Public Health and Environmental Laboratories Technical Guidance

October 2022

Updates and Links:

- CDC Think Ebola: Identify-Isolate-Inform Patients Under Investigation
- CDC Ebola: Personal Protection Equipment (PPE) Donning and Doffing Procedures
- CDC Guidance on Managing and Testing Routine Clinical Specimens for the Assessment and Care of PUI.
- Collection, Transport, and Submission of Specimens from Persons Under Investigation for Sudan ebolavirus Testing (CDC)
- CDC Biosafety Risk Assessment and Risk Mitigation Training Links
- NJDOH Biothreat Response Laboratory PCR Test for the Detection of Ebola virus
- Emergency Department Preparedness Training (CDC)
- Specimen Storage and Shipping Guidance (CDC)
- CDC Viral Special Pathogens Branch Diagnostic Specimen Submission form

Attachments:

- NJDOH Shipper's Certification for Ground Transport – Attachment I
- World Courier Account Application Form – Attachment II
- NJDOH BioThreat Response Laboratory LAB-05 with Chain of Custody-Attachment **III**

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ACRONYMS:

APHIS	Animal and Plant Health Inspection Service
BSC:	Biosafety Cabinet
BTRL:	BioThreat Response Laboratory of the PHEL
CDC:	Centers for Disease Control and Prevention
CDS:	New Jersey Communicable Disease Service
DASH	Data and Specimen Handling Form
DSAT:	Division of Select Agents and Toxins (CDC/APHIS)
EAH	Ebola Assessment Hospital
ETC	Ebola Treatment Center
EUA	Emergency Use Authorization.
EVD	Ebola Virus Disease
FDA	Food and Drug Administration
Frontline	Acute Care Hospitals, emergency care settings, or urgent care clinic
IZDP:	Infectious and Zoonotic Disease Program of the CDS
LRN	Laboratory Response Network
PHEL:	New Jersey Public Health and Environmental Laboratories
PHL	Public Health Laboratory
PUIs	Persons Under Investigation
RT PCR	Real-Time Polymerase Chain Reaction
SEBOV	Sudan ebolavirus
TAT	Turn Around Time from specimen receipt to test results
USDOT	United State Department of Transportation
VHF	Viral Hemorrhagic Fever
VSPB	Viral Special Pathogens Branch (CDC)

I. PURPOSE:

On October 6, 2022, the Centers for Disease Control and Prevention (CDC) issued a health alert in response to the *Ebolavirus* disease outbreak caused by the Sudan virus (species *Sudan ebolavirus*) in central Uganda. This guidance provides specific recommendations that will assist healthcare facilities and local health departments in developing preparedness and biosafety mitigation plans to minimize the risk of exposure to *Sudan ebolavirus* (SEBOV), from patients arriving in the US from areas with Ebola outbreaks. As a precaution, healthcare facilities should be prepared to conduct an initial risk assessment, on patients arriving from or traveling through countries with an active Ebola virus outbreak, for signs, symptoms, and other epidemiologic risk factors of EVD. Early identification of person meeting "patient under investigation" or PUI criteria for EVD should prompt a coordinated response with clinicians, including infectious disease practitioners, and local/state public health officials.

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, clothes, bedding, etc., that have been contaminated with infected body fluids. EVD is not spread through airborne transmission. The early symptoms of Ebola virus infection are difficult to distinguish from other, more common infectious diseases such as malaria, influenza, COVID-19, or typhoid fever. Assess a patient's signs and symptoms along with their travel history and epidemiologic risk factors before initiating immediate infection control measures.

EVD symptoms can appear anywhere from 2 to 21 days after infection. Illness typically progresses from "dry" symptoms (fever, aches, fatigue) to "wet" symptoms (diarrhea and vomiting). A person with Ebola is not contagious until the appearance of symptoms and through the later stages of the disease, as well as postmortem.

Persons with unrecognized EVD may 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, isolate, and inform according to the CDC's Think Ebola: Early recognition is critical for infection control.

I. IDENTIFY:

Initial Risk Assessment of Signs and Symptoms:

- International travel to an area with an active Ebola virus outbreak in the past 21 days. While traveling abroad did you attend a funeral, care for someone who was sick, or have any contact with a domestic or wild animal in an area with an active Ebola virus outbreak?

  OR

- In contact with someone with confirmed or suspected to have EVD.

  AND

- Fever (≥ 100.4ºF/38.0ºC)
- Other symptoms are
  - Severe headache
  - Aches and pains (muscle and joint pain)
  - Weakness and fatigue
  - Gastrointestinal symptoms abdominal pain, diarrhea, and vomiting
  - Sore throat
  - Vomiting
  - Red eyes, skin rash, and hiccups
  - Unexplained hemorrhage (bleeding or bruising)
- Frontline hospitals should use the NJDOH Ebola Investigation Worksheet questions to guide the assessment of Ebola risk factors.

- **Consideration of Ebola should not delay diagnostic assessments, laboratory testing, and appropriate care for other, more likely medical conditions.**
- **If the patient has signs or symptoms consistent with EVD, relevant travel history, and epidemiolocal risk factors:**
  - ✓ **Immediately isolate the patient**
- **If the patient is arriving by EMS transport, the ED should be prepared to receive the patient in a designated area (away from other patients) and have a process in place for safely transporting the patient on the stretcher to the isolation area with minimal contact with non-essential healthcare workers or the public.**

II. ISOLATE

- Isolate the patient in a private room with a private bathroom or covered, bedside commode and close the door.
- Adhere to infection prevention and control procedures to prevent transmission through direct or indirect contact, including wearing appropriate PPE and using dedicated equipment. Refer to Ebola Preparedness PPE Guidelines.
- Use only essential healthcare workers trained in their designated roles for patient care. Limit the healthcare personnel who enter the room.
- Keep a log of everyone who enters and leaves the patient's room.
- Consider alternative diagnoses and evaluate appropriately.
- Perform only necessary tests and procedures.
- Avoid aerosol-generating procedures.
- Follow CDC guidelines for cleaning, disinfecting, and managing waste

III. INFORM

- Notify your facility's infection control program and other appropriate staff.
- Contact your local public health authorities within the patient's jurisdiction.
  Click on the link provided for a current directory of NJ local health departments: NJ Local Department of Public Health
- The local health department will contact the NJDOH's Communicable Disease Service (CDS).

IV. EVALUATION: Risk Exposure and Management of PUI

A. Collect and document travel history for discussion with state or local public health departments:

1) Where did they travel?
   i. Did they travel to districts currently affected by the outbreak?
2) Why did they travel?
   i. For work? (Was work done in a laboratory that handles VHF specimens of primates from VHF endemic regions)
   ii. Visit family?
3) What activities did they take part in during the 21 days before illness onset?
   i. Attend or participate in a funeral?
   ii. Care for anyone who was sick or died?
4) Did they travel with others?
   i. If yes, are their travel companions ill?
5) Did they have contact (including sexual contact) with someone suspected or confirmed to have Ebola?
6) Did they have contact with someone previously diagnosed or has recovered from Ebola Virus Disease?

B. CDC recommends that Ebola testing should only be ordered and performed for patients who meet the criteria for Persons Under Investigation for Ebola virus disease. Before collecting specimens for Ebola testing, clinical laboratories must first contact their local health department. Public health officials will determine if testing for the Ebola virus is warranted.

VI. EVALUATION: Differential Diagnoses for Consideration in a Returning Traveler with Fever

The CDC provides specific differential guidelines if illness presentation is not consistent with malaria or if malaria has been ruled out. Fever in returned travelers may be caused by other infections such as pneumonia and pyelonephritis. The following diagnoses should be considered based on specific clinical presentation and travel itinerary/place of possible exposure.

Common Clinical Findings	Infections to Consider after Travel
Fever and rash	Dengue, chikungunya, Zika, spotted fever or typhus group rickettsioses,typhoid fever (skin lesions may be sparse or absent), acute HIV infection, measles, varicella, mononucleosis, parvovirus B19, meningococcemia (lesions usually sparse)
Fever and abdominal pain	Typhoid fever, hepatitis, other viral syndrome, travelers' diarrhea, amebic liver abscess
Undifferentiated fever and normal or low white blood cell count	Dengue, rickettsial infections (scrub typhus, spotted fevers without rash), typhoid fever, chikungunya, Zika, acute HIV infection, early stage viral hemorrhagic fevers, other viral infections
Fever and hemorrhage	Viral hemorrhagic fevers (dengue and others), leptospirosis, rickettsial infections, meningococcemia
Fever and eosinophilia	Acute schistosomiasis, drug hypersensitivity reaction, fascioliasis, and other parasitic infections (rare)
Fever and respiratory symptoms	Acute schistosomiasis, Q fever, leptospirosis, pneumonic plague, tularemia, Middle East Respiratory Syndrome (MERS), endemic mycoses (histoplasmosis, blastomycosis, coccidioidomycosis, etc), other viral pneumonias, influenza, bacterial pneumonia, legionellosis
Fever and altered mental status	Scrub typhus, viral or bacterial meningoencephalitis (including meningococcal meningitis and arboviral encephalitis), East African trypanosomiasis, eosinophilic meningitis (Angiostrongyliasis), rabies
Mononucleosis syndrome	Epstein–Barr virus infection, cytomegalovirus infection, toxoplasmosis, acute HIV infection
Fever persisting >2 weeks	Typhoid fever, acute schistosomiasis, Q fever, Epstein-Barr virus infection, cytomegalovirus infection, toxoplasmosis, acute HIV infection, brucellosis, tuberculosis, , visceral leishmaniasis (rare)
Fever with onset >6 weeks after travel	*Plasmodium vivax* or *ovale* malaria, acute hepatitis (B, C, or E), tuberculosis, amebic liver abscess, visceral leishmaniasis

Access detailed information on clinical presentation, diagnosis, laboratory testing, treatment (if available), and patient management, by clicking on the link provided below:
Diagnoses for Consideration in a Returning Traveler with Fever | Viral Hemorrhagic Fevers (VHFs) | CDC

VI. PREPAREDNESS: ACUTE HEALTHCARE FACILITIES' EMERGENCY RESPONSE

A. Frontline Healthcare Facilities

Most U.S. acute care facilities that are equipped for emergency care (such as hospital-based emergency departments and other emergency care settings including urgent care clinics and critical access hospitals) are in this tier. Frontline healthcare facilities do not include primary care offices and other nonemergent ambulatory care settings. Preparedness guidance for these settings can be found at CDC Guidance for Clinicians in Primary Care Offices and Non-Emergent Ambulatory Settings.

Frontline healthcare facilities are not expected to provide prolonged care (>12–24 hours) for a severely ill patient. Clinical laboratories should be prepared to provide supportive testing to ensure patient care is not compromised while patients are being assessed for EVD. Frontline hospitals should follow appropriate infection control precautions and should have the capacity to perform basic diagnostic testing. Based on patient assessment, if EVD is suspected, the frontline hospital should notify their local health department (LHD) immediately by telephone. A directory of LHDs is available at www.localhealth.nj.gov

B. Ebola Assessment Hospitals

Ebola assessment hospitals are facilities prepared to provide up to 96 hours of evaluation and care for PUIs until the diagnosis is either confirmed or ruled out and until discharge or transfer is completed. Ebola assessment hospitals should be prepared to transport patients with confirmed EVD to an Ebola treatment center. Ebola assessment hospitals may also receive patients transferred from frontline healthcare facilities that are not prepared to provide evaluation, arrange for testing, and care for PUIs. Ebola assessment hospitals should ensure there is no delay in the care for these patients by being prepared to test, manage, and treat alternative etiologies of febrile illness (malaria, influenza) as clinically indicated.

C. Ebola Treatment Centers

Ebola treatment centers are facilities that plan to care for and manage a patient with confirmed EVD for the duration of the patient's illness. State and local decisions to designate Ebola treatment centers are informed by the results of a CDC site visit conducted by an interdisciplinary team of subject matter experts. Site visits assess the hospitals' ability to meet the minimum criteria (including infection control capacity, physical infrastructure, staffing resources, PPE supplies, waste management processes, worker safety training, environmental services, and laboratory setup). Staff must be trained in and have practiced putting on and taking off (donning and doffing) PPE for Ebola, as well as providing clinical care using PPE.

VII. PREPAREDNESS: CLINICAL LABORATORY MANAGING AND TESTING ROUTINE CLINICAL SPECIMENS

A. Clinical laboratories, especially those in Ebola Assessment and Ebola Treatment Hospitals, should provide a timely and minimum menu of testing to ensure that medical evaluation is not delayed for any patient. For low-risk patients, frontline hospitals should have the capacity to perform these tests to identify the more likely cause of febrile illness. Aside from the clinical symptoms, the decision to perform the Ebola assay will be guided by some key clinical laboratory test results. The following are the basic diagnostic tests that clinical laboratories/frontline facilities should be prepared to perform:

1. A complete blood count (CBC), including differential, and platelet count.
2. Sodium, potassium, bicarbonate, blood urea nitrogen, creatinine, and glucose concentrations
3. Liver function tests
4. Coagulation testing, specifically prothrombin time (PT), expressed as an international normalized ratio (INR)
5. Urinalysis (dipstick)
6. Blood culture for bacterial pathogens (Automated Instruments and Manual Laboratory Cultures)
7. Malaria testing (smear or rapid testing or PCR).
8. Consider using a multiplex instrument molecular assay to detect respiratory viruses like Influenza virus testing during periods when influenza prevalence is high in addition to testing for SARS-CoV-2.

Provisions should be made to perform these tests on-site without delay when clinically indicated. Per CDC, proper donning and doffing with PPE, strict adherence of laboratory staff to standard laboratory safety precautions and decontamination procedures are adequate for processing specimens safely from patients under investigation (PUI) for Ebola.

***NOTE: *Ebolavirus* can be detected in blood after the onset of symptoms. However, it may take up to three days after symptoms start for the virus to reach detectable levels. Polymerase chain reaction (PCR) is one of the most used diagnostic methods because of its ability to detect low levels of virus.**

After consultation with public health officials, specimens from PUIs will be submitted to the NJ PHEL Biothreat Response Laboratory (BTRL) for EVD PCR testing. PCR testing of PUI specimens should be done at PHEL, regardless of the result of any in-house testing that is performed to evaluate for Ebola virus infection**.**

A risk assessment should be initiated by each institution to determine isolation procedures, location, and placement of PUI, specimen collection, onsite test menu, and patient and specimen transport.

B. Frontline Hospital Initial Clinical Care Management of PUI with Signs and Symptoms of EVD Unconfirmed by Laboratory Testing

- Diagnostic tests that will not immediately change the treatment of the patient should not be performed if they require transporting the patient. Testing should be performed inside the patient's isolation room whenever possible.

- Dedicated medical equipment (preferably disposable, when possible) should be used for the provision of patient care. If equipment is used in an isolation room and removed, ensure appropriate decontamination has been done before placing the equipment back in service.

- Limit the use of needles and other sharps as much as possible. All needles and sharps should be handled with extreme care and disposed of in puncture-proof, sealed containers. Prevent needlestick and sharps injuries by adhering to correct sharps handling practices and using needleless IV systems whenever possible.

- Phlebotomy, procedures, and laboratory testing should be limited to the minimum necessary for essential diagnostic evaluation and medical care.

- Avoid Aerosol Generating Procedures (AGPs) for PUIs and patients with EVD. If performing AGPs, use a combination of measures to reduce exposures from aerosol-generating procedures.

- Examples of AGPs/ procedures listed by the CDC include but are not limited to Bilevel Positive Airway Pressure (BiPAP), bronchoscopy, sputum induction, intubation and extubation, and open suctioning of airways.

- Visitors SHOULD NOT BE PRESENT during aerosol-generating procedures; limit the number of health care providers (HCP) present during the procedure to only those essential for patient care.

- Conduct the procedures in a private room and ideally in an Airborne Infection Isolation Room (AIIR) when feasible. Room doors should be kept closed during the procedure except when entering or leaving the room, and entry and exit should be minimized during and shortly after the procedure.

- HCP should wear appropriate PPE during aerosol-generating procedures.

- Conduct environmental surface cleaning following procedures. Immediately clean and disinfect any visibly contaminated PPE surfaces, equipment, or patient care area surfaces using the appropriate disinfectant.

- If reusable eye protection or face shields are used, perform decontamination before reuse. If possible, consider single-use face protection

- Reusable respirator use is discouraged. Single-use disposable filtering face-piece respirators are recommended.

- HCP should perform hand hygiene frequently, including before and after all patient contact, contact with potentially infectious material, and before putting on and upon removal of PPE, including gloves.

- Healthcare facilities should ensure that supplies for performing hand hygiene are readily available.

VIII. PREPAREDNESS: CLINICAL LABORATORY RISK ASSESSMENT AND RISK MITIGATION

A. Laboratory risk assessment is a process used to identify:

1. the hazards associated with a known or potentially infectious agent
2. the likelihood of a person's exposure to that agent or material including activities that increase transmission risk
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)

A risk assessment of all processes, procedures, and activities must be performed to determine the potential for exposure to the specimen through the 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 the use of appropriate PPE.

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.

B. Clinical laboratory's 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, and splashes of the specimen when performing testing and using equipment)
- Biological Safety Cabinet certification, operation, and safe work practices to determine if instruments placed inside the BSC disrupt the operation and protective functions.
- Surface decontamination procedures, including spill response. Refer to CDC Decontamination Guidelines.
- Decontamination of instruments and equipment: 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.
- Infectious waste management
- Engineering controls and safety equipment must be maintained and ready for use.
- Laboratory communication protocols – the use of a phone, intercom, or an observer to relay urgent communications.
- Laboratory design: Laboratories with open floor plans, should consider the risk of exposure to employees present in surrounding areas that are not directly involved with the testing of that sample
- Minimize the risk of laboratory transmission when testing patient specimens by limiting the number of staff engaged in testing, evaluating, isolating equipment for testing, and performing testing in a dedicated space
- Laboratory entry and exit procedures must be posted and visible at each point of entry or exit.
- PPE selection and use – risk-based training. Scheduled inventory control. Task and procedure-specific checklist.
- Facility ventilation and filtration – daily function checks, audible or visible failure notification.
- Employee medical surveillance and exposure-response – location and access to emergency contact information.
- Safe sharps handling and available Sharps' disposable container at the point of testing.
- Personnel safety training and competency assessment must be completed before testing begins.

C. PREPAREDNESS: CLINICAL LABORATORY RISK ASSESSMENT SUMMARY

Procedure	Recommendation
Centrifugation	Should be performed in sealed buckets or sealed rotors. The buckets or rotor should be opened inside a certified and operable BSC. Buckets must be disinfected before reuse
Homogenization	Procedures requiring homogenization of any specimen type should be avoided or performed with extreme care due to the risk of spray or splash and should be performed inside a certified and operable BSC
Clinical chemistry and hematology	Numerous issues pertaining to routine testing in these areas need to be considered and are highly variable depending on the type of equipment used, volume of testing performed, laboratory workflow and layout, and many other factors. A full risk assessment should be done at each site, including options for decontamination[15]. For automated instruments, decontamination procedures should be those advised by the manufacturer or vendor for enveloped viruses.
Malaria testing	Thin blood smears should be fixed in methanol for 15-30 minutes and dried before staining. The use of additional heat inactivation is not considered necessary for Ebola decontamination and has been found by some parasitologists to disrupt the parasite's morphology. Thick blood films should not be hemolyzed with water but should be stained with Giemsa stain that includes Triton X-100 to inactivate the Ebola virus. Validated malaria PCR assays that have been approved by the Clinical Laboratory An evaluation Program for clinical use may be used to detect malarial parasites. Malaria antigen detection kits may assist with the initial urgent assessment but must be recognized as being inherently less sensitive than smear microscopy or PCR, at least one of which must be performed as soon as possible. The effects of some inactivation/decontamination procedures on the performance of some rapid antigen tests for malaria have been investigated[16]. **Note: Immediate blood smears with same-day results are recommended for malaria testing. If rapid diagnostic testing or PCR is performed, a blood smear with pre-treatment blood should also be processed to determine the percentage of red cells infected. Facilities that do not have the expertise or CLIA certificate to perform definitive malaria testing on-site should contact CDS to facilitate malaria testing at PHEL.** For more detailed guidance, see the CDC recommendations on Malaria testing for suspected Ebola patients at: http://www.cdc.gov/malaria/new_info/2014/malaria_ebola.htm
Blood Cultures	Systems using plastic blood culture bottles are preferred. Blood culture in glass bottles should be avoided.
Other specimens for bacterial culture	"Pan-cultures" should not be performed. Procedures essential for patient management should be performed in a BSC with the use of appropriate PPE. Identification or characterization of subsequently cultured bacteria or fungi can be performed with standard precautions.
Wet preps	Should be avoided.

Viral cultures	DO NOT perform viral culture, including the use of rapid culture systems, on any specimen.
Pre-transfusion testing	Please refer to the American Association of Blood Banks' Ebola information sheet www.aabb.org/programs/clinical/Pages/Infection-Control-for-Handling-Blood-Specimens-from-Suspected-Ebola-Patients.aspx
Post-mortem examinations	Should only be performed under the explicit recommendation of the CDC and with their guidance. In the event of a fatality in a suspected or confirmed EVD patient, the Northern Regional Medical Examiner's Office must immediately be contacted at 973-648-4500 and request to have someone from the Office of the Chief State Medical Examiner contact them due to an EVD decedent.
Specimen storage	Except for circumstances where retention is required by regulations, long- term storage of specimens is discouraged. It is recommended that specimens collected from suspected or presumptive positive EVD cases be isolated from other specimens in the laboratory and if stored, the refrigerator or freezer unit must be kept locked at all times. A chain of custody form must ALWAYS accompany the specimen. Immediately after testing has been completed and the sample has been confirmed by the CDC, the samples should be disposed of in compliance with the Waste management protocol below. Note – Details of specimen decontamination and disposal should be documented for any samples from a presumptive or confirmed positive EVD patient, or a PUI of unknown status. The CDC does not classify samples tested and resulted as presumptive positive for Ebola Sudan Virus by the DoD's BioFire FilmArray Next Generation Diagnostic System (NGDS) Warrior PCR Assay as select agent samples, that classification is reserved for positive cultures confirmed by the CDC only, they do reserve the right to request information and confirmation of destruction/disposal.
Specimen decontamination and disposal	Decontaminate the outside of the specimen container using a piece of gauze soaked with a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant, with label claims for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) and wipe the outside of the specimen container. The gauze and the disinfected specimen container should then be placed in a plastic bag and packaged with other contaminated waste for appropriate disposal or autoclaving. A list of EPA-registered disinfectants can be found at: https://www.epa.gov/pesticide-registration/disinfectants-emerging-viral-pathogens-evps-list-q Note: Bleach or acidic chemicals must NOT be mixed with any other reagent containing guanidine isothiocyanate, nor should they be disposed of together in the same container, as reactive compounds and toxic gases are formed if they interact.

IX. RESPONSE: Public Health, Communicable Disease Services, and CDC Emergency Operation Center

NJ Procedure for communication and approval of specimen submission to PHEL

The CDC in collaboration with the US Department of Defense has authorized the use of BioFire FilmArray Next Generation Diagnostic System (NGDS) PCR Warrior panel for the presumptive diagnosis of *Sudan ebolavirus*.

A. Contact Local or State Public Health Authorities Immediately

The decision to test for EVD must be made in conjunction with the patient's clinical care team, the LHD, CDS/NJDOH, and CDC's Viral Special Pathogens Branch (VSPB). Hospitals should contact their state and/or local health departments. NJDOH will facilitate consultation with CDC if indicated.

Each patient will require evaluation on a case-by-case basis. Hospital officials should contact the local health department within the patient's jurisdiction. See the link provided for the current directory: https://www.nj.gov/health/lh/documents/LocalHealthDirectory.pdf. The local health department will contact the NJDOH's Communicable Disease Service.

If the hospital is unable to reach local health officials, contact the Communicable Disease Service directly at 609-826-5964 (business hours) or 609-392-2020 (after hours).

Public health officials will determine the need for Ebola virus testing and if testing is not performed at PHEL, where the specimens will be sent. The need for testing specimens **other than blood** can be discussed with NJDOH.

B. Obtain NJDOH Approval for Ebola Sudan Virus Testing

If public health authorities determine a need for Ebola virus testing, the submitter will be given a CDS approval (case) number. This number should be used on all paperwork and specimen labels and will be used to track information regarding the case.

Alert the laboratory to prepare materials for blood draw and shipment and to make sure that they have 2 certified shippers on site to package the specimen for transport. Order the test in your system and create specimen labels.

X. RESPONSE: Specimen collection, packaging, and shipping to NJ PHEL

It is advisable to preassemble collection materials and to notify staff in advance of specimen collection.

A. Pre-Specimen Collection - Materials Needed:

- Two 4-ml minimum Lavender top EDTA **plastic** tubes – adults
- Two I mL minimum Pediatric EDTA plastic blood collection tubes-
- Small clear biohazard Ziploc bags
- Absorbent material
- Cold Category A shipping system: Triple Packaging system - Outer UN Certified Class 6.2 box with internal support for the secondary container, secondary container (rigid plastic screw cap), bubble wrap to support specimens inside the secondary container, e.g. Infecon 3000, USDOT Infectious Substance label.
- Overpack box - Styrofoam lined to accept the inner cold container e.g., Infecon 6000 plus Overpack label
- Sufficient cooled gel packs to fill Infecon 6000 (note, gel packs may be refrigerated or frozen) –
  - Specimens are required to be at 2-8^{O}C. **Do NOT Freeze the sample.**
- Dangerous Goods Shippers Declaration and LAB-05 form required.

B. **Collecting site should always be prepared to pack and ship Category A Infections substances: Two persons certified within the past two years** to ship Category A Infectious substances – persons should be on call to ship 24/7. Note: FREE online Packaging and Shipping training is available at **www.cdc.gov/labtraining.**

C. Preparing for Specimen Collection:

Prepare two Ebola Go-Kit - one for the PATIENT ROOM and one for the STAGING AREA.

1) **For PATIENT ROOM (Hot Zone, Full PPE is required)**

- EDTA tubes,
- two Ziploc bags, each containing sufficient absorbent material to absorb the entire contents of the tube
- Specimen labels
- spray bottle with 10% v/v bleach prepared fresh daily.

2) **For STAGING AREA (Warm Zone, Full PPE required if adjacent to patient room, laboratory PPE required if remote from patient room)**

- Separate spray bottle with 10% v/v bleach prepared fresh daily
- Disposable gloves
- rigid specimen carrier (to carry specimen from patient area to staging area)
- Rigid plastic screw cap secondary container from UN-certified Class 6.2 ambient shipping system

The remainder of the preparation for specimen collection can be done in a clean area in the laboratory with no gloves and a clean lab coat. The remainder of the materials for shipping should remain in a clean area in the laboratory and should NOT be brought into either the patient's room or the staging area where specimen collection and decontamination occur

D. **Specimen Collection**

1) Transport an "Ebola Go Kit" into the area (Warm Zone) adjacent to the patient.

2) Confirm needed "Ebola Go Kit" supplies are available before proceeding: two purple top tubes, Ziploc bags with absorbent material, specimen labels, and a spray bottle with freshly prepared 10%v/v bleach (prepared fresh daily)

3) **INSIDE THE PATIENT'S ROOM**

a. Draw two (3 or 4 ml) plastic EDTA tubes. Fill tubes.
b. Decontaminate the outside of the tubes.
c. Label the tubes with the patient's name, hospital ID#, DOB, date, time, collector's initials, and CDS approval number.
d. Place each tube in a separate Ziploc bag with absorbent material.
e. Remove all air from the bag.
f. Decon the outside of the bags with 10%v/v bleach.
g. Hand the bags to the person transporting the specimen to the staging area to place inside a rigid specimen carrier.
h. Staging area may be near the patient care area or in the laboratory.

E. **Package Blood: Begins in Staging Area, Completed in Clean Area**

1) **STAGING AREA:**

a. Staff should always wear PPE appropriate to the risk. If a Biological Safety Cabinet is available, the next step should be conducted in the cabinet.

b. Gloves, an impermeable lab coat, and face protection are required if working outside the BSC. Skin, eyes, nose, and mouth should be barrier protected.
c. Gloves, an impermeable lab coat is required if working inside the BSC. The BSC can serve as a shield, however, face protection should be worn if desired.
d. Remove the deconned Ziploc bags from the rigid specimen carrier.
e. Have a second person read the patient ID information to you to check against the labels. Do not touch any paperwork.
f. Decon the outside of the bags again with 10%v/v bleach and change gloves before handling again.
g. Wrap each Ziploc bag individually in bubble wrap.
h. Place both Ziploc bags inside the Category A rigid plastic secondary container.
i. Screw the container shut and decon the outside of the container with 10% bleach. Remove gloves and hand containers to the person in the clean area to finish packaging.

F. **CLEAN AREA SPECIMEN PACKAGING:**

1) Finish packaging the specimen as Category A according to the IATA packaging instruction. Use an overpack for cold packs to maintain the temperature at 2-8 C.
2) Prepare three copies of the Shipper's Certification for Ground Transport and one copy of the LAB-05 with Chain of Custody.
3) Specimen Storage: Accession, package, and ship immediately after collection. If there is a delay in shipping, the package may be stored at 2-8°C until picked up by the courier. Secure the package in a locked refrigerator until the courier arrives on site.
4) Have the courier sign the Chain of Custody. Keep a copy of all paperwork.

G. **SPECIMEN TRANSPORT TO PHEL**

1) Specimen may be transported via hospital or PHEL emergency courier for same-day delivery.
2) **All specimens that are being transported from the hospital laboratory to NJ PHEL should be labeled as Infectious substance, affecting humans (Suspected Category A Infectious Substance) on the shipping papers and the outer container**.
3) Couriers must use the COC form.
4) The bag with labels/forms must be attached to the package.
5) The sentinel laboratory must notify the BTRL Manager before the courier leaves the pickup site.

XI. RESPONSE: Ebola virus testing at NJ PHEL

The US Department of Defense (DoD) has developed an assay, BioFire FilmArray Next Generation Diagnostic (NGDS) Warrior PCR Assay, which is used on the FilmArray 2.0 instrument, to detect biothreat pathogens including Ebola Virus (Zaire and Sudan) and Marburg Virus. The New Jersey Department of Health (NJDOH) Public Health and Environmental Laboratories (PHEL) uses this assay for the in vitro qualitative detection of Ebola virus RNA (both Zaire and the Sudan *ebolavirus*) in clinical specimens from individuals meeting Ebola virus clinical and/or epidemiological criteria.

PHEL also performs the Laboratory Response Network (LRN) and Centers for Disease Control & Prevention (CDC) Ebola Virus NP Real-Time RT-PCR Assay; Ebola Virus VP40 Real-Time RT-PCR Assay. Note that this test is specific for *Zaire ebolavirus* species) and does not detect other Ebola species or other VHF etiologies.

This assay is to be used for testing individuals designated by the NJ Communicable Disease Service in conjunction with the CDC as Persons under Investigation (PUI) for Ebola Viral Disease (EVD). Additional assays for testing known Ebola cases or those suspected of having other viral hemorrhagic fevers are available at the Centers for Disease Control and Prevention (CDC) Viral Special Pathogens Branch (VSPB).

Two full, 4 mL lavender top EDTA tubes of blood are required. One tube is used for the initial test for Ebola at the State Public Health Laboratory; the second tube is for confirmatory testing at CDC for positives or when special studies at CDC are required on negative samples. These samples cannot be shared or aliquoted for other laboratory tests.

A. **Turn Around Time (TAT) of the Ebola Assay at NJ PHEL**

Within 24 hrs. after receipt at PHEL (most specimens received by 8 am are tested and resulted by PHEL by 6 pm):

TAT is the longest time that it could take to "turn a specimen around" and produce a result after a specimen is received in the laboratory. The TAT for the initial DoD FilmArray NGDS Warrior Panel assay (Zaire and Sudan) and Ebola Virus NP Real-Time RT-PCR Assay; Ebola Virus VP40 Real-Time RT-PCR Assay ***after the specimen is received in the PHEL laboratory will not exceed 24 hours.*** The TAT will vary (within 24 hours), depending on:

1) When the specimen is received (between 8 AM and 5 PM or after regular PHEL business hours).

2) Whether there are problems associated with the specimen collection, handling, packaging, and paperwork requiring correction before analysis can proceed.

3) Time the alert to on-call laboratory staff is provided for off-hours testing requests. Time is needed to communicate to all partners in the chain to assemble staff for testing during off-peak hours and for staff travel time to the laboratory.

B. Samples that are presumptive positive by the initial DoD FilmArray NGDS Warrior Panel assay (Zaire and Sudan) or the Ebola Virus NP Real-Time RT-PCR Assay; Ebola Virus VP40 Real-Time RT-PCR Assay (Zaire) are shipped to the CDC using World Courier. Given the limited resource available for shipping positive Ebola samples it is expected that sample may not arrive at the CDC until 24 to 48hrs after the initial result is obtained on a weekday and longer if the initial result is obtained on a Friday unless the case is emergent enough that the CDC provides a mechanism for urgent delivery of the specimen. ***Once the sample is received at the CDC a panel of tests is performed and reported within 24 hours.***

   All of the above emphasize the importance of strict adherence to protocols, rechecking all steps in the collection packaging, shipping, completion of forms, and submission to minimize problems that could delay the TAT and impact patient care.

C. **Results Reporting and interpretation**

   Results will be reported using LRN Results messenger and will be emailed to the submitter. Test results will also be entered into the Communicable Disease Reporting and Surveillance System (CDRSS).

1) **If the initial specimen tests negative:** A negative test presumes that Ebola virus RNA was not present in the specimen at the detection level of the assay. However, negative results do not rule out Ebola, and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness, the timing of specimen collection, and the type and risk of exposure will inform patient management and isolation decisions. A negative DoD FilmArray NGDS Warrior Panel Assay (Zaire and Sudan) or the EBOV VP40 rRT-PCR Assay test result should not be interpreted as demonstrating that the patient does not have Ebola, particularly if it has only been a few days since the onset of symptoms. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate Ebola is likely, and diagnostic tests for other causes of hemorrhagic illness are negative. Risks to a patient of a false negative result include delayed treatment, potential lack of treatment, or stopping treatment too soon. If Ebola is suspected by exposure history together with clinical findings, re-testing should be considered in consultation with public health authorities.

   For negative results on specimens collected less than 3 days post-onset of symptoms, and if the patient is still symptomatic, repeat testing is recommended, unless EVD is no longer in the differential diagnosis. Requests for repeat

testing must be approved through the Communicable Disease Service. Testing for other viral hemorrhagic fevers at the CDC Special Pathogens Branch must be arranged through the Communicable Disease Service.

2) **If the initial specimen tests positive**:

Samples that test positive using this assay are considered presumptive positive for the DoD FilmArray NGDS Warrior Panel assay (Zaire and Sudan) and the Ebola Virus NP Real-Time RT-PCR Assay; Ebola Virus VP40 Real-Time RT-PCR Assay will be submitted to CDC for confirmatory testing.

A positive test result from the DoD FilmArray NGDS Warrior Panel assay (Zaire and Sudan) as well as the EBOV VP40 rRT-PCR indicates that RNA from the Ebola virus was detected, and the patient is presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis and patient management decisions. For information on Ebola and guidelines on patient management, please refer to: http://www.cdc.gov/vhf/ebola/index.html.

XII. RESPONSE: Follow-up Testing at CDC Viral Special Pathogens Branch

The need for follow-up testing will be determined in consultation with the New Jersey Communicable Disease Service and the CDC. If further testing is required, the NJPHEL will arrange the transport of presumptive positive specimens to the CDC via World Courier.

In the event of an emergency where laboratories receive instructions directly from the CDC or the NJ DOH CDS to ship specimens directly to the CDC, World Courier has been identified as the sole source for transporting samples to the CDC VSPB.

Specimens other than blood may be directly submitted to the CDC after consultation with the Viral Special Pathogens Branch at 470-312-0094.

A. Packaging and Shipping Specimens from PUI to the CDC

- **Reminder NO specimens will be accepted by the CDC without prior consultation with the NJDOH Communicable Disease Service. Approved specimens should only be shipped directly to the CDC if instructed to do so.**
- Maintain a minimum of two certified shippers.
- Establish an account with World Courier. Currently, World Courier is the only courier that transports presumptive positive Ebola specimens. A new account application form is attached.

Contact:

Nicole Blue, Accounts Receivable Manager - North America
AmerisourceBergen, World Courier Inc
1313 Fourth Avenue
New Hyde Park, NY 11040
Tel: 516-916-5178
www.worldcourier.com

- Include the CDC Infectious Disease (CDC Form 50.34) and specimen submission forms pdf icon[PDF – 182KB, 508].
- Label the outer packaging in accordance with I.A.T.A. regulations to prevent leakage (triple packaging).
- All specimens – being transported to the CDC should be labelled as Infectious substance, affecting humans (Suspected Category A Infectious Substance) on the shipping papers and on the outer container.
- On the **outside** of the box, specify how the specimen should be stored: **refrigerated** or **frozen**.

- Send specimens by overnight courier (World Courier). International submitters should consider door-to-door shipment via air transport to expedite specimen delivery to CDC.

Forms required for follow-up testing at CDC:

- CDC DASH pre-filled with NJ Contact information) and
- CDC VSPB form, (Linked) and hospital chain of custody form. NOTE: CDC DASH FORM IS SEPARATE FROM THIS DOCUMENT

The CDC DASH form must be used AS IS - with all the NJDOH contact information in the top right corner intact. Altering this NJDOH information in the form may result in delays in analysis

References:

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4. Francesconi P, Yoti Z, Declich S, et al (2003): Ebola Hemorrhagic Fever Transmission and Risk Factors of Contacts, Uganda. Emerg Infect Dis 9:1430-37
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18. Procedures on tests for frequently Measured Analytes in Plasma. Clin Chem 50: 944-46.
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Attachment I **Created by New Jersey Department of Health**

Shipper's Certification for Ground Transportation of Hazardous Materials
(To be completed when transporting hazardous materials by hospital courier)
(One signed copy retained by shipper for 375 Days)

Shipper's Reference Number(s)_____

Shipper: (Name)_____

Shipper's Address: _____

_____
(Include Street number- Street- City- State- Zip Code)

Consignee: (Name) _____

Consignee's Address: _____

_____
(Include Street number- Street- City- State- Zip Code)

Nature and Quantity of Hazardous Material:

Hazardous Materials Identification					
UN No.	**Proper Shipping Name (technical name)**	**Hazard Class or Division**	**Packing Group**	**Quantity, Number and Type of Packages**	**Packaging Instruction (#)**

Emergency response telephone number: _____

SHIPPER'S CERTIFICATION: "This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the US Department of Transportation."

Printed Name/Title of Signatory:_____

Place:_____

Signature: _____ Date:_____

Attachment II

New Customer Account Application Form

World Courier®
AmerisourceBergen

CUSTOMER BILLING INFORMATION

COMPANY NAME:

TAX ID / FEIN Number:

Company Registered Address	**Street:**		
	Additional Add:		
	City:	**State:**	**Post Code:**

Billing Address (if different to Registered)	**Street:**		
	Additional Add:		
	City:	**State:**	**Post Code:**

Payer / Parent Details (if different to Registered & Billing)	**Payer Company Name:**		
	Street:		
	Additional Add:		
	City:	**State:**	**Post Code:**

ACCOUNTS PAYABLE CONTACT DETAILS and INVOICE REQUIREMENTS

CONTACT NAME:

EMAIL ADDRESS:

LOCATION ADDRESS: REGISTERED ☐ BILLING ☐ PAYER ☐

Telephone: **Fax:**

STATEMENT email address:

INVOICE email address (if different):

World Courier Net Terms (From date of invoice) is 30 Days.

Monthly Est.Sales Revenue: ☐ **4k or less**

More than 4k (Please indicate amount)

Page 1 of 3

New Customer Account Application Form

World Courier®
AmerisourceBergen

Reference Required on the Invoice: Yes ☐ No ☐

If **YES**, please specify.

Any other special INVOICE requirements i.e. PO Number etc…? Yes ☐ No ☐

If **YES**, please specify:

World Courier will not be responsible for providing missing or incorrect Purchase Order numbers or other required references. Payment cannot be withheld for this reason.

CCSF&CONDITIONS OF CARRIAGE

Is this account an IAC (Indirect Air Carrier) Yes☐ NO☐

If YES, Please provide IAC#

Is the account a CCSF (Certified Cargo Screening Facility)? YES ☐ NO☐

Have you applied to become a CCSF? Yes☐ NO☐

Shipments are subject to World Courier's current CONDITIONS OF CARRIAGE, refer to: www.worldcourier.com

GENERAL INFORMATION

STATUS: Public Ltd ☐ Private Ltd. ☐ Partnership ☐ Sole Trader ☐

Non- Profit Organisation ☐ **Other** ☐

Is the Company part of a group? Yes ☐ **No** ☐ if yes,(please complete below)

Parent Company Details:

NATURE OF BUSINESS:

Type of commodities to be shipped with WORLD COURIER (please tick all that apply):

Electronics ☐ **Chemicals (non Pharma)** ☐ **Spare Parts / AOG** ☐

Pharmaceuticals* ☐ **Food** ☐

Biological - Animals ☐ **Biological Human**☐ **Synthetic Material** ☐

Page 2 of 3

New Customer Account Application Form

World Courier
AmerisourceBergen

Temperature – Controlled ☐ **Dangerous Goods** ☐ **Radioactive** ☐

Other (please specify)

CONDITIONS OF CARRIAGE

All shipments are subject to World Courier's current CONDITIONS OF CARRIAGE, refer to: www.worldcourier.com

I/We confirm that the above information is both true and correct. I/We understand that all work undertaken by World Courier is subject to the conditions of carriage.

I/We understand that advanced payment may be required for the initial shipment with World Courier.

Authorized Signature:		**Date:**	
Printed Name:			
Position:			

Applicant authorizes World Courier and any credit agency or any service engaged by World Courier to obtain, verify or otherwise investigate any information, reference, statements, credit reports or other information obtained with respect to Applicant as World Courier deems appropriate.

Page 3 of 3

World Courier website: World courier new account request form

New Jersey Department of Health, Public Health and Environmental Laboratories

REQUEST FOR TESTING OF CLINICAL SPECIMENS FOR SUSPECTED PATHOGENS OF PUBLIC HEALTH SIGNIFICANCE AND CHAIN OF CUSTODY

PHEL Use Only

BT-H

IMPORTANT: All sample/specimen submitters must email a copy of the completed LAB-5 form to DOH-BTEPI-PHEL@doh.nj.gov prior to shipment in addition to the required hard copy. Specimens must be pre-approved by the Communicable Disease Service (609-826-5964) prior to submission. Additional sheets or documentation may be attached if needed.

CDRSS Case number: _____

Name of requesting agency/institution:

_____

Address: _____

City: _____

State: _____ Zip: _____

Phone: _____ Fax: _____

Email: _____

Name of Submitter: _____

Specimen/sample collected by: _____

Collection pickup site: _____

Collection Date: _____ Time: _____

Date shipped to PHEL: _____

Attending Physician: _____

Physician address: _____

Physician Email: _____

Physician Phone: _____

SPECIMEN INFORMATION:

Suspected agent(s):

☐*Bacillus anthracis* ☐ *Francisella tularensis*

☐*Brucella* spp. ☐Orthopox

☐*Burkholderia* spp. ☐*Yersinia pestis*

☐*Coxiella burnetii* ☐Antibiotic resistant isolate

☐*Ebola* Virus ☐ Other: _____

Type of specimen/sample:

☐Culture-Bacteria ☐ Whole Blood

☐CSF ☐Serum ☐Urine

☐Other: _____

PATIENT INFORMATION:

Patient Name: _____

Sex: ☐M ☐F DOB/Age: _____

Travel in the past 6 months (locations & dates):

_____

Date of symptom onset: _____

Pregnancy status at onset (trimester): ☐1st ☐2nd ☐3rd ☐N/A

Is the patient hospitalized?	☐Yes ☐No
Is the patient alive?	☐Yes ☐No
Did the patient experience skin lesions?	☐Yes ☐No
Lymphadenopathy?	☐Yes ☐No
Dyspnea?	☐Yes ☐No
Fever?	☐Yes ☐No
Were there any positive blood cultures?	☐Yes ☐No

Other signs/symptoms: _____

Were any specimens handled outside of a biosafety cabinet?

☐ **Yes** ☐ **No**

Biochemical Information (bacterial isolates):

Gram positive	☐Yes ☐No
Large rods	☐Yes ☐No
Gram negative	☐Yes ☐No
☐ Coccobacilli ☐Rods	☐Curved
Rapid growth on blood agar	☐Yes ☐No
Poor growth after 24h	☐Yes ☐No
Growth on MacConkey Agar	☐Yes ☐No
Lactose fermentation	☐ Yes ☐ No
Hemolytic	☐Yes ☐No
Motile	☐Yes ☐No
Oxidase positive	☐Yes ☐No
Catalase positive	☐Yes ☐No
Urease positive	☐Yes ☐No
Indole negative	☐Yes ☐No
Satellite negative	☐Yes ☐ No
β-lactamase positive	☐Yes ☐No
Antibiotic Resistant	☐ Yes ☐ No
☐ Colistin ☐ Polymixin B ☐ Penicillin ☐ _____	
Growth Temperatures	☐ 25°C ☐ 37°C ☐ 42°C

LAB-05 Clinical

OVER

Attachment III LAB-5 Clinical Specimen Rule out for Select Agent and Chain of Custody

Culture Description: ______________________________

Colony Morphology (if applicable): Check all that apply

Growth medium used: ☐ BAP ☐ CHOC ☐ MAC ☐ EMB ☐ Other:			
Time of growth when observation took place: hours			
Form		**Margin**	
Elevation		**Color**	

☐ **REJECTED:** (PHEL Use Only)

☐ Improper package ☐Unannounced ☐No case number ☐ Improper documentation ☐ Other__________________

CHAIN OF CUSTODY (Required for suspected Select Agents)

X______________________ Relinquished by (Print)	Date: _________ Time: ________	X______________________ Received by (Print)
X______________________ Relinquished by (Signature)		X______________________ Received by (Signature)
X______________________ Relinquished by (Print)	Date: _________ Time: ________	X______________________ Received by (Print)
X______________________ Relinquished by (Signature)		X______________________ Received by (Signature)
X______________________ Relinquished by (Print)	Date: _________ Time: ________	X______________________ Received by (Print)
X______________________ Relinquished by (Signature)		X______________________ Received by (Signature)
X______________________ Relinquished by (Print)	Date: _________ Time: ________	X______________________ Received by (Print)
X______________________ Relinquished by (Signature)		X______________________ Received by (Signature)
X______________________ Relinquished by (Print)	Date: _________ Time: ________	X______________________ Received by (Print)
X______________________ Relinquished by (Signature)		X______________________ Received by (Signature)

LAB-05 Clinical