

Appendix 6

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Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease

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Page Summary

Who this is for: Laboratory and other healthcare personnel handling and testing routine clinical specimens when concern about Ebola virus disease (EVD) has been raised by a physician.

What this is for: To provide updated guidance for management and evaluation of routine clinical specimens for differential testing and diagnoses other than EVD.

How to use: This guidance should be use as a supplement to CDC's [*Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing in the United States*](#)

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Purpose

<http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/safe-specimen-management.html> 9/25/2015

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Due to a heightened concern in the United States about Ebola, this document provides guidance for clinical laboratories on testing needed for the assessment and care of patients for which Ebola Virus Disease (EVD) is a concern, while minimizing risk to laboratory personnel.

Scope

This document updates and replaces the previously posted document: *How U.S. Laboratories Can Safely Manage Specimens from Persons Under Investigation for Ebola Virus Disease*.

Clinicians should maintain a high index of suspicion and consult their local and state health departments and CDC when ill travelers from Ebola-affected countries are identified; it is important to recognize that the likelihood of EVD even among symptomatic travelers returning from these countries is very low. In the hospital setting, where policies and procedures should be in place to safeguard health care workers, consideration of Ebola should not delay diagnostic assessments, laboratory testing, and appropriate care for other, more likely medical conditions¹. This guidance is based on input received from numerous hospital and laboratory directors, infectious disease physicians, CDC Ebola response teams, and state health officials.

Key Points

1. CDC recommends that Ebola testing be conducted only for persons who meet the criteria for persons under investigation (PUIs) for EVD: A person who has both consistent signs or symptoms and risk factors as follows:
 - Elevated body temperature or subjective fever or symptoms, including severe headache, fatigue, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage; **AND**
 - An epidemiological risk factor within the 21 days before the onset of symptoms.
2. If there is a clinical suspicion of Ebola, a determination whether a patient is, or is not a PUI should be made in consultation with public health officials as quickly as possible in order to ensure that patient care is not compromised. The period of time between when a clinical suspicion for Ebola is raised to the time a PUI determination is made can vary. Clinical laboratories, especially those in Ebola Assessment and Ebola Treatment Hospitals, should be prepared to provide a timely and minimum menu of testing to ensure that medical evaluation is not delayed for any patient; in the U.S., most of these persons will not have EVD, but have had another etiology for their illness¹. Timely identification of these other etiologies is essential to appropriate patient care.
3. Presumptive testing for Ebola virus is available at 52 IRN laboratories (<http://emergency.cdc.gov/irn/>) located throughout the United States. Hospitals should follow their state and/or local health department procedures for notifying and consulting about Ebola virus testing requests before contacting CDC.

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4. Any presumptive positive Ebola test result must be confirmed at the CDC to inform public health decisions. For guidance on confirmatory Ebola virus testing, refer to [Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing in the United States](#)
5. If a hospital chooses to use a commercial Ebola virus test, specimens should also be submitted to an LRN facility or CDC for definitive Ebola virus testing^{2,3}.
6. To minimize risk to personnel, a risk assessment must be performed by the laboratory director, safety officer, and other responsible persons to determine the potential for exposure from sprays, splashes, or aerosols generated during all laboratory processes, procedures, and activities. Risks should be mitigated by implementing engineering controls, administrative and work practice controls, and use of appropriate personal protective equipment (PPE).
7. To date, CDC considers the risk of acquiring EVD or other viral hemorrhagic diseases through laboratory testing to be low, but not zero risk. (See [Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure](#)). Some recommended measures to minimize the risk of laboratory transmission when testing patient specimens include: limiting the number of staff engaged in testing, evaluating and segregating equipment used for testing, and performing testing in a dedicated space.
8. The decision to perform testing in a hospital care laboratory using existing instrumentation, or alternatively, acquiring dedicated point of care (POC) instrumentation should be carefully evaluated. Considerations may include whether Ebola patient testing may lead to core laboratory instrumentation being removed from service, and the planning should include how to mitigate such potential outcomes.
9. The United States Occupational Safety and Health Administration (OSHA) [Bloodborne Pathogens Standard \(29 CFR 1910.1030\)](#) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) was developed to reduce the potential exposure of personnel to blood borne pathogens. All U.S. laboratories handling patient specimens are required to comply with this standard at all times; strict adherence is an initial step in providing protection to personnel.
10. U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their local and/or state health departments and CDC (770-488-7100).

Background

Ebola virus is transmitted through contact with infected blood or body fluids (e.g., urine, feces, and vomit) from symptomatic persons and with objects such as needles that have been contaminated with infected body fluids. PUIs for EVD should be managed by following appropriate precautions to prevent transmission of Ebola virus to others and contamination of the hospital environment. See [CDC's infection control guidance](#).

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In consultation with public health authorities, states are identifying hospitals which are capable of assessing persons that meet the criteria for persons under investigation (PUIs) for EVD. (see Interim Guidance for U.S. Hospital Preparedness for Patients with Possible or Confirmed Ebola Virus Disease: A Framework for a Tiered Approach and Interim Guidance for Preparing Ebola Assessment Hospitals). This document provides information that may be appropriate for all clinical laboratories. The guidance is especially important for Ebola Assessment Hospitals, which are designated facilities that are prepared to receive, isolate, and evaluate a PUI while the need for Ebola testing is assessed. If testing is warranted, these hospitals continue to provide patient care until an Ebola diagnosis can be confirmed or ruled out, and until a discharge or transfer is completed. Most PUIs will be identified through active monitoring of returned travelers, and directed to an Assessment Hospital. It is also possible that persons with unrecognized EVD will present to a Frontline healthcare facility (an acute care hospital or other emergency care setting including urgent care clinic, or critical access hospital) without prior notification; these facilities should be prepared to promptly identify and isolate these patients according to the CDC's guidance for emergency departments. Frontline healthcare facilities are not expected to provide prolonged care (> 12–24 hours) for a severely ill patient. It is important to remember that due to the potential stigma associated with EVD, patients returning from affected countries may be reluctant to disclose their travel history.

Clinical Laboratory Testing of Clinical Specimens when Ebola Virus Disease is a Concern

CDC recommends that Ebola testing be conducted only for persons who meet the criteria for PUIs and have compatible clinical syndromes. If there is a clinical suspicion of Ebola, a PUI determination and medical evaluation should be made as quickly as possible in order to ensure patient care is not compromised. Most PUIs have had other etiologies for their illness such as malaria, influenza and other respiratory illnesses, typhoid fever, and other bacterial or viral infections¹. Clinical laboratories should be prepared to provide sufficient testing to ensure patient care is not compromised while patients undergo assessment. The clinician should determine specific testing according to the patient presentation and travel history.

- U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their relevant local and state public health authorities. In joint consultation with CDC (770-488-7100), these agencies will assist in determining whether criteria for a PUI are met and appropriate measures for monitoring the patient will be determined in consultation with the attending health care provider.
- The decision to test for Ebola should not be made without consultation with public health officials. CDC should be notified immediately if a decision is made to test. CDC considers a single diagnostic test used in the absence of a confirmatory diagnostic algorithm insufficient for public

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health decision-making. If a hospital chooses to use a commercial Ebola virus test, specimens should also be submitted concurrently to an LRN facility or CDC for definitive Ebola virus testing^{2,3}.

CDC and state health department laboratories are available to assist hospitals in the selection, interpretation, and sourcing of additional laboratory tests needed to manage PUIs.

Although laboratory testing for patients for which there is a clinical suspicion of EVD, or a patient with confirmed EVD will likely vary, assessment and treatment facilities should consider how they might safely perform the following laboratory tests (if indicated) or, if unable to safely perform specific tests, identify alternative approaches to patient management (e.g. empiric treatments, alternative diagnostic strategies):

- A complete blood count (CBC), including differential, and platelet count
- Sodium, potassium, chloride, bicarbonate, calcium, blood urea nitrogen, creatinine, and glucose concentrations
- Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin
- Coagulation testing, specifically prothrombin time (PT), expressed as international normalized ratio (INR)
- Blood culture for bacterial pathogens (for information on automated or manual blood cultures, see "Laboratory Equipment" section of this document).
- Malaria testing (smear or rapid tests)

Note: While not all facilities may have the capacity to definitively diagnose malaria, any facility capable of performing a complete blood count should be able to review the blood smear to provide an initial presumptive diagnosis regarding the presence or absence of malaria parasites. Facilities that do not have the capacity to perform definitive malaria testing on site should contact their state health department to facilitate the definitive diagnosis; CDC and the state health departments can assist with providing a diagnosis of malaria in a timely fashion. More information can be found at [CDC's malaria website \(http://www.cdc.gov/malaria/new_info/2014/malaria_ebola.htm\)](http://www.cdc.gov/malaria/new_info/2014/malaria_ebola.htm).

- Influenza virus testing⁴
- Respiratory Syncytial Virus (RSV) and other respiratory virus testing⁴
- Rapid group A strep testing on throat swabs
- Urinalysis

Ebola treatment hospitals should be able to provide the above tests, as well as additional testing required to manage a patient with EVD.

* Negative results when using point of care rapid diagnostics on respiratory specimens from older children and adults do not exclude infection because of their lower sensitivity compared with molecular assays. However, rapid RSV antigen testing in smaller children has been shown to be effective.

+ Molecular assays for numerous respiratory viruses are often available as multiplex assays and may aid in diagnosis of common respiratory infections

Compliance with Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard

All laboratory personnel who collect, handle, or test human specimens must comply with the United States Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR § 1910.1030) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)⁴. Performance of site-specific risk assessments should consider the path of the sample throughout the laboratory, including all work processes, procedures and tasks to identify potential exposure risks and to mitigate these risks by implementing engineering controls, administrative controls (including work practices), and appropriate PPE. This is a well-recognized standard that was developed to protect laboratory personnel from exposure. U.S. hospitals have safely managed patients with viral hemorrhagic fevers (VHF), even when the diagnosis of VHF was only made after patient discharge^{5, 6, 7, 8, 9}.

Risk Assessment and Mitigation

Laboratory risk assessment is a process used to identify: 1) the hazards associated with a known or potentially infectious agent and the activities being conducted with them; 2) the likelihood of a person's exposure to that agent or material; and 3) the consequences of such an exposure to personnel or equipment (e.g., a laboratory acquired infection or the need to take a machine off-line for extended periods)¹⁰.

A risk assessment of all processes, procedures, and activities in the laboratory must be performed to determine the potential for exposure to the specimen through generation of aerosols, sprays, splashes, or spills. Based on the assessment, a plan to mitigate the identified risks should be implemented using engineering controls, administrative controls (including work practices), and use of appropriate PPE (see section below).

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CDC is aware of hospitals that have safely used instruments in their core laboratories to test specimens when EVD is a concern, however, following risk assessment, laboratories may choose to use point of care testing or other alternative procedures to minimize disruption to the core laboratory and minimize risk to laboratory personnel.

Some items for clinical laboratories to focus on during their site-specific risk assessment should include:

- Specimen management and transport, including the path of the sample through the laboratory particularly avoiding transport through high-traffic areas or pneumatic tube systems
- Equipment hazards (e.g., the potential for creating aerosols, sprays, splashes of the specimen when performing testing and using equipment)
- Biological Safety Cabinet certification, operation and safe work practices
- Decontamination procedures, including spill response, and methods for decontamination of equipment
- Infectious waste management
- Laboratory design
 - Laboratories that have open room designs should also consider the risk of exposure to workers present in the area but that are not directly involved with testing of a particular sample
 - Some recommended measures to minimize the risk of laboratory transmission when testing patient specimens include: limiting the number of staff engaged in testing, evaluating and segregating equipment used for testing, and performing testing in a dedicated space
- Engineering controls and safety equipment
- Laboratory communication protocols
- Laboratory entry and exit procedures
- PPE selection and use
- Facility ventilation and filtration
- Employee medical surveillance and exposure response
- Safe sharps handling
- Personnel safety training and competencies

Additional information on conducting a risk assessment can be found in the CLSI Document M29-A4 "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition"¹¹.

PPE

Laboratory workers may use a variety of PPE to prevent transmission of infectious pathogens to staff during the collection, processing, and testing of patient specimens.

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Appropriate PPE should be based on a risk assessment of the situation, the work being done, as well as the capabilities of the user. Too much PPE can be just as hazardous as too little, resulting in limited visibility, mobility and potential heat stress issues; ill-fitting PPE can cause distraction and reduced sensory perception.

- PPE must be provided to the employees free of cost by the employer as required by the OSHA bloodborne pathogens standard
- PPE must prevent blood or other potentially infectious materials from passing through and reaching the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes
- Each laboratory should work with its institution's infection control and laboratory safety departments to ensure laboratory personnel safety
- PPE selected must not be compromised by chemicals used in laboratory procedures
- Consideration may be given to using a buddy system to ensure that safe donning and doffing procedures are followed
- Consultation with CDC is available to assist laboratories with selecting appropriate PPE (770-488-7100)

Laboratory staff **must** be trained in the proper donning and doffing of PPE. The proper donning and doffing of PPE is critical for worker safety, and strict adherence to protocols is essential.

1. PPE to be used during specimen collection

Healthcare personnel including laboratory staff that collect patient specimens from a confirmed patient or a PUI exhibiting obvious bleeding, vomiting or diarrhea or who is clinically unstable and/or will require invasive or aerosol-generating procedures should wear the PPE described in the [hospital guidance](#).

Healthcare personnel caring for a PUI who is clinically stable and does not have bleeding, vomiting or diarrhea can wear the alternate ensemble described in the [ED guidance](#) and on the [Assessment hospital page](#).

2. PPE to be used when performing laboratory testing

It is strongly recommended to work inside a certified Class I or certified Class II biosafety cabinet (BSC) when handling or manipulating patient specimens. When all proper procedures are strictly followed, a Class I BSC will protect the worker, and a Class II BSC will protect the worker and the sample from contamination.

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When manipulating clinical specimens when EVD is a concern, staff should use a combination of engineering controls, work practices and PPE to protect their mouth, nose, eyes and bare skin from coming into contact with patient specimens, including:

- Proper use of a certified Class I or Class II biosafety cabinet AND
 - Disposable gloves
 - Solid-front wrap around gowns that are fluid-resistant or fluid-impermeable
 - Surgical mask to cover all of nose and mouth
 - Eye protection such as a full face shield or goggles/safety glasses with side shields
- Manufacturer-installed safety features for instruments that reduce the likelihood of exposure

Clinical laboratories may decide to include additional PPE that may necessitate additional requirements, (i.e., staff must be fit tested and medically cleared to wear an N-95 respirator). The facility must provide additional training and have staff practice these procedures using the PPE before using them in the workplace. Using unfamiliar equipment or PPE without sufficient training and practice may lead to inadvertent breaches in safe practices and may increase a person's risk of contaminating his or her clothes, mouth, or eyes, especially when removing PPE. Consistency of these planned procedures is essential to protect personnel.

Laboratory Equipment

Some laboratory equipment used for routine testing may not be appropriate for testing specimens from PUIs because: (a) The equipment may generate an aerosol or (b) recommended disinfectants to inactivate Ebola virus may affect the performance of the instrument or void the manufacturer's warranty. CDC and FDA are currently working with manufacturers to assess and resolve the safety issues of laboratory equipment for testing specimens from PUIs.

Some considerations regarding use of laboratory equipment are:

- Laboratories should consider using equipment with closed tube systems in which the specimen container (e.g., vacutainer tube) stays capped during testing.
- Centrifugation can pose a risk of aerosolization. If centrifugation is necessary for testing, centrifuges should have sealed buckets or sealed rotors. After centrifugation, the sealed buckets or rotors should be opened inside a biosafety cabinet.
- Automated blood culture instruments have been used in the core lab after careful evaluation of the risk assessment, ensuring that the outside of the bottle is cleaned with a disinfectant labeled for non-enveloped viruses before putting it in the instrument, and ensuring that staff who handle the bottles are wearing gloves. Alternatively, benchtop blood culture instruments are available, or blood culture bottles may be incubated manually in separate incubators and monitored for turbidity as an indication of growth. Subculture of any positive blood culture

bottles should be performed within a biosafety cabinet in a separate laboratory area segregated from the core lab, preferably by using commercially available "venting unit" devices that sheath the needle during extraction of blood from the bottle to prevent needlesticks.

Point of Care (POC) Testing

If POC instruments are used, the clinical laboratory director must ensure they meet their intended use, as approved by the Food and Drug Administration (FDA). This information is specified in the "Intended Use" section of the Product Insert.

1. If the intended use of the instrument **excludes testing of critically ill patients**:
 - a. Then use of the POC instrument for testing critically ill patients is considered off-label use. Before reporting patient results, the laboratory must establish the performance specifications for accuracy, precision, sensitivity, specificity, reportable range of test results, reference intervals and any other performance characteristic required for test performance in a critically ill patient population. Validation must be performed **prior to use** for testing patient specimens.
 - b. In addition to establishing performance specifications for the specific use of the test, the laboratory must also comply with the relevant provisions of the CLIA regulations (<http://www.cdc.gov/clia/Regulatory/default.aspx>) (42 CFR Part 493) and document performance of quality control and proficiency testing, and that relevant laboratory education/experience qualifications are met by laboratory directors and testing personnel.
2. It is recommended to place point of care (POC) instruments within an enclosure or behind a barrier to contain any splashes or potential aerosols that may be generated.
 - a. If placed inside a BSC, ensure that appropriate airflow is not compromised by overloading the inside of the BSC, or by blocking the front or back air intake grilles. Consideration should be given to verifying inward airflow at the front opening of the BSC while instruments are operating.
 - b. When a BSC is not available or possible, then additional safety equipment should be used to contain any splashes or potential aerosols generated. This could be a small benchtop BSC, a PCR workstation (e.g., "dead air box"), a plexiglass splash shield, or other physical containment device.
3. If clinical laboratories decide to add POC instruments specifically for testing specimens from PUIs, staff should be trained and should practice these procedures in advance while wearing the appropriate PPE.

NOTE: See Appendix 1 for questions to consider when selecting instruments and for a list of instruments identified by institutions that have cared for patients with EVD. This list does not indicate an endorsement of the product nor should this be considered a complete list of all test instruments that may be acceptable.

Transporting Patient Specimens within the Facility

- Primary specimen containers should only be handled with proper PPE, including gloves.
- Before removing patient specimens from the site of care, it is advisable to plan the route of the sample from the bedside to the laboratory or testing area in order to avoid high-traffic areas.
- Before removing patient specimens from the site of care, the outside of the specimen containers should be decontaminated with an approved disinfectant as described in [Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus](#).

Note: Recommended disinfectants are those known to kill non-enveloped viruses and can be found in List L of [Disinfectants for Use Against the Ebola Virus \(http://www.epa.gov/oppad001/list-l-ebola-virus.html\)](http://www.epa.gov/oppad001/list-l-ebola-virus.html). This list of registered disinfectants meets the CDC's criteria for use against the Ebola virus on hard, non-porous surfaces.

- In compliance with 29 CFR §1910.1030, specimens should be placed in a durable, leak-proof secondary container.
- After placement in a secondary container, specimens should be hand-carried to the laboratory. DO NOT use any pneumatic tube system (automated or vacuum specimen delivery system) for transporting specimens.

Transporting Specimens from PUIs to Sites Outside of the Facility

Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT). Specimens from PUIs or patients confirmed to have Ebola virus infection should be packaged and shipped as Category A infectious substances. For guidance on packaging and shipping, refer to [Guidance for Collection, Transport and Submission of Samples for Ebola Virus Testing in the United States](#) and the DOT [Hazardous Materials Regulations \(HMR\) \(http://www.ecfr.gov/cgi-bin/text-idx?SID=dde5869266c7e8f4c8b22f63ee53c2db&tp=/ecfrbrowse/Title49/49C/subchapC.tpl\)](http://www.ecfr.gov/cgi-bin/text-idx?SID=dde5869266c7e8f4c8b22f63ee53c2db&tp=/ecfrbrowse/Title49/49C/subchapC.tpl).

Decontamination

As noted above, recommended disinfectants are those known to kill non-enveloped viruses and can be found in List L of [Disinfectants for Use Against the Ebola Virus \(http://www.epa.gov/oppad001/list-l-ebola-virus.html\)](http://www.epa.gov/oppad001/list-l-ebola-virus.html). These disinfectants should be used for cleaning and disinfecting of testing surfaces, handling spills, and cleaning and decontamination of laboratory equipment.

1. Cleaning and Disinfecting of Testing Surfaces

See the [Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus](#) for recommendations regarding the cleaning and disinfection of patient care area surfaces including the management of blood and body fluid spills. These recommendations also apply to cleaning and disinfecting in a laboratory where specimens are being processed from PUIs or patients with confirmed EVD.

2. Handling Spills

The basic principles for blood or body substance spill management are outlined in the OSHA Bloodborne Pathogens Standard⁴. CDC guidelines recommend removal of bulk spill material, cleaning the site, and then disinfecting the site with a disinfectant effective against the potential agent. Points to consider are:

- Limit the number of personnel involved in the clean-up
- Develop protocols for safely remediating spills containing broken glass
- Before any spill clean-up is initiated, ensure staff are trained and wear recommended PPE to protect against direct skin and mucous membrane exposure of cleaning chemicals, contamination, and splashes, including, at a minimum:
 - Disposable gloves
 - Solid-front wrap-around gowns that are fluid-resistant or fluid-impermeable
 - N-95 rated respirator (staff must be fit tested and medically cleared), or surgical mask to cover all of nose and mouth
 - Eye protection such as a full face shield or goggles/safety glasses with side shields
- All materials used for cleanup must be treated as infectious and disposed of in a biohazard waste container

3. Decontamination of Equipment

- For decontamination of laboratory instruments and equipment, use of an EPA-registered hospital disinfectant with label claims for non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, and poliovirus) for cleaning and decontaminating surfaces or objects is recommended.
- The laboratory should consult in advance with the manufacturer to ensure the most appropriate selection of such disinfectants and their use on the equipment. Some disinfectants can be detrimental (i.e., corrosive) to the instrument's surface.
- The Operator's Manual should be consulted to see what the manufacturer recommends when taking the equipment out of commission or preparing for maintenance or repairs. CDC is aware of the challenges laboratory workers and their institutions face when these instructions are not

provided in the manuals and is in consultation with FDA and the manufacturers to resolve these issues.

If an instrument is contaminated during use and there is no procedure for decontamination of the internal compartments without compromising the instrument operability, then the instrument may need to be removed from service as there are no other validated methods for ensuring that any remaining viral particles are no longer viable.

Laboratory Waste Management

- Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT) and, when transported in commerce, is regulated by DOT's Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Any item transported in commerce that is contaminated or suspected of being contaminated with a Category A infectious substance must be packaged and transported in accordance with the HMR. This includes untreated patient specimens from PUIs, medical equipment, sharps, linens, and used health care products (such as soiled absorbent pads or dressings, kidney-shaped emesis pans, portable toilets, used PPE (e.g. gowns, masks, gloves, goggles, face shields, respirators, booties, etc.), or byproducts of cleaning.
- For solid waste generated during laboratory testing, OSHA Bloodborne Pathogen Standard (29 CFR § 1910.1030) specifies that:
 1. Potentially infectious materials shall be placed in a primary container which prevents leakage during collection, handling, processing, storage, transport, or shipping
 2. The primary container shall be placed within a second container which is puncture-resistant and prevents leakage during handling, processing, storage, transport, or shipping
- If available and proper procedures are strictly adhered to, steam sterilization (autoclaving) as a waste treatment process will inactivate the virus. If used, there are numerous requirements that must be followed for the safe and effective operation of autoclaves. After waste from PUIs or confirmed for EVD has been autoclaved, it can be combined with the laboratory waste stream as regulated (non-class A) medical waste.
- If an autoclave is not available in the facility, other arrangements must be made with a licensed external waste contractor to transport, treat, and dispose of the waste. Permits are required and other restrictions may apply based on state or local regulations.
- The regulations associated with disposal of biohazards are complex, and vary by state and local requirements. Check with your state's medical waste management program for more guidance on solid and liquid waste.
- Waste generated during the handling and testing of specimens from PUIs or patients with confirmed EVD is not subject to Federal Select Agent regulations (42 CFR § 73.3(d)(1)), **UNLESS viable** Ebola virus is **intentionally** isolated from that waste.

Considerations of Select Agent Concerns

As outlined in the [Interim Guidance Regarding Compliance with Select Agent Regulations for Laboratories Handling Patient Specimens that are Known or Suspected to Contain Ebola Virus¹³](#), specimens from PUIs are not select agents. Patient specimens that have been proven to contain infectious Ebola virus by viral isolation may be classified as select agents. CDC will work with the facility to determine proper reporting and handling of specimens from these patients.

Appendix 1: Laboratory Equipment

A. Selecting Laboratory Equipment

Clinical laboratories need to be prepared to test clinical specimens to support patient care when EVD is a concern. Below are suggested questions to facilitate decision making regarding selecting or using laboratory instruments to test these specimens.

1. Is the specimen contained within a closed chamber and does it remain contained within a closed chamber throughout testing?
2. Even if the specimen remains contained within a closed chamber, has an evaluation been performed to determine if the manufacturer's safety features are effective in protecting instrument operators from exposure to aerosols or sprays from patient specimens?
3. If the specimen container is opened during testing, have the potential routes of exposure to the operator during sample preparation and testing been identified, and have engineering controls and/or PPE been implemented?
4. Does the instrument employ wash and decontamination solutions in its test system to adequately inactivate bloodborne pathogens, including Ebola virus?
5. Does the manufacturer provide hazard warnings and PPE guidance with their troubleshooting instructions?
6. Have the potential exposure routes associated with handling and transport of the instrument's on-board waste collection been identified and PPE evaluated and implemented?
7. How close is the instrument to other operations in the laboratory?
8. Are there instructions for cleaning and decontaminating the instrument, including track systems?
9. Do recommended disinfectants meet the EPA requirements for inactivating non-enveloped viruses?

For POC instruments under consideration for use in isolation areas, refer to questions 1-8 above in addition to the following:

1. What are the size and operational requirements of the entire test system? Consider the instrument’s environmental operating requirements including temperature and humidity, and proper reagent storage (e.g., refrigerator or freezer).
2. Does the “Intended Use” statement of the device labeling allow for testing critically ill patients? (FDA has not approved the use of some devices for testing critically ill patients.)
3. If the instrument is placed inside a BSC, will it compromise the proper BSC operation and protective functions (e.g., air flow)?
4. Is the instrument difficult to operate while wearing required PPE?
5. Is the instrument easily decontaminated?

Laboratory equipment used by some laboratories testing Ebola virus-positive specimens

Some U.S. hospitals have treated patients who tested positive for Ebola virus. The following table lists instruments these hospitals selected to conduct clinical laboratory testing on these patients. The conditions under which hospital laboratories used these instruments varied; some chose to place these instruments in a biosafety cabinet, whereas others operated them under BSL 2 or BSL 3 conditions^{14, 15}.

Note: POC testing instruments placed inside a biosafety cabinet (BSC) may interfere with the BSC airflow and compromise staff safety. Care should be taken not to overload the BSC with equipment, and consideration should be given to verifying inward airflow at the front opening of the BSC while instruments inside are operating.

The following is a list generated from **institutions other than CDC**. This list is for information only and is **not intended as a CDC endorsement of these instruments or practices**, nor should this be considered a complete list of all test instruments that may be acceptable.

Clinical Chemistry

Manufacturer	Device
Beckman Coulter	DxC88oi
Abbott Laboratories	ISTAT
Abaxis	Piccolo Xpress

Coagulation

Manufacturer	Device

Manufacturer	Device
ITC	Hemochron Signature Elite
F. Hoffman-La Roche	CoaguChek

Hematology

Manufacturer	Device
Sysmex	XN 9000 pocH 100i

Microbiology

Test	Method
Blood Culture	Plastic bottles/manual monitoring method
Malaria	Smear fixed in methanol for 15 mins Alere BinaxNOW
Ebola virus testing	Biofire FilmArray*

*If used, this test result is presumptive only and must be confirmed at CDC.

References

1. Karwowski et al. Clinical Inquiries Regarding Ebola Virus Disease Received by CDC – United States, July 9–November 15, 2014. MMWR Morb Mortal Wkly Rep. December 5, 2014. 63(Early Release);1-5) Available at URL:
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National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (</ncezid/dw-index.html>)

Division of Healthcare Quality Promotion (DHQP) (</ncezid/dhqp/index.html>)

Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 1 of 9



Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing

Updated: January 30, 2015

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Purpose



Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 2 of 9

Guidance for Collection, Transport, and Submission of Specimens for Ebola Virus Testing in the United States

POST-TESTING & CONSULTATION
Patients should follow local procedures for local health department procedures for notification and consultation for testing requirements.

WHEN SPECIMENS SHOULD BE COLLECTED FOR EBOLA TESTING
Ebola virus is detected in blood only after the onset of symptoms, usually fever. It may remain at a detectable concentration for 10 days in most laboratory tests. Thus, it is generally detectable by real-time PCR from 3 to 10 days after being first symptomatic.
Ideally, specimens should be taken when a symptomatic patient arrives at a healthcare facility and is suspected of having exposure to Ebola. However, if the onset of symptoms is 3-4 days, a later specimen may be needed to completely rule out Ebola virus, if the test specimen tests negative.

PREFERRED SPECIMENS FOR EBOLA TESTING
A minimum volume of 4mL of whole blood (stored until 2009 is preferred) is preferred and should be stored at room temperature. Serum, plasma, or whole blood can be used for Ebola testing.
Specimens should be shipped at 2-8°C (refrigerated). Do not submit specimens in glass containers. Use a leak-proof container for specimens processed in pipette tubes.
Specimens other than blood may be submitted after consult with CDC.
2-8°C

DIAGNOSTIC TESTING FOR EBOLA VIRUS
Real-time PCR testing for Ebola virus is available at more than 100 Laboratory Reference Panels (LRP) laboratories located throughout the United States. LRP laboratories are currently using an FDA-approved Emergency Use Authorization assay to detect the Ebola virus (genetic Zaire ebolavirus). Serological test (antibody) assays are considered presumptive evidence for Ebola Zaire Virus by real-time PCR and should be submitted to CDC for additional evaluation.

TRANSPORTING SPECIMENS WITHIN THE HOSPITAL/INSTITUTION
In compliance with 29 CFR 1910.103, specimens should be placed in a solution, additional secondary container be transported within a facility, or within the risk of leakage or spill, do not use any pneumatic tube system for transporting suspected Ebola virus specimens.

PACKAGING & SHIPPING CLINICAL SPECIMENS
Specimens collected for Ebola virus testing should be packaged and shipped without attempting to open collection tubes or vials or attempt to open.
Specimens for transport should be packaged following the biohazard packaging system that consists of a primary leak-proof container wrapped with absorbent material, secondary container, leak-proof, and an outer shipping package.
State and federal regulatory and state or local health requirements should be consulted before shipping. Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT). Specimens with presumptive serological results from patients confirmed to have Ebola virus disease should be packaged and shipped as Category A infectious substances.
Packaging and shipping Category A infectious substances must be performed by people trained and certified in compliance with DOT or International Air Transport Association (IATA) regulations and shipping rules. For guidance on packaging and shipping rules, visit the Department of Transportation's "Packaging and Submission of Specimens for Ebola Virus Testing in the United States" and the DOT Hazardous Materials Regulations Center at 1-800-431-4922.

Guidance for Collection, Transport, and Submission of Specimens for Ebola Virus Testing in the United States (PDF - 1 page)

To provide guidance for laboratory workers on collecting, transporting and submitting specimens for Ebola virus testing.

Scope

Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 3 of 9

This guidance document replaces the previously posted document: *"Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation (PUIs) for Ebola Virus Disease (EVD) in the United States."*

This document complements the updated CDC *"Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease"* which provides guidance for clinical laboratories on testing needed for assessment and care of patients for whom Ebola Virus Disease (EVD) may be a concern, while minimizing risk to laboratory personnel.

This guidance is based on input received from numerous hospital and laboratory directors, infectious disease physicians, CDC Ebola response teams, and state health officials.

Key Points

1. CDC recommends that Ebola testing be conducted only for persons who meet the criteria for persons under investigation (PUIs) for EVD. A PUI is a person who has both consistent signs and/or symptoms, including:
 - Elevated body temperature or subjective fever or symptoms, including severe headache, fatigue, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage, AND
 - An epidemiological risk factor within the 21 days preceding the onset of symptoms.
2. U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their local and/or state public health authorities. These agencies will work with CDC to determine whether a patient is or is not a PUI, and whether testing is indicated. Patient status should be determined as quickly as possible in order to ensure that patient care is not compromised.
3. Presumptive testing for Ebola virus is available at over 50 LRN laboratories (<http://emergency.cdc.gov/lrn/>) located throughout the United States. Any presumptive positive Ebola test result must be confirmed at the CDC to inform public health decisions.
4. If it is determined that testing for Ebola virus is indicated, at least 4 mL of whole blood collected in a plastic tube preserved with EDTA is the preferred sample for testing. Specimens should be shipped with refrigerant to maintain 2°–8°C to the designated LRN laboratory.
5. If the PUI symptoms have been present for <3 days, a second sample collected 72 hours after onset of symptoms may be required to definitively rule out Ebola.
6. To minimize risk to personnel, a site-specific risk assessment must be performed by the laboratory director, safety officer, and other responsible persons prior to receiving specimens in order to determine the potential for exposure from sprays, splashes, or aerosols generated during all laboratory processes, procedures, and activities. Risks should be mitigated by implementing engineering controls, administrative and work practice controls, and use of appropriate personal protective equipment (PPE).

7. Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT) and transport of samples from PUIs or patients confirmed or suspected of having EVD is regulated by DOT's Hazardous Materials Regulations (HMR) 49 CFR 171-180 (<http://www.ecfr.gov/cgi-bin/text-idx?SID=2a97f2935677211e1785ac643163d2a9&node=49:2.1.1.3.10.5.25.33&rgn=div8>). Specimens for shipment should be packaged following the basic triple packaging system consisting of (1) a primary container (a sealable specimen container) wrapped with absorbent material, (2) a secondary container (watertight, leak-proof), and (3) an outer shipping package.
8. The United States Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) was developed to reduce the potential exposure of personnel to bloodborne pathogens. All U.S. laboratories handling patient specimens are required to comply with this standard at all times; strict adherence is an initial step in providing protection to personnel.

Background

Ebola virus can cause a severe, often fatal disease in humans and nonhuman primates. It is transmitted through contact with infected blood or body fluids (e.g., urine, stool, and vomit) and with objects such as needles that have been contaminated with infected body fluids. The incubation period is usually 8–10 days (ranging from 2 to 21 days). Patients can transmit Ebola virus once symptoms appear and through the later stages of disease, as well as postmortem. PUIs should be managed by following appropriate precautions to prevent transmission of Ebola virus to others and the hospital environment; for guidance on infection control, see CDC infection control guidance.

Diagnosing Ebola in a person who has been infected for only a few days may be complicated. The early symptoms of Ebola infection are difficult to distinguish from other, more common infectious diseases such as malaria, influenza, and typhoid fever. Ebola virus is detected in blood only after onset of symptoms, most notably fever, which accompany the rise in circulating virus; however, it may take up to 3 days after symptoms begin for the virus to reach detectable levels.

CDC recommends that Ebola testing be conducted only for persons who meet the criteria for persons under investigation (PUIs) for Ebola virus disease. Presumptive Ebola testing is available at over 50 LRN laboratories and confirmatory Ebola testing is available at the CDC. U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their local and state public health authorities before contacting CDC. In joint consultation with CDC (770-488-7100), these agencies will assist in determining whether testing is indicated. **No specimens will be accepted by CDC laboratories without prior consultation with CDC.**

Collecting Specimens for Ebola Testing

- Specimens should be obtained when a patient meets the criteria for person under investigation (PUI) including patients with clinical signs, symptoms, and epidemiologic risk factors for Ebola virus disease. If the first specimen is obtained 1-3 days after the onset of symptoms and tests negative and the patient remains symptomatic without another diagnosis, a later specimen may be needed to rule-out Ebola virus infection.
- Staff who collect specimens from PUIs should wear appropriate PPE and should refer to [Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus in U.S. Hospitals, Including Procedures for Putting On \(Donning\) and Removing \(Doffing\)](#).
- For adults, a minimum volume of 4 mL whole blood is preferable. For pediatric samples, a minimum of 1 mL whole blood should be collected in pediatric-sized collection tubes. Blood must be collected in **plastic** collection tubes. Do not transport or ship specimens in glass containers or in heparinized tubes.
- Whole blood preserved with EDTA is preferred, but whole blood preserved with sodium polyanethol sulfonate, citrate or with clot activator is also acceptable.
- Do not separate and remove serum or plasma from the primary collection container.
- Specimens should be packaged and transported at 2°-8°C with cold-packs to the final testing destination.
- Specimens other than blood may be submitted after consultation with CDC by calling the EOC at 770-488-7100.

Storing Clinical Specimens for Ebola Testing

If necessary, short-term storage of specimens before shipping should be at 4°C or frozen.

Diagnostic Testing for Ebola Virus

Real-time PCR testing for Ebola virus is available at over 50 LRN laboratories located throughout the United States. LRN laboratories are currently using an FDA approved Emergency Use Only (EUA) assay to detect the Ebola (Zaire species) virus. Samples that test positive using this assay are considered presumptive positive for Ebola Zaire RNA by real time RT-PCR and should be submitted to CDC for additional evaluation.

Transporting Specimens within the Facility

- PPE to be worn during transport within the facility should be determined by a site-specific risk assessment, and may vary among facilities. Recommendations for PPE include disposable fluid-resistant closed lab coat, disposable gloves, covered legs and closed-toed shoes.

Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 6 of 9

- Before removing patient specimens from the site of care, it is advisable to plan the route of the sample from the patient area to the location where it will be packed for shipping in order to avoid high traffic areas.
- Before removing patient specimens from the site of care, the outside of the specimen containers should be decontaminated with an approved disinfectant as described in [Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus](#).

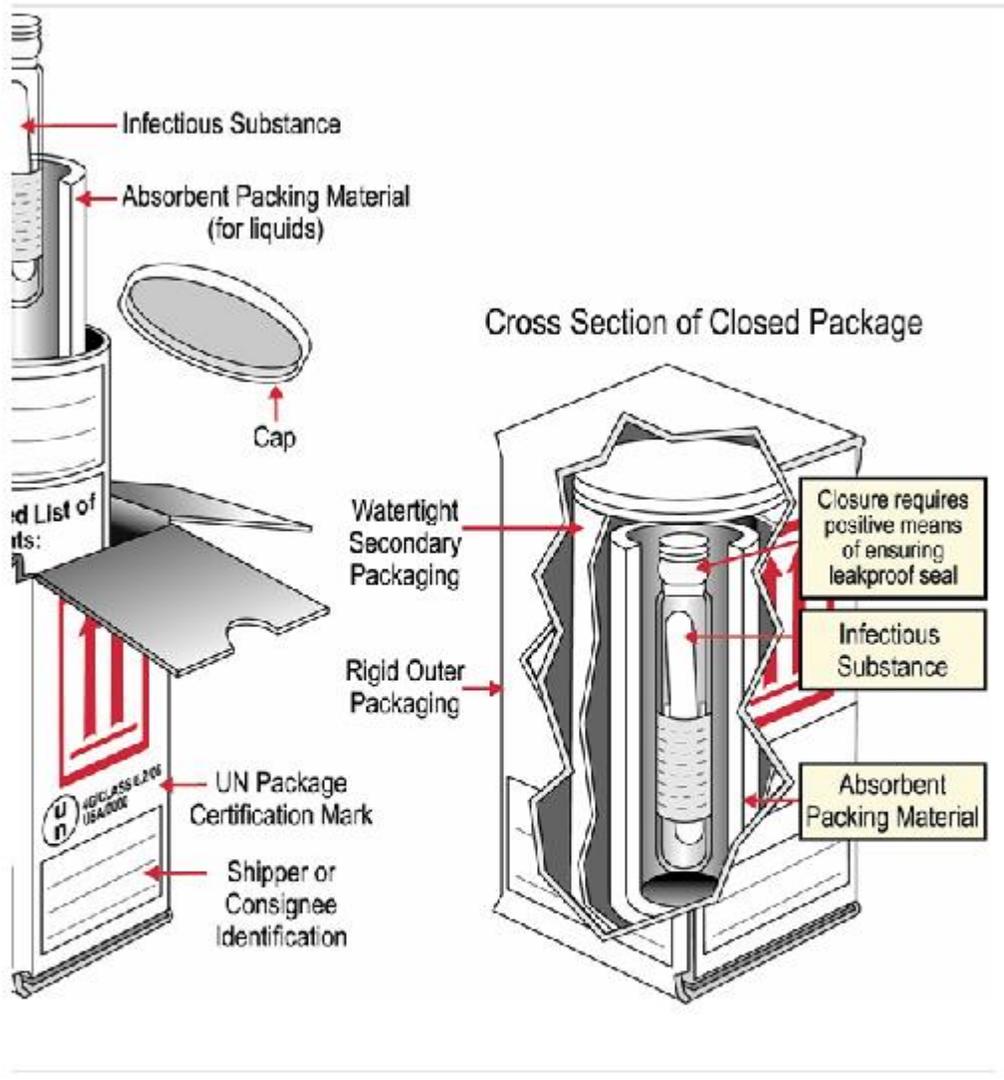
Note: Recommended disinfectants are those known to kill non-enveloped viruses and can be found in List L of EPA's [Disinfectants for Use Against the Ebola Virus](#) (<http://www.epa.gov/oppad001/list-l-ebola-virus.html>). This list of registered disinfectants meets the CDC's criteria for use against the Ebola virus on hard, non-porous surfaces.

- In compliance with OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030 (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)), specimens should be placed in a durable, leak-proof secondary container.
- After placing in a secondary container, specimens should be hand-carried to the laboratory or packing area. DO NOT use any pneumatic tube system (automated or vacuum specimen delivery system) for transporting specimens.

Transporting Specimens for Ebola Testing to Sites Outside the Facility

- Samples from patients that are suspected of or confirmed to have Ebola virus infection should be packaged and shipped as Category A infectious substances in accordance with the DOT's [Hazardous Materials Regulations \(HMR\) 49 CFR 171-180](#) (<http://www.ecfr.gov/cgi-bin/text-idx?SID=6094f4c86cef1403550ec3f80babfb85&tpl=/ecfrbrowse/Title49/49C/subchapC.tpl>).
- All persons packing and shipping infectious substances must be trained and certified in compliance with DOT or the [International Air Transport Association](#) (<http://www.iata.org/Pages/default.aspx>) (IATA) requirements every two years.
- Specimens collected for Ebola virus testing should be packed and shipped without attempting to open collection tubes or aliquot specimens. Opening the tubes destroys the vacuum seal and thus increases the risk of leakage during transport.
- Specimens for shipment should be packaged following the [basic triple packaging system](#), which consists of (1) a primary container (a sealable specimen container) wrapped with absorbent material, (2) a secondary container (watertight, leak-proof), and (3) an outer shipping package. For questions about (packaging) transportation regulations, contact the U.S. DOT Hazardous Materials Information Center at 1-800-467-4922.

Packing and Shipping Clinical Specimens for Confirmation at CDC



The following steps should be followed by persons certified to ship infectious substances.

1. Because guidelines may vary state to state, contact your state and/or local health department prior to shipping.

Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 8 of 9

2. Email tracking number to [EOCEVENT246@CDC.GOV \(mailto:EOCEVENT246@CDC.GOV\)](mailto:EOCEVENT246@CDC.GOV)
3. Do not ship for weekend delivery unless instructed to do so by CDC.
4. Ship to:

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

5. Include the following information inside the package: your name, the patient's name, test(s) requested, date of collection, laboratory or accession number, and [CDC Form 50.34](http://www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf) [PDF - 1 page] (<http://www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf>) and [Viral Special Pathogens Branch specimen submission forms](http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf) [PDF - 2 pages] (<http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>).
6. On the **outside** of the box, specify how the specimen should be stored: **refrigerated**.
7. Include documentation required by DOT or IATA.

Occupational Health

Potential exposures to blood, body fluids, and other infectious materials must be reported immediately according to your institution's policies and procedures.

When to Contact CDC

Hospitals should contact their state and/or local health department before contacting CDC. CDC is available for consultation at 770-488-7100.

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

Additional Resources and Information

- [Instructions for Submitting Diagnostic Specimens to CDC's Viral Special Pathogens Branch](http://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html) (<http://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>)
- [Viral Special Pathogens Branch Specimen Submission Information](http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf) [PDF - 2 pages] (<http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>)
- [Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals](#)
- [HAN 364: Guidelines for Evaluation of US Patients Suspected of Having Ebola Virus Disease](http://content.govdelivery.com/accounts/USCDC/bulletins/c7bea0) (<http://content.govdelivery.com/accounts/USCDC/bulletins/c7bea0>)

Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 9 of 9

- [Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008](http://www.cdc.gov/hicpac/disinfection_sterilization/6_Disinfection.html)
(http://www.cdc.gov/hicpac/disinfection_sterilization/6_Disinfection.html)
- [Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories](http://www.cdc.gov/MMWR/pdf/other/su6101.pdf)
[PDF - 105 pages] (<http://www.cdc.gov/MMWR/pdf/other/su6101.pdf>)
- [Submitting Specimens to CDC Specimen Submission Form](http://www.cdc.gov/laboratory/specimen-submission/form.html)
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