



Public Health and Environmental Laboratories Technical Guidance

December 2014

Update: Ebola Testing Algorithm, NJDOH Recommendation Regarding FDA EUA Tests and Clinical Laboratory Testing

Attachments:

- Packaging and Shipping Online Training brochure – Attachment I
- NJDOH BioThreat Response Laboratory LAB-05 with Chain of Custody – Attachment II
- NJDOH Shipper’s Certification for Ground Transport – Attachment III
- World Courier Account Application Form – Attachment IV
- CDC Viral Special Pathogens Branch form – Attachment V
- New CDC DASH form (effective 12/5/14) – Separate Document

This guidance updates salient points addressed in the November 20, 2014 NJDOH PHEL teleconference to include, Ebola testing algorithm and Turn Around Times(TAT), laboratory safety recommendations and recommendations regarding the FDA Emergency Use Authorization (EUA) Ebola assays. Please note that the risk assessment table has been updated and contains *new information* regarding clinical laboratory testing and biosafety.

Use of PHEL Technical Bulletins:

- The November 12, 2014 PHEL Technical bulletin was presented as a two page document. Please copy it double-sided, place in a protective sleeve and post in the laboratory, the Emergency Department, the patient care area(s) and any other sites in your facility designated for Ebola patient care.
- When updates to the bulletin are issued, it will be necessary to replace the posted copies with the new version(s). Please keep a record of the locations where the bulletin has been posted so all the old copies are replaced with the new version containing the current information.

Ebola Assays: Turnaround Time (TAT)

- TAT by definition 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. As stated in the November 12, 2014 Technical Bulletin, the TAT for the initial r-RT PCR Ebola- Zaire assay **after the specimen is received in the PHEL laboratory will not exceed 24 hours.** The TAT will vary (within the 24 hours), depending on:
 - When the specimen was received (between 8AM and 5PM or after regular PHEL business hours).
 - Whether there are problems associated with the specimen collection, handling, packaging and paperwork requiring correction before analysis can proceed.
 - 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.

Ebola Assays: Turnaround Time (TAT), cont.

- Samples that are positive in the initial PHEL r-RT PCR Ebola Zaire test are shipped to CDC using World Courier. Given the limitation in shipping positive Ebola samples it is expected that sample may not arrive at CDC until 24 to 48hrs after the initial result is obtained on a weekday and longer if initial result is obtained on a Friday unless the case is emergent enough that CDC provides a mechanism for urgent delivery of the specimen. **Once the sample is received at CDC a panel of tests is performed and reported within 24 hours.**
- All of the above emphasize the importance of following protocols, rechecking at all steps in the collection packaging, shipping, completion of forms and submission to minimize problems that could delay the TAT and impact patient care.

Clinical Laboratory Testing on Patients Under Investigation for Ebola

The NJ Communicable Disease Service in conjunction with Local health and the CDC has the responsibility to determine whether Ebola disease is high on the list of differential diagnoses and whether the suspicion is high enough to warrant specific Ebola testing at PHEL. Aside from the clinical symptoms the decision to perform the Ebola assay is based on some key clinical laboratory test results.. The basic diagnostic tests of interest are:

- Chemistry (BMPs LFTs, Mg etc.)
- Blood Gas
- CBC
- PT/INR
- Blood Culture
- Malaria- either by smear or antigen test

Every acute care hospital in New Jersey needs to be able to perform this testing. Provisions should be made to perform these tests on site when ordered and as soon as possible. CDC has repeatedly indicated that proper donning and doffing with PPE, strict adherence of laboratory staff to standard laboratory safety precautions and decontamination procedures are adequate for safe processing in the laboratory of specimens from patient under investigation for Ebola. A risk assessment by each institution is a must to determine where and what laboratory testing should be performed. In the PHEL October 10th 2014 survey of New Jersey hospital laboratories the majority of the respondents indicated that Ebola specimens will be processed in the routine laboratory and roughly 30 percent in a specially designated area away from the clinical laboratory .

Ebola Testing Algorithm

The Department of Defense rRT-PCR Ebola Zaire test assay is currently available through the NJDOH Public Health and Environmental Laboratories (PHEL) and sixteen other public health laboratories nationwide. 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).

Each hospital laboratory should prepare to collect and ship specimens to NJ PHEL for initial diagnostic testing, and if required, to the CDC for prognostic follow-up testing.

Ebola Testing Algorithm – Initial Testing at PHEL

1. Prepare materials and staff for response

a. Materials on hand and prepared for shipment of specimens.

- 3 or 4 ml lavender top EDTA plastic tubes
- small clear biohazard Ziploc bags
- Absorbent material
- Ambient Category A shipping system: Outer UN Certified Class 6.2 box with internal support for secondary container, secondary container (rigid plastic screw cap), bubble wrap to support specimens inside secondary container, USDOT Infectious Substance label, e.g. Infecon 3000
- Overpack box - Styrofoam lined to accept the inner ambient 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 is required to be at 2-8 C, however, freezing is not a problem for this analysis
- Dangerous Goods Shippers Declaration and LAB-05 form

b. 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 available at www.cdc.gov/labtraining (Attached)

c. Prepare Ebola Go-Kit in TWO PIECES – for PATIENT ROOM and for STAGING AREA.

- **For PATIENT ROOM (Hot Zone, Full PPE 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.
- **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

Ebola Testing Algorithm, cont.

- The remainder of the specimen preparation can be done in a clean area in the laboratory with no gloves and 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 decon occurs.

2. Contact Public Health Authorities

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 link for current directory: <http://nj.gov/health/lh/directory/lhdselectcounty.shtml> The local health department with contact the Communicable Disease Service.

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

Local health officials, the Communicable Disease Service and the CDC will determine the need for testing and where the specimens should be sent. The New Jersey Public Health Laboratory, in addition to 16 other state public health laboratories, has the capacity to perform the Department of Defense, rRT-PCR Ebola Zaire assay and will be the likely testing site for initial test.

3. Receipt of Testing Approval

If public health authorities determine a need for testing the patient, you will be given a CDS approval (case) number. This number should be used on all paperwork and specimen labels and will be a means of tracking 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 hand to package the specimen for transport. Order the test in your system and create labels.

4. Collect Blood

Have the laboratory prepare an "Ebola Go Kit" to bring into the patient area. (see above)

- a. Supply patient care area with purple top tubes, Ziploc bags with absorbent material, specimen labels and spray bottle with freshly prepared 10%v/v bleach (prepared fresh daily)

PATIENT ROOM

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

Ebola Testing Algorithm, cont.

5. Package Blood: Begins in Staging Area, Completed in Clean Area

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, impermeable lab coat and face protection are required if working outside the BSC. Skin, eyes, nose and mouth should be barrier protected.
- c. Gloves, impermeable lab coat are 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 container to person in clean area to finish packaging.

CLEAN AREA:

- a. 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.
- b. Prepare three copies of the Shipper's Certification for Ground Transport and one copy of the LAB-05 with Chain of Custody.
- c. Have the courier sign the Chain of Custody. Keep a copy of all paperwork.

6. Results

If the initial specimen tests negative: 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.

If the initial specimen tests positive: The PHEL will send the specimen to CDC for confirmatory testing. The patient may be moved to a different facility for follow-up care, however, all clinical laboratories should be prepared for the event that the patient will be cared for in their facility.

Ebola Testing Algorithm, cont.

Ebola Testing Algorithm – Followup Testing at CDC (positive patients)

The need for follow-up testing will be determined in consultation with the New Jersey Communicable Disease Service and CDC.

1. Prepare materials and staff for response

- a. Maintain materials as described above. Note: different collection tubes or containers may be required, but should be commonly available in clinical laboratories. The Communicable Disease Service will provide advice on types of samples to collect and shipment temperature conditions required.
- b. Maintain a minimum of two certified shippers as described above.
- c. **Establish an account with World Courier. Currently World Courier is the only courier which will carry Ebola specimens. Account application form is attached.**

Contact:

Jessica Deveau
jdeveau@worldcourier.com
1-516-354-2600 x3038
1313 Fourth Avenue
New Hyde Park, NY 11040

- d. Forms required for followup testing at CDC.: CDC DASH (effective 12/5/14 pre-filled with NJ Contact information) and CDC VSPB form,(Attached) and hospital chain of custody form. NOTE; CDC DASH FORM IS SEPARATE FROM THIS DOCUMENT
- e. ***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***

2. Testing approved by Communicable Disease Service and CDC Viral Special Pathogens Branch

Molecular EVD testing with other FDA-approved devices.

The FDA has issued EUA approval for some commercially available EVD tests. The New Jersey Department of Health does not recommend utilization of FDA EUA methods at this time. All such tests carry the FDA provision that patient results obtained with these assays, including positive test results, should not be used for patient management decisions.

Updated Risk Assessment of Procedures

Procedure	Recommendation
Centrifugation	Should be performed with biohazard sealed buckets or sealed rotor. The buckets or rotor should be opened inside a BSC2.
Homogenization	Procedures requiring homogenization of any specimen type should be avoided or performed with extreme care due to the risk of spray or splash.
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 made 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	<p>Malaria antigen detection kits may assist with 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.</p> <p>The effects of some inactivation/decontamination procedures on the performance of some rapid antigen tests for malaria have been investigated¹⁶. Thin blood smears should be fixed in methanol for 15-30 minutes and dried prior to staining. The use of additional heat inactivation is not considered necessary for Ebola decontamination and has been found by some parasitologists to cause disruption to the parasite morphology.</p> <p>Thick blood films should not be hemolysed with water, but should be stained with Giemsa stain that includes Triton X-100 to inactivate Ebola virus.</p> <p>Validated malaria PCR assays that have been approved by the Clinical Laboratory Evaluation Program for clinical use may be used to detect malarial parasites.</p> <p>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</p>

Updated Risk Assessment of Procedures, cont.

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 BSC2 with PPE as described above. 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 any rapid culture systems, on any specimen.
Pre-transfusion testing	Please refer to the American Association of Blood Banks’ Ebola information sheet http://www.aabb.org/press/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 in New York City (NYC), the NYC Office of the Chief Medical Examiner (OCME) must be contacted immediately. The OCME will take custody of the decedent and make the final determination about disposition of the remains. Facilities outside of NYC should contact their coroner or medical examiner for further guidance on the procedure in their locality.
Specimen storage	<p>With the exception of circumstances where retention is required by regulations, long- term storage of specimens is discouraged. It is recommended that specimens collected from suspected or confirmed EVD cases be isolated from other specimens in the laboratory. As soon as is practical after testing has been completed and it has been confirmed by the CDC or PHL that the samples are not needed for further evaluations, they should be disposed of in an appropriate manner (see below).</p> <p>Note – details of specimen decontamination and disposal should be documented for any samples from a confirmed EVD patient, or a PUI of unknown status. While the relevant division at CDC has agreed to not classify these as select agent samples, that classification being reserved for positive cultures, they do reserve the right to request information and confirmation of destruction/disposal.</p>

Updated Risk Assessment of Procedures, cont.

Specimen decontamination and disposal	<p>Wet a piece of gauze with a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) and wipe the outside of the specimen container.</p> <p>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.</p> <p>A list of EPA-registered disinfectants can be found at: http://www.epa.gov/oppad001/list-l-ebola-virus.html</p> <p>Note: Bleach or acidic chemicals must NOT be mixed with TRIZOL or 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.</p>
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References

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Attachment I

Packaging and Shipping Division 6.2 Materials: What the Laboratorian Should Know - 2014

Sponsored by the Centers for Disease Control and Prevention
National Laboratory Training Network

Course Number

P.A.C.E.® Course Number: 288-26-14

FL Course Number: 20-461824

Description

Individuals who perform any duties related to packaging and shipping Division 6.2 Materials must receive training on a recurring basis. This eLearning course will assist laboratorians or others who package or ship laboratory materials to meet that requirement. Additionally, the course will inform supervisors or other employers of their responsibilities regarding certification of employees.

This course is intended to assist with meeting training requirements and will assist individuals seeking either initial certification or recertification. A series of exercises and case studies will allow participants the opportunity to expand their knowledge of the regulatory requirements, practice applying the regulations as they participate in realistic scenarios, and properly document training as a part of the certification process their employers will complete.

The course contains numerous job aids which will assist in course completion and be useful as learners are called upon to perform the duties related to this course.

Audience

This basic to intermediate level course is intended for learners who perform any portion of the classification, packaging, documentation or shipping processes for Division 6.2 Materials. It will also benefit supervisors and employers who must complete the certification process.

Objectives

At the conclusion of this program, the participant will be able to:

- Summarize the source of regulatory oversight for packing and shipping hazardous laboratory materials.
- Discuss training and certification requirements for hazardous materials with your employer.
- Categorize hazardous materials prior to shipping.
- Label hazardous materials in accordance with DOT, IATA, and USPS regulations.
- Demonstrate the ability to properly document the shipment of laboratory-related hazardous materials.
- Recognize security threats associated with shipping laboratory specimens.

Registration - Free Registration

- Locate the course online at www.cdc.gov/labtraining
- Follow the link to register for the course in TRAIN.
- If you have difficulty with the online registration process, please email labtraining@cdc.gov.
- For additional program information, email labtraining@cdc.gov or (404) 498-6022

Continuing Education

The Centers for Disease Control and Prevention Laboratory Training Branch is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. This course is approved for 2.0 contact hours.

This course has been approved for 2.0 contact hours in the category of Supervision/Administration, Quality Control/Quality Assurance, and Safety for Florida Laboratory Licensees.

Special Needs

Course content is closed captioned where applicable and optimized for a screen reader. For a complete list of courses, visit www.cdc.gov/labtraining labtraining@cdc.gov or call (404) 498-6022.

**New Jersey Department of Health
Public Health Infrastructure, Laboratories and Emergency
Preparedness**

REQUEST FOR TESTING OF SUSPECTED SELECT AGENTS AND CHAIN OF CUSTODY

CLINICAL SPECIMENS/REFERRED CULTURE	ENVIRONMENTAL/OTHER SAMPLES																		
NJDOH Case Number: _____ Lab Accession Number: _____ <i>(Lab Use Only)</i> Name of Requesting Agency/Institution: _____ Address: _____ City: _____ State: _____ Zip: _____ Phone: _____ Fax: _____ Name of Attending Physician: _____ Patient Name: _____ <i>(Last)</i> <i>(First)</i> Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female DOB/Age: _____ Collection Date: _____ <i>(MM/DD/YYYY)</i> <i>(MM/DD/YYYY)</i> Describe Specimen: _____ <input type="checkbox"/> Bacteria <input type="checkbox"/> Fungi <input type="checkbox"/> Virus <input type="checkbox"/> Parasite Biochemical Reactions (if applicable): Growth at <input type="checkbox"/> 25°C <input type="checkbox"/> 37°C <table style="width:100%; border: none;"> <tr> <td>Gram stain</td><td><input type="checkbox"/> + <input type="checkbox"/> -</td> <td>Oxidase</td><td><input type="checkbox"/> + <input type="checkbox"/> -</td> <td>Colistin (R)</td><td><input type="checkbox"/> + <input type="checkbox"/> -</td> </tr> <tr> <td>Motility</td><td><input type="checkbox"/> <input type="checkbox"/></td> <td>Catalase</td><td><input type="checkbox"/> <input type="checkbox"/></td> <td>Indole</td><td><input type="checkbox"/> <input type="checkbox"/></td> </tr> <tr> <td>Hemolysis</td><td><input type="checkbox"/> <input type="checkbox"/></td> <td>Urease</td><td><input type="checkbox"/> <input type="checkbox"/></td> <td>B-lactamase</td><td><input type="checkbox"/> <input type="checkbox"/></td> </tr> </table> Suspected Select Agent: _____ NOTE: An NJDOH approval (case) number is required for testing to proceed. To obtain case numbers for clinical specimens, call CDS at 609-826-5964, Mon.-Fri., 8:00 AM to 5:00 PM; 609-392-2020 all other times.	Gram stain	<input type="checkbox"/> + <input type="checkbox"/> -	Oxidase	<input type="checkbox"/> + <input type="checkbox"/> -	Colistin (R)	<input type="checkbox"/> + <input type="checkbox"/> -	Motility	<input type="checkbox"/> <input type="checkbox"/>	Catalase	<input type="checkbox"/> <input type="checkbox"/>	Indole	<input type="checkbox"/> <input type="checkbox"/>	Hemolysis	<input type="checkbox"/> <input type="checkbox"/>	Urease	<input type="checkbox"/> <input type="checkbox"/>	B-lactamase	<input type="checkbox"/> <input type="checkbox"/>	NJDOH PHILEP Case Number: _____ Lab Accession Number: _____ <i>(Lab Use Only)</i> Name of Requesting Agency/Institution: _____ Address: _____ City: _____ State: _____ Zip: _____ Phone: _____ Fax: _____ Sample Collected By: _____ Collection/Pickup Site: _____ Collection Date & Time: _____ / _____ <input type="checkbox"/> AM <input type="checkbox"/> PM <i>(MM/DD/YYYY)</i> Describe Sample: _____ Analysis Requested (Suspected Select Agent): _____ NOTE: Environmental samples that test negative for Select Agents must be retrieved by a local or state law enforcement officer 30 days after result notification. Samples that are not claimed after 30 days will be destroyed. I, _____ <i>(submitter signature)</i> acknowledge this statement on _____ <i>(MM/DD/YYYY)</i> NOTE: For environmental samples call PHILEP at 609-341-2008, Mon.-Fri., 8:00 AM to 5:00 PM; 609-392-2020 all other times.
Gram stain	<input type="checkbox"/> + <input type="checkbox"/> -	Oxidase	<input type="checkbox"/> + <input type="checkbox"/> -	Colistin (R)	<input type="checkbox"/> + <input type="checkbox"/> -														
Motility	<input type="checkbox"/> <input type="checkbox"/>	Catalase	<input type="checkbox"/> <input type="checkbox"/>	Indole	<input type="checkbox"/> <input type="checkbox"/>														
Hemolysis	<input type="checkbox"/> <input type="checkbox"/>	Urease	<input type="checkbox"/> <input type="checkbox"/>	B-lactamase	<input type="checkbox"/> <input type="checkbox"/>														

CHAIN OF CUSTODY			
X	Relinquished by (Print) _____	Date: _____	Time: _____
X	Relinquished by (Signature) _____		
X	Relinquished by (Print) _____	Date: _____	Time: _____
X	Relinquished by (Signature) _____		
X	Relinquished by (Print) _____	Date: _____	Time: _____
X	Relinquished by (Signature) _____		

Page of Pages

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) _____

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

Consignee: (Name) _____

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

Nature and Quantity of Hazardous Material:

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

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: _____

_____: Date: _____

(Signature)



Customer Profile / New Account Request

For Internal Use Only:

WC Rep Name: _____ Territory Code: _____ WIC Code: _____

CLIENT INFORMATION

Company Name: _____	Department: _____
Contact Name: _____	Title: _____
Address: _____	State: _____
City: _____	Zip: _____
Phone: _____	Fax: _____
Email: _____	Federal Tax ID: _____

Company Name: _____ consents to screening of all cargo tendered to World Courier, Inc. and their authorized representatives from this date forward.

All shipments are subject to Conditions of Carriage

Is the account an IAC (Indirect Air Carrier)? _____ If yes, please provide IAC # : _____

Is the account a CCSF (Certified Cargo Screening Facility)? _____ Have you applied to become a CCSF? _____

BILLING INFORMATION

Please complete if different from above

Company Name: _____	Contact Name: _____
Address: _____	State: _____
City: _____	Zip: _____
Phone # : _____	Fax # : _____
Email: _____	Charge Code: _____
PO Number: _____	Billing Ref: _____

Client Signature

World Courier

_____/Date _____/Date

F-AD_USA/2011/031/

**** NO SPECIMENS ACCEPTED WITHOUT PRIOR CONSULTATION ****
 Call (404) 639-1510 or (404) 639-1115 for authorization to ship specimens.

Instructions for submitting Diagnostic Specimens to CDC's Viral Special Pathogens Branch

1 Label all samples with the following information: Patient's name or ID number, specimen ID number, date of collection

<p>For PCR/virus isolation, submit:</p> <ul style="list-style-type: none"> • Preferred: whole blood (purple, yellow, or blue top tube), fresh frozen tissue. Serum can also be used if only sample available. • Minimum sample volume: 4 mL • Fresh frozen tissues should be at least 1 cm³, except for biopsies. • Please ship sample frozen on dry ice in a plastic tube. Do not freeze glass tubes. 	<p>For serologic testing, submit:</p> <ul style="list-style-type: none"> • Serum (red top tube or serum separator) -- or -- • Whole blood (purple, green, or blue top tube) • Minimum sample volume: 4 mL • Please ship sample refrigerated or frozen on ice packs. 	<p>Immunohistochemistry, submit:</p> <ul style="list-style-type: none"> • Formalin-fixed or paraffin-embedded tissues may be submitted: Preferred: lung, kidney, liver, spleen Other tissues can be submitted if available. • Paraffin blocks are preferred, particularly if death was not recent. • Ship paraffin blocks or formalin-fixed tissue at room temperature. Do not freeze. • An autopsy or surgical report must accompany the specimen.
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The following forms should be completed for each patient:

- CDC Specimen Submission Form
- VSPB Diagnostic Specimen Submission Form, on following page.
- For Hantavirus Pulmonary Syndrome testing, also submit the HPS Case Report Form
- Include a copy of all above Forms with the specimens.

Specimen packaging requirements:

- Please contact your state health department for approval to submit a specimen to CDC for laboratory testing.
- Contact your state and/or local health department and CDC to determine the proper category for shipment based on clinical history and risk assessment by CDC. State guidelines may differ and state or local health departments should be consulted prior to shipping.
- Package in accordance with the International Air Transport Association, regulations to prevent leakage. (See <https://www.iata.org/publications/dgr/Pages/manuals.aspx> and http://www.hercenter.org/regsandstandards/Transporting_Infectious_Substances_Safely.pdf)
- Include the following information on the Diagnostic Specimen Submission Form: your name, the patient's name, test(s) requested, date of collection, laboratory or accession number, and the type of specimen being shipped.
- On the outside of the box, specify how the specimen should be stored: **Frozen, Refrigerated, or Do Not Refrigerate.**
- Send specimens by overnight courier. International submitters should consider door-to-door shipment via air transport to expedite specimen delivery to CDC.
- Be sure to check '**Saturday Delivery**' if desired.
- Email the tracking number to the Viral Special Pathogens Branch.

5 HOW TO SUBMIT THE SPECIMENS AND FORMS TO CDC

<p>Specimen submission address (if approved by state):</p> <p>Centers for Disease Control and Prevention ATTN STAT LAB: VSPB, Unit #70 1600 Clifton Road NE Atlanta, GA 30333 Phone: (404) 639-1115</p>	<p>Form submission by email:</p> <p>Hit the 'Send to CDC' button at the bottom right of page 2. Your computer will generate an email containing the completed information. Hit the 'Send' button in your email application to send the email to CDC. Acknowledgement of receipt is not provided.</p>	<p>Form submission by fax:</p> <p>(404) 639-1118 or (404) 639-1509</p>
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Viral Special Pathogens Branch Diagnostic Specimen Submission Form

• Hantavirus Pulmonary Syndrome (HPS)* and other hantaviruses	• Tick-borne Encephalitis	PLEASE COMPLETE ONE FORM PER PATIENT
• Ebola HF*	• Lymphocytic choriomeningitis (LCM)	
• Marburg HF*	• Hemorrhagic Fever with Renal Syndrome (HFRS)	
• Lassa Fever*	• Rift Valley Fever	
• Crimean-Congo hemorrhagic fever (CCHF)*	• Other hemorrhagic fevers: _____	

*indicates a Notifiable Disease

Please check off boxes to indicate testing request(s).

PATIENT NAME:	Patient ID no.:
DOB:	DATE OF SYMPTOM ONSET:
CLINICAL DESCRIPTION:	

No.	Specimen ID No.	State Lab ID No.	Date collected	Specimen type
1				
2				
3				
4				
5				

FOR STATE HEALTH DEPARTMENTS	
Report/send results to:	Phone no., fax no., and email address:
Person's name:	
Affiliation:	
State Health Lab:	Phone no. and email address:
Person shipping specimen(s):	
Affiliation:	Phone no. and email address:
Physician's name:	
Affiliation:	Phone no. and email address:
State health department contact:	Phone no. and email address:
	Airway bill # (if known):

Instructions: You must have internet access and an email address to submit this Form electronically. Upon hitting the 'Send to CDC' button, a PDF is created, attached to an email, which you should then send to the address which appears in the address header; you may also cc: others. Acknowledgement of receipt by CDC is not provided. To print this form in order to fax or mail it, be sure to Save this form first.

SEND TO CDC

For hantavirus/HPS, be sure to provide a copy of this Form - to your

