



County of Santa Cruz

HEALTH SERVICES AGENCY

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Communicable Disease Unit

PUBLIC HEALTH ALERT

To: Clinical Microbiology Laboratories in Santa Cruz County

From: Duncan C. Gillies, Director, Santa Cruz County Public Health Laboratory

Date: October 8, 2014

This Laboratory Alert is being sent to provide your facility with the most current laboratory information and guidance currently available relating to Ebola virus disease (EVD).

CURRENT SITUATION

- The 2014 Ebola epidemic is the largest in history, affecting multiple countries in West Africa. (<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html#areas>)
- A small number of cases in Lagos and Port Harcourt, Nigeria, have been associated with a man from Liberia who traveled to Lagos and died from Ebola, but the virus does not appear to have been widely spread in Nigeria.
- On 9/30/2014, the CDC confirmed the first case of Ebola to be diagnosed in the United States in a traveler from Liberia. (<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>).
- CDC and partners are taking precautions to prevent the spread of Ebola within the United States. CDC is working with other U.S. government agencies, the World Health Organization (WHO), and other domestic and international partners and has activated its Emergency Operations Center to help coordinate technical assistance and control activities with partners.
- CDC has also deployed teams of public health experts to West Africa and will continue to send experts to the affected countries.

INFORMATION

- EVD is one of numerous viral hemorrhagic fevers (VHF).
- It is a severe, often fatal disease in human and nonhuman primates.
- EVD is spread by direct contact with the blood or secretions of an infected person or exposure to objects that have been contaminated with infected secretions.
- The incubation period is usually 9 – 10 days but can range from 2 – 21 days.
- Patients can transmit the virus while symptomatic as well as postmortem.

- For the latest updates on Ebola activity, please visit:
<http://www.cdc.gov/vhf/ebola/index.html>.

Communication Regarding Suspected EVD Cases

All suspected cases of EVD must be reported immediately to both the Santa Cruz County Public Health Department's Communicable Disease Unit (during business hours call (831) 454-4114; after hours and weekends call the Health Officer on call at (831) 471-1170 and to the California Department of Public Health (CDPH).

Infection Control for Collecting and Handling Specimens

It is expected that all laboratorians and other healthcare personnel collecting or handling specimens follow established standards compliant with the OSHA bloodborne pathogens standard which encompasses blood and other potentially infectious materials. This includes wearing appropriate personal protective equipment (PPE) and adhering to engineered safeguards for all specimens regardless of whether or not they are identified as infectious.

Recommendations for specimen collection: Full face shield or goggles with N95 fitted face-piece or PAPR to cover all of the nose and mouth, gloves and fluid resistant or impermeable gowns.

Recommendations for laboratory testing: Full face shield or goggles with N95 fitted face-piece or PAPR to cover all of the nose and mouth, gloves, fluid resistant or impermeable gowns AND use of a certified class II Biosafety Cabinet (BSC) or plexiglass shield splash guard, as well as manufacturer-installed safety features for instruments.

Specimen Handling for Routine Laboratory Testing (not for Ebola Diagnosis)

Routine laboratory testing includes traditional chemistry, hematology and other laboratory testing used to support and treat patients. Precautions as described above offer appropriate protection for healthcare personnel performing laboratory testing on specimens from patients with suspected infection with Ebola virus. These precautions include both manufacturer installed safety features for instruments and the environment as well as PPE specified above. (The new interim guidance for Environmental Infection Control in Hospitals for Ebola virus recommends "given the low infectious dose, potential of high virus titers in the blood of ill patients, and disease severity, higher levels of precaution are warranted to reduce the potential risk posed by contaminated surfaces in the patient care environment." "As a precaution, selection of a disinfectant or a disinfectant product with a higher potency than what is normally required for an enveloped virus is being recommended at this time. EPA –registered hospital disinfectants with label claims against non-enveloped viruses are broadly antiviral and capable of inactivating both enveloped and non-enveloped viruses."

When used according to the manufacturer's instructions, Environmental Protection Agency (EPA)-registered disinfectants routinely used to decontaminate the laboratory environment (bench tops and surfaces) and the laboratory instrumentation are sufficient to inactivate enveloped viruses, such as influenza, hepatitis C and Ebola viruses.

Laboratory Testing

The CDC updated guidance (Interim Guidance for Specimen Collection, Transport, Testing and Submission for Patients with Suspected Infection with Ebola Virus Disease) remains unchanged and is available at: <http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>. The guidance document is also briefly summarized below:

Preferred Specimens for Ebola Testing

- A minimum of 4ml whole blood preserved with EDTA, clot activator, sodium polyanethol sulfonate (SPS), or citrate in ***plastic*** collection tubes can be submitted for EVD testing.
- Paired sera (min of 4ml whole blood collected in serum separator tubes) for IgG and IgM testing submitted in ***plastic*** tubes. *Do not open tubes to remove serum.*
- Specimens other than blood may be submitted upon approval/request from the Santa Cruz County Disease Control Unit in consult with CDPH and CDC.

Do not submit specimens to CDC in glass containers. Do not submit specimens preserved in heparin tubes.

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 the facility.

To reduce the risk of breakage or leaks, pneumatic tube systems should not be used for transporting suspected EVD specimens.

Required Forms

Please use the following links for the CDC DASH form (CDC 50.34) and Special Pathogens unit specimen collection form when specimens are going to be sent for Ebola testing. Both of these forms must be filled out on-line and are required when sending specimens. County of Santa Cruz Disease Control Unit staff has experience with these forms and will be available on site to assist in completing them.

<http://www.cdc.gov/laboratory/specimen-submission/form.html>

<http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Packaging and Shipping Clinical Specimens to CDC

Specimens collected for EVD 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 receptacle (a sealable specimen bag) wrapped with absorbent material, secondary receptacle (watertight, leak-proof), and an outer shipping package.

Specimens should be sent by an overnight courier directly to CDC.

- Specimens stored at 4°C should be sent on 1-2 cold packs.

- Frozen specimens should be sent on dry ice.

Specimens for ruling out Ebola virus infection will likely fall under Category A for shipping, defined as: infectious substances that are capable of causing permanent disability, life threatening or fatal disease to humans or animals when exposure occur. In addition, the following criteria also support classifying specimens as Category A:

- Clinical and laboratory features strongly suggestive for Ebola virus infection, or
- Direct contact with a confirmed or symptomatic case, or
- Casual contact with a confirmed or symptomatic case.

Use the attached IATA DGD 2014 for Cat A No Dry Ice fillable PDF shipping declaration when packaging specimens to be transported under Category A requirements.

There may be occasions when shipping Category B, defined as an infectious substance that does not meet the criteria for Category A is appropriate, if Ebola virus infection is not the likely cause of disease. Submitters should consult with Santa Cruz County Disease Control Unit, the Santa Cruz County Public Health Laboratory and CDPH in these situations.

The shipper must be trained and certified by the employer to package and ship in accordance with International Air Transport Association (IATA) and Federal Department of Transportation (DOT) regulations. Shippers should contact the Santa Cruz County Public Health Laboratory (831) 454-5445 for packaging and shipping assistance if they are unfamiliar with IATA regulations and training or if they require category A shipping containers.

County of Santa Cruz Public Health Laboratory staff has the experience, materials, training and certification to comply with these regulations and will be available to assist on site.

The only available courier for shipping Category A and risk group 4 agents (require Biosafety Level 4 handling, such as Ebola virus) is World Courier: (516) 354-2600 or (800) 221-6600 24/7 availability. County of Santa Cruz Public Health Laboratory has established an account with World Courier to use if needed.

Ship directly to:

Centers for Disease Control and Prevention
ATTN STAT LAB: VSPB, UNIT #70
1600 Clifton Road NE
Atlanta, GA 30333
Phone: (770) 488-7100

- Hospitals must contact the Santa Cruz County Disease Control Unit for notification and consultation for Ebola testing requests prior to sending specimens directly to CDC. The Santa Cruz County Disease Control Unit will work with CDPH to assess whether testing for Ebola virus is indicated.
- No specimens will be accepted by CDC without prior approval from the Santa Cruz County Disease Control Unit in consult with CDPH.
- Email tracking number to CDPH at cder@cdph.ca.gov and EOCEVENT246@CDC.GOV.
- Do not ship for weekend delivery unless instructed by CDC.

Diagnostic Testing for Ebola Performed at CDC

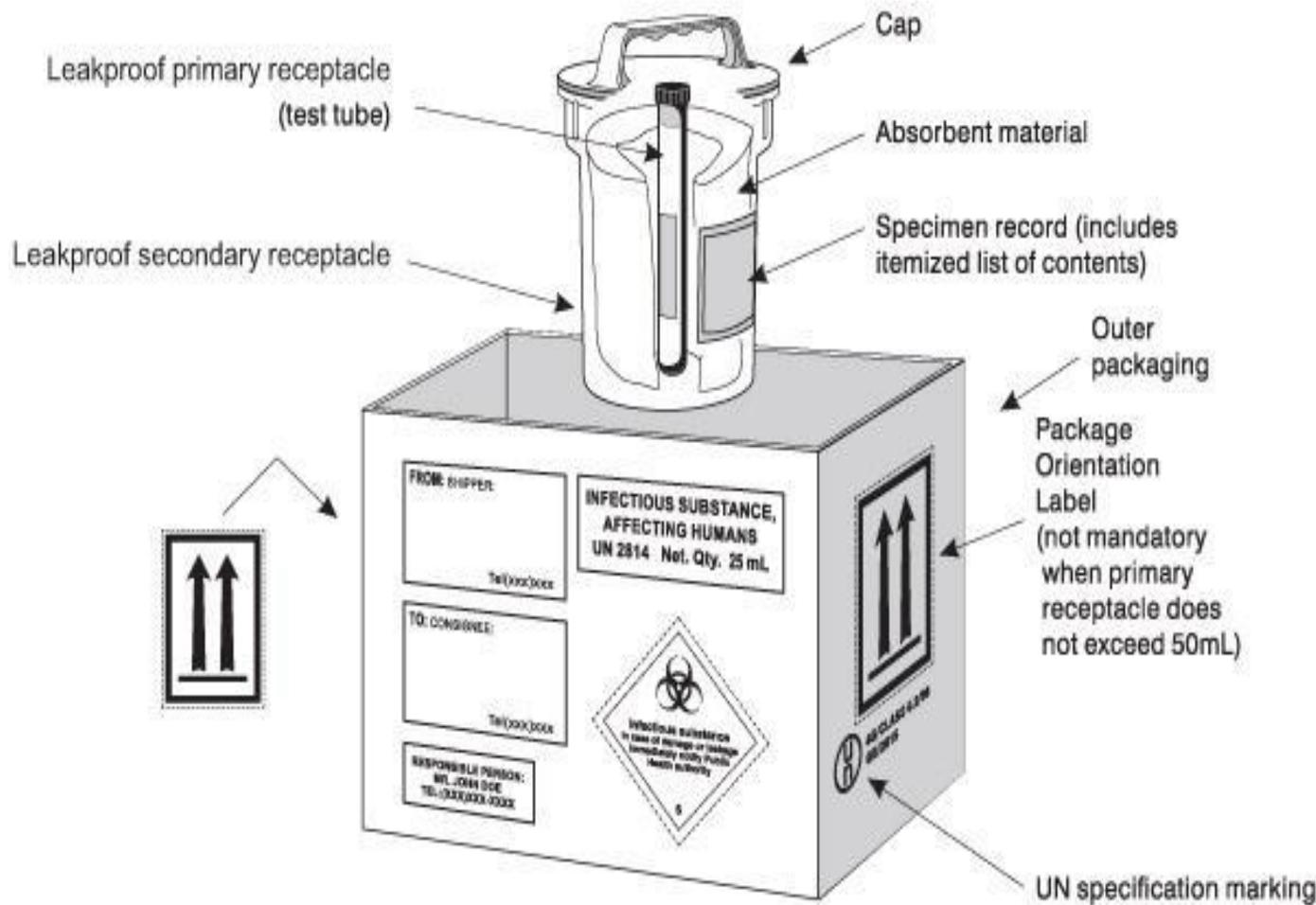
Several diagnostic tests are available for detection of EVD. Acute infections will be confirmed using a real-time RT-PCR assay in a CLIA-accredited laboratory. Virus isolation may also be attempted. Serological testing for IgM and IgG antibodies will be completed for certain specimens and to monitor the immune response in confirmed EVD patients.

Ebola Contact Information

Santa Cruz County Disease Control Unit (831) 454-4114; after hours call Health Officer on call at (831) 471-1170.

Santa Cruz County Public Health Laboratory: (831) 454-5445.

Category A Shipping Guidelines and Diagram



1. The smallest external dimension of the outer packaging must not be less than 100mm; The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95kPa.