendations for specimen collection by staff: Any person collecting specimens from a patient with a case of suspected Ebola virus disease should wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth Additional PPE may be required in certain situations.

Additional Information: http://www.cdc.gov/HAI/prevent/ppe.html
PACKING AND SHIPPING SPECIMENS

Specimens should be packaged and shipped as Category A Infectious Substances (UN2814). Only certified shippers are permitted to package and ship Category A Infectious Substances. An insulated basic triple packaging system should be used which consists of a primary container (a sealable specimen bag) wrapped with absorbent material, secondary container (watertight, leak-proof), and an insulated outer shipping package. See Figure 1. Be sure to include enough cold packs to ensure maintenance of proper temperatures during overnight shipping. Packages must meet all requirements set forth in the current DOT Hazardous Materials Regulations and/or ICAO Technical Instructions. OLS will provide shipping addresses and contact information during initial consultation.

Figure 1. Example of Category A Infectious Substance Diagram (non-insulated)
TESTING AVAILABLE

At this time, the Office of Laboratory Services is not performing any testing for this virus. All specimens will be forwarded to CDC for appropriate testing. Acute infections will be confirmed using a real-time RT-PCR assay. Virus isolation may also be attempted if deemed necessary. Serologic testing for IgM and IgG antibodies will be completed for certain specimens and to monitor immune response in confirmed EVD patients.

ADDITIONAL INFORMATION

WV Ebola Information Resource Center:

http://www.dhhr.wv.gov/bph/Pages/Ebola.aspx

Division of Infectious Disease Epidemiology Ebola Information:


CDC Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease in the United States:


CONTACT INFORMATION

Office of Laboratory Services

Threat Preparedness Bioterrorism Response Section
304-558-3530 extension 2301

Microbiology Section
304-558-3530 extension 2602

Division of Infectious Disease Epidemiology

304-558-5358 extension 1