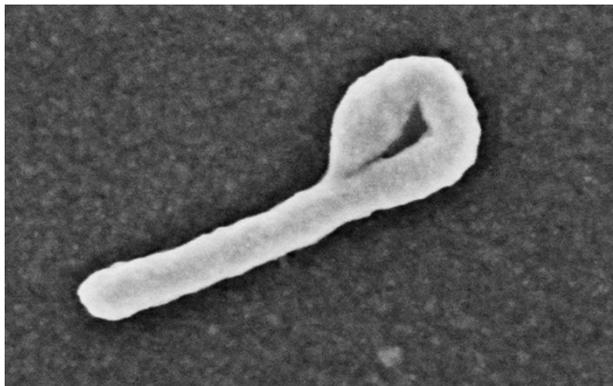


Ebola Virus Testing & Shipping Overview With Q & A Session

October 30, 2014



Welcome & Introductions

- Thank you everyone for participating
- Webinar panel introductions
- Today's presentation will be recorded and distributed after via the Oregon LRN (Laboratory Response Network) and HAN (Health Alert Network) messaging systems
 - Information to register for either of these alerting systems is contained at the end of this presentation

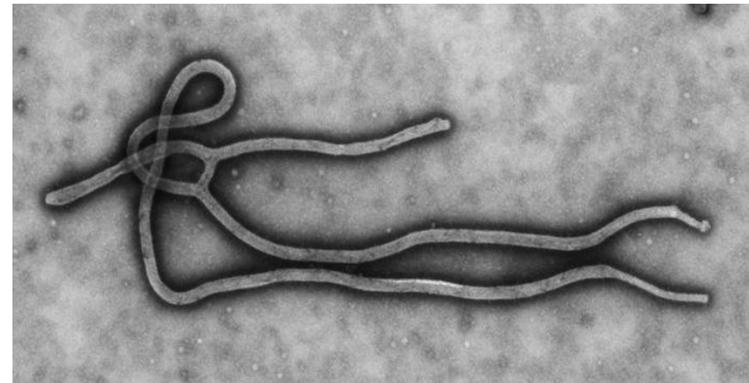
Submitting Questions

- Webinar participants will be in a listen only mode
- To submit a question during this presentation please use the “CHAT box” feature in your webinar window



Outline

- Ebola virus testing
 - Reporting Suspect Case
 - Public Health Consultation
 - Approval process
 - Sample Collection, Handling and Shipping
 - Laboratory testing
 - Result turn around times
- Ebola virus shipping
 - “Suspect” Category A
 - Shipping Materials
 - Transport
 - Training
- Review previously submitted questions
- Discuss webinar participant questions
- What you can do to prepare?



- Case Definition for Ebola Virus Disease (EVD)
- Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease in the United States
- Factsheet: Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease  [PDF - 1 page]
- Interim Guidance for Monitoring and Movement of Persons with Ebola Virus Disease Exposure
- Guidance: Air Medical Transport for Patients with Ebola
- Procedures for Personal Protective Equipment
- Ebola virus disease Information for Clinicians in U.S. Healthcare Settings
- Interim Guidance: EMS Systems & 9-1-1 PSAPs: Management of Patients in the U.S.
- Safe Management of Patients with Ebola Virus Disease (EVD) in U.S. Hospitals
- Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals
- Guidance for Safe Handling of Human Remains of Ebola Patients in U. S. Hospitals and Mortuaries
- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus

<http://www.cdc.gov/vhf/ebola/>

More >

Process Overview



1. Report Suspect Case



2. Public Health Consultation



3. Testing Approval



4. Sample Collection and Shipping



5. Laboratory Testing

Testing Overview

Report Suspect Case

- All suspected Ebola virus disease (EVD) cases are required by law to be **REPORTED** to the public health department *immediately (24/7)*
 - Healthcare providers and clinical labs must call local health department
 - County Health Departments must call state health department
- **Call 971-673-1111** to reach the state health department doctor on call



Local Health Department Directory

Baker County
Benton County
Clackamas County
Clatsop County
Columbia County
Coos County
Crook County
Curry County
Deschutes County
Douglas County
Gilliam County
Grant County

Harney County
Hood River County
Jackson County
Jefferson County
Josephine County
Klamath County
Lake County
Lane County
Lincoln County
Linn County
Malheur County
Marion County

Morrow County
Multnomah County
Polk County
Sherman County
Tillamook County
Umatilla County
Union County
Wallowa County
Wasco County
Washington County
Wheeler County
Yamhill County



Healthoregon.org/LHD

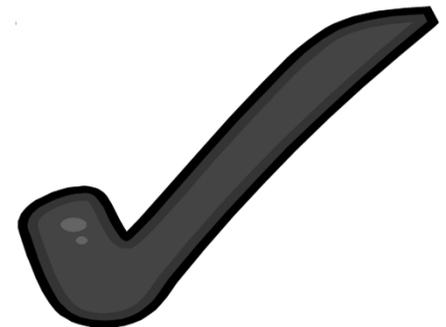
Public Health Consultation

- Local and State Public Health Officials will work with you and the Centers for Disease Control and Prevention (CDC) to assess and determine the testing needs
- Suspect case must meet case definition based on symptoms and any travel or exposure history
- Public Health Officials must approve laboratory testing



Testing Approval

- The CDC will not accept specimens or assign a testing laboratory without **prior public health consultation and approval**
- If testing is warranted after consultation, the CDC will provide direction on where the submitting laboratory is to send the sample for testing



Testing Laboratories



- The Oregon State Public Health Laboratory (OSPHL) currently **does not** accept specimens for Ebola virus testing
- Specimens must be submitted directly from you to the one of the CDC determined laboratories
- Testing will occur at one of the designated LRN Public Health Reference Laboratories that has the Ebola virus assay or to the CDC, whichever option allows for the fastest turnaround time that can assist with patient care
- Currently 24 designated laboratories nationwide

Submitting Samples

- You must work with the Oregon State Public Health Laboratory (OSPHL) and State Health Department to complete the required CDC testing forms prior to any specimen submission
- Instructions for completing these forms are contained on the OSPHL Ebola webpage for submitting samples
 - <http://public.health.oregon.gov/LaboratoryServices/SubmittingSamples/Pages/Ebola-Testing.aspx>
 - <http://bit.ly/phlevd> (short link)



OSPHL Ebola Webpage

<http://bit.ly/phlevd>

The screenshot shows the Oregon Health Authority Public Health website. The main navigation bar includes a search box, links for About Us, Contact Us, and Jobs, and a menu with categories: Topics A to Z, Data & Statistics, Forms & Publications, News & Advisories, Licensing & Certification, Rules & Regulations, and Public Health Directory. The breadcrumb trail reads: Public Health > Laboratory Services > Submitting Samples. The page title is "Submitting Samples for Ebola Virus Testing Through the CDC". A "SHARE" button is visible in the top right. The main content area contains a "Contact Us" box for State Public Health Laboratory Services and a detailed text block explaining that OSPHL does not accept specimens for Ebola virus testing; instead, specimens must be submitted directly to a CDC-determined laboratory after prior consultation with the state health department. Below this, a section titled "Please follow these steps:" lists six numbered instructions: 1. Report suspect cases to the local health department immediately and call 971-673-1111. 2. Collect, prepare, and store specimen(s) according to CDC's interim guidance. 3. Complete two forms: the Viral Special Pathogens Branch (VSPB) Diagnostic Submission Form and the OSPHL CDC Specimen Submission Short Form. A note states: "Do not send specimen(s) to the CDC until steps 4 and 5 are complete." 4. Fax the OSPHL Short Form to the OSPHL Virology Department at 503-693-5605 and call 503-693-4100 to notify. 5. The OSPHL will complete the official CDC Specimen Submission Form on your behalf and fax or e-mail it to your facility. 6. Submit your specimen(s) to the testing laboratory determined by the CDC with the official CDC Specimen Submission Form (with barcode) and the VSPB form. A left sidebar contains a "Test Menu Search" box with a grid of letters A-Z and a "View All Lab Tests" link. Below that is a "Submitting Samples" section with a list of links, including "Submitting Samples for Ebola Virus Testing" which is highlighted. Other links include Notice of Privacy Practices, Submission of Specimens, Submitting Enteric Outbreak Specimens, Submitting Samples for Enterovirus 68 Testing, Submitting Flu Specimens, Submitting Specimens for Influenza-Like Illness (ILI) Outbreak Testing pamphlet (pdf), OSPHL Specimen Rejection Policy, Courier Service, Specimen Shipping and Transport (non-courier), and Billing Information.

Submitting Samples

Notice of Privacy Practices

Submission of Specimens

Submitting Enteric Outbreak Specimens

Submitting Samples for Ebola Virus Testing

Submitting Samples for Enterovirus 68 Testing

Submitting Flu Specimens

Submitting Specimens for Influenza-Like Illness (ILI) Outbreak Testing pamphlet (pdf)

OSPHL Specimen Rejection Policy

Courier Service

Specimen Shipping and Transport (non-courier)

Billing Information

Public Health > Laboratory Services > Submitting Samples

Submitting Samples for Ebola Virus Testing Through the CDC

The Oregon State Public Health Laboratory (OSPHL) **does not** accept specimens for Ebola virus testing. Specimens must be submitted **directly** to a laboratory determined by the Centers for Disease Control and Prevention (CDC). The CDC will not accept specimens or assign a testing laboratory without **prior consultation**. The state health department usually does this consultation.

Contact Us

State Public Health Laboratory Services

Submitters must work with OSPHL to complete required CDC forms prior to specimen submission.

Please follow these steps:

1. **Report** suspect cases to the local health department **immediately**. Call 971-673-1111 to reach the state health department doctor on call.
2. **Collect**, prepare, and store specimen(s) according to the CDC's interim guidance.
3. **Complete** the following two forms:
 - 📄 Viral Special Pathogens Branch (VSPB) Diagnostic Submission Form
 - 📄 OSPHL CDC Specimen Submission Short Form

Do not send specimen(s) to the CDC until steps 4 and 5 are complete.
4. **Fax** the OSPHL Short Form to the OSPHL Virology Department at 503-693-5605. Call the OSPHL at 503-693-4100 to notify us that this form was sent.
5. The OSPHL will complete the official CDC Specimen Submission Form on your behalf, and fax or e-mail it to your facility. This form includes a barcode that the CDC requires.
6. **Submit** your specimen(s) to the testing laboratory determined by the CDC with the official **CDC Specimen Submission Form (with barcode)** and the **VSPB form**. (Do not submit the OSPHL Short Form with the specimen.)

Preferred Specimens For Testing

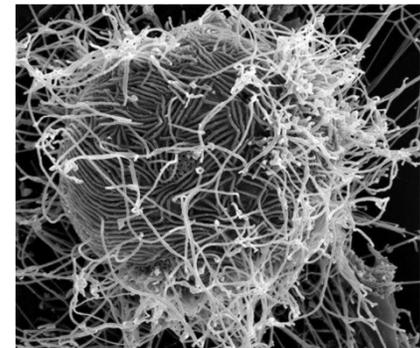
- A minimum volume of 4mL whole blood in *plastic* collection tubes
- **DO NOT** submit specimens in glass containers or in heparinized tubes
- Whole blood preserved with EDTA is preferred but whole blood preserved with; sodium polyanethol sulfonate (SPS), citrate, or with clot activator is acceptable
- It is not necessary to separate and remove serum or plasma from the primary collection container

Preferred Specimens For Testing

- Specimens should be immediately stored or transported at 2-8°C or frozen on cold-packs
- Short-term storage of specimens prior to shipping to CDC should be at 4°C or frozen
- Specimens other than blood may be submitted upon consult with the CDC

Ebola Lab Testing

- As of 10/24/2014, 10 LRN Public Health Laboratories nationwide have performed 36 tests
 - On 9/30/2014 the State Laboratory in Austin, TX, along with CDC confirmed the first case of Ebola in the United States
 - On 10/23/2014, the New York City Public Health LRN Reference Laboratory and the CDC confirmed the fourth case of Ebola in the US



Testing Overview

- The Emergency Use Authorization (EUA) Ebola virus laboratory test conducted at approved Public Health Laboratories is the EUA Ebola Zaire (EZ1) rRT-PCR Assay
 - <http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM408334.pdf>
- Currently 24 Public Health LRN Laboratory locations nationwide provide this testing capability
 - Initial molecular diagnostic testing
 - CDC currently performs all confirmatory testing

Results Turn Around Time

- Laboratory test results “Turn Around Time” may depend on several factors;
 - When and how you ship the samples
 - i.e., FedEx Priority overnight vs. alternate transport
 - Late in the afternoon vs. morning send out, etc.
 - Which determined location sample(s) will be sent
 - Time of receipt in testing laboratory
 - PCR test can generally be completed in 4-6 hours

Shipping Overview

Sample Collection & Precautions

- Collect, prepare, and store specimen(s) according to the CDC interim guidance
 - <http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>
 - Specimen Handling
 - Environmental Cleaning and Lab Waste
 - Preferred Specimens
 - Packaging and Shipping Specimens
 - Testing Information



Safety Precautions



- CDC Guidance for Healthcare Workers
 - <http://www.cdc.gov/vhf/ebola/hcp/index.html>
 - <http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>
- The recent enhanced personal protective equipment (PPE) guidance is centered on three principles:
 - Rigorous training and competency with PPE, including donning and doffing in a systemic manner
 - No skin exposure when PPE is worn
 - PPE donning and doffing supervised by a trained monitor

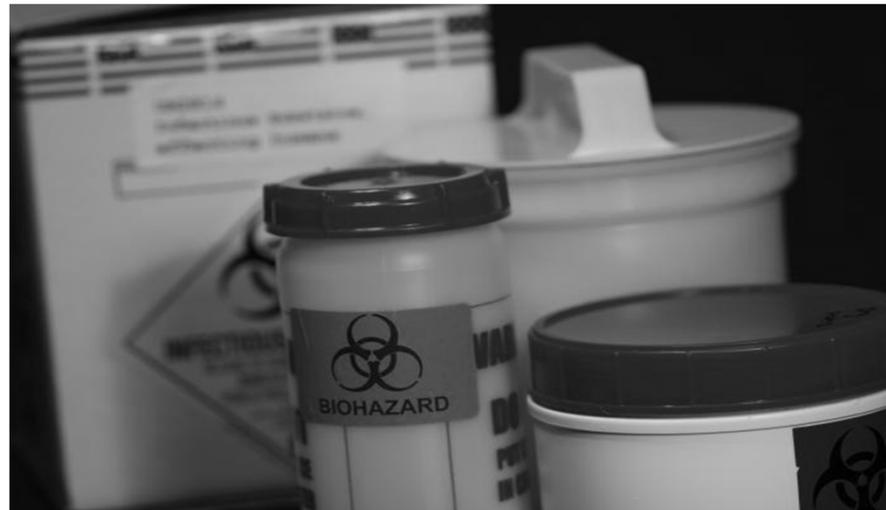
Ebola Associated Waste

- CDC Waste Management Guidance
 - <http://www.cdc.gov/vhf/ebola/hcp/medical-waste-management.html>
- For additional questions please contact:
- ebola.oregon@state.or.us



Ebola Sample Shipping

- US Department of Transportation (DOT) Guidance
 - <http://phmsa.dot.gov/hazmat/phmsa-provides-guidance-for-transporting-ebola-contaminated-items>
- The SHIPPER is responsible for meeting all infectious substance shipping requirements

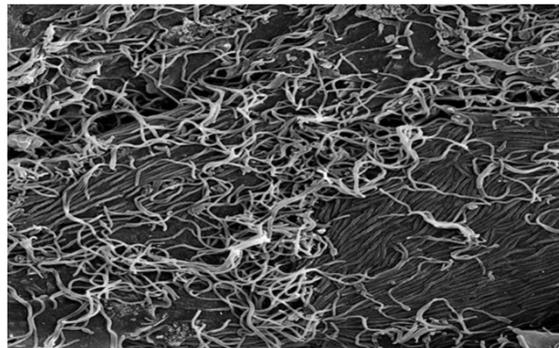


Category A Substances (UN 2814)

- **Category A**: An infectious substance in a form capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs
 - **Category A poses a higher degree of risk than Category B**
- Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions or **professional judgment** concerning the individual circumstances of the source
 - **Ebola virus must be classified as a Category A infectious substance for shipping purposes**

“Suspect” Category A

- The classification “**Suspect Category A**” may be applied for shipping a sample for initial Ebola virus testing
- If the patient or sample has already been identified as potentially containing Ebola virus, the “suspect” classification cannot be used and sample must be classified as just “Category A”

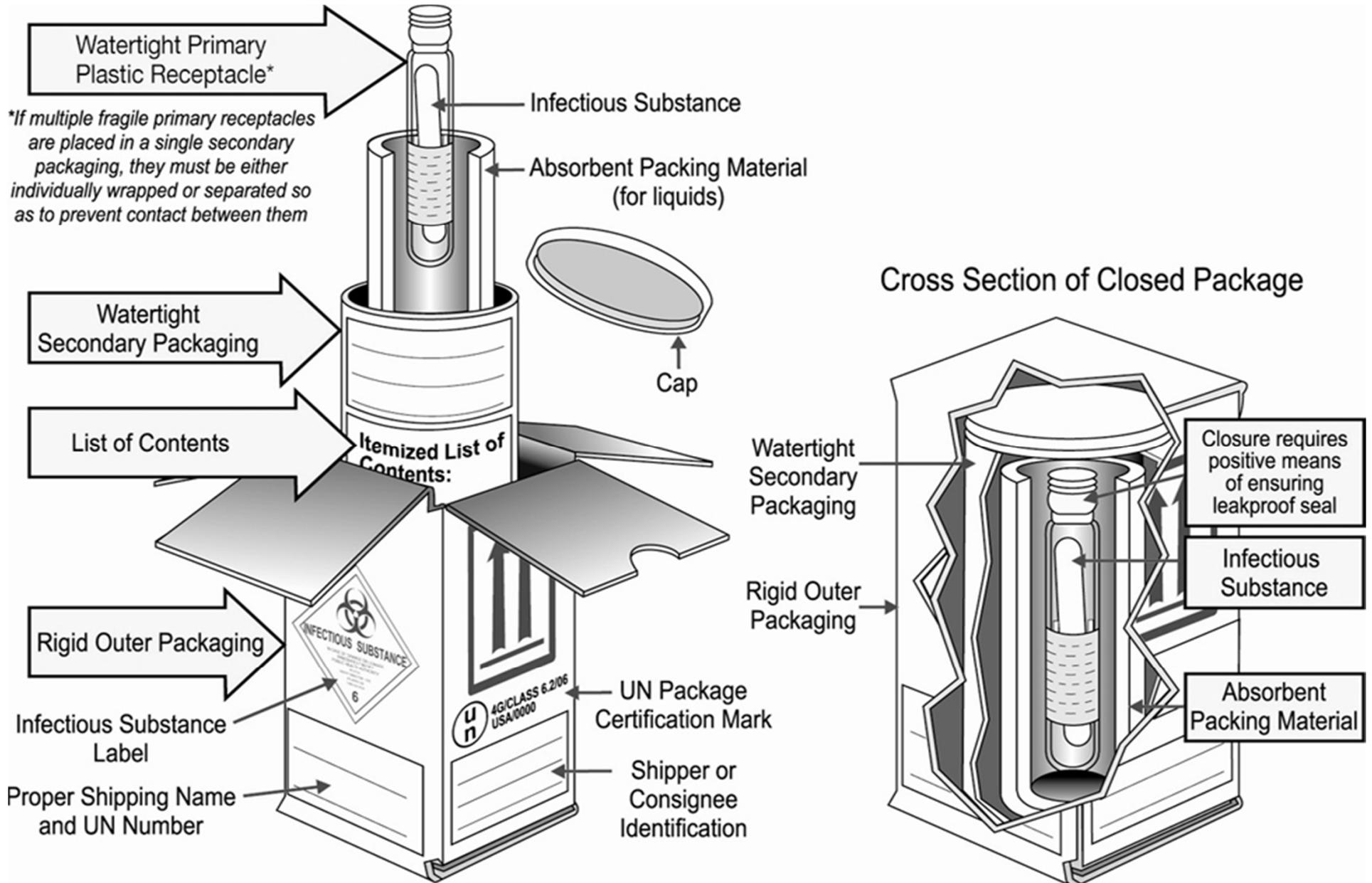


Known Ebola Samples

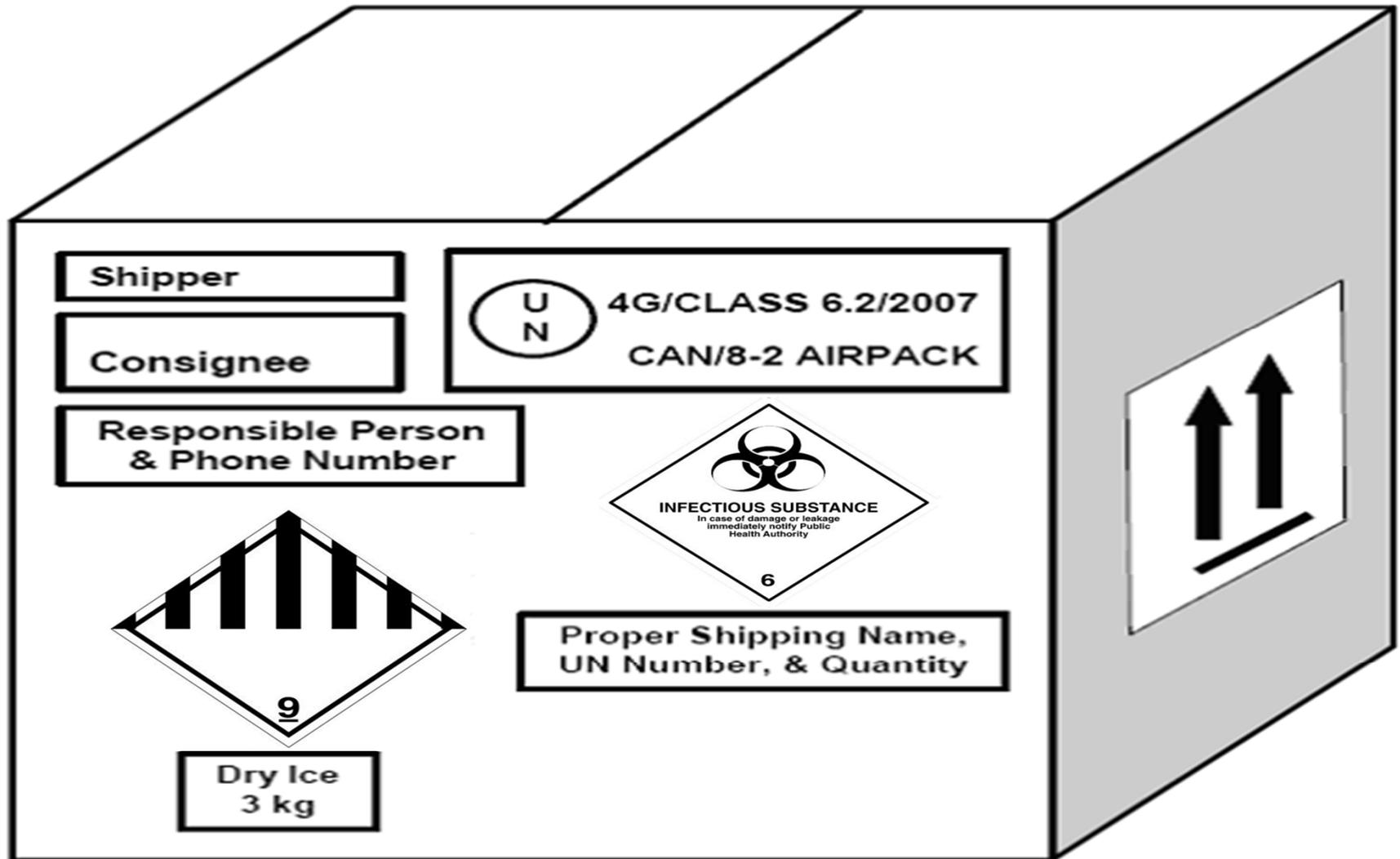
- Material from known Ebola virus patients or samples must conform to Category A shipping requirements, and additional Tier 1 Select Agent Regulations (<http://www.selectagents.gov/>)
- Ebola virus is a Tier 1 Select Agent
 - <http://www.cdc.gov/vhf/ebola/hcp/select-agent-regulations.html>



Category A Shipping Example



Category A With Dry Ice Example



A completely labeled outer package. The primary container inside the package contains a Category A infectious substance and is packed according to PI 602.

- **Category A shipping materials can be purchased from several vendors, some common examples are:**
- <http://www.saftpak.com/>
- http://www.labeline.com/store_uk/index.php?app=cms&ns=display&ref=dangerous_goods_packaging&sid=qd0ue2017770q1ej216h9dbbzn56je8s
- http://www.dgsupplies.com/Infectious-Packaging_c_93.html
- http://www.casingcorp.com/new_fr1000a-p-1.htm
- <http://www.labelmaster.com/shop/unpackaging/infectious-substance-packaging>
- http://www.keikaventures.com/s_infectsubstance_diag_specimen.php
- <http://www.airseacontainers.com/>

Category A Transport

- **FedEx** is currently refusing to accept **known** Ebola samples because of the regulatory variation FX-09 since Ebola virus is a Risk Group 4 organism
 - FedEx is currently still accepting “Suspect” Category A shipments
- **World Courier** is an example commercial courier service currently accepting **known** Ebola samples
 - <http://www.worldcourier.com/>
- **Private couriers** may transport Category A substances if they are appropriately trained and able to transport a select agent (if **known** to be Ebola)

Category A Preparedness

- Ensure your facility has appropriate plans or arrangements to potentially ship Category A materials
 - Discuss your current and potential courier options
 - Setup free accounts with FedEx or World Courier ahead of time
 - Consult with Public Health Officials for specific questions or guidance
 - Have Category A materials on hand and have trained personnel

Transport Guidance or Questions

- For any additional questions or guidance regarding Category A transport, please send inquiries to:

ebola.oregon@state.or.us

Who Needs Training?

- Category A infectious substance training applies to any individual who;
 - Loads, unloads or handles shipment
 - Marks, labels or otherwise prepares containers or packagings for transport
 - Prepares a Shipper's Declaration for dangerous goods or is responsible for documentation
 - Is responsible for safety of transporting dangerous goods

Category A Training

- According to **49 CFR Part 172.704(a)**, the training must cover the following:
 - General awareness/familiarization with hazardous substances and regulations, and
 - **Function-specific training** of tasks
 - i.e., how to appropriately classify, pack, label shipments
- **Facility Specific Safety, Security Awareness, and Emergency Response** information



Category A Training

- Several commercial training options are available for initial and/or refresher infectious substance shipping training
- There is a free online **refresher** course from CDC and the NLTN (National Laboratory Training Network) available here:

<https://cdc.train.org/DesktopShell.aspx>

- Participants will need to create a free CDC TRAIN account and then search for the course to register
 - Course ID is 1048174, or can be found by keyword search “Shipping”
 - The complete title of the online course is “Packing and Shipping Division 6.2 Materials 2014”

Category A Training

- The OSPHL has announced it will be offering free regional shipping training courses to train appropriate personnel how to ship infectious substances and dry ice
- Contact your local health department to establish and coordinate a regional training in your area

Additional Shipping Guidance

- The American Society of Microbiology (ASM) and the Association of Public Health Laboratories (APHL) offer Sentinel Laboratory Guidelines for Packing and Shipping of Infectious Substances
- www.asm.org/images/pdf/Clinical/ps11-15-10final.pdf



Questions & Answers

Previously Submitted Questions

- **Q:** *When should samples be collected?*
- **A:** Ebola virus is detected in blood only after the onset of symptoms, usually fever
 - It may take up to 3 days after symptoms appear for the virus to reach detectable levels
 - Virus is generally detectable by real-time RT-PCR from 3-10 days after symptoms appear
 - If the onset of symptoms is <3 days, a later specimen may be needed to completely rule-out Ebola virus, if the first specimen tests negative
- **Specimens ideally should be taken when a symptomatic patient reports to a healthcare facility and is suspected of having an Ebola exposure**

Previously Submitted Questions

- **Q:** *Will the State Public Health Lab or county public health offices package and transport any samples to the CDC designated lab for the actual Ebola testing?*
- **A:** No. All responsibilities for classification, packaging and shipping are that of the shipper. Facilities must have their own trained personnel classify and package specimens. Transport can be conducted by a commercial or contracted courier but the transporter must be appropriately trained.

Previously Submitted Questions

- *Q: What are the expectations for Oregon hospitals and clinical labs?*
- **A:** Have appropriate Category A materials on hand, and have appropriate staff trained to ship a Category A sample
 - i.e., Complete Category A shipping box with labels, absorbent and cushioning material, documentation, and inner primary and secondary containers
- Have Category A transport option(s)

Previously Submitted Questions

- *Q: What lab is designated for the Ebola confirmation testing in our state?*
- **A:** Currently the CDC must confirm all Ebola virus samples. There are currently no labs in Oregon performing the initial DoD/LRN RT-PCR assay or confirmatory Ebola virus testing.

Previously Submitted Questions

- *Q: What assistance will be provided by public health in the event testing is needed?*
- **A:** Public health officials will provide technical guidance, consultation and assistance to walk you thru the procedures of obtaining approval for testing, and then assist with the forms you will need to send samples to be tested at CDC or their designated lab.

Previously Submitted Questions

- *Q: Could you please specify the responsibilities of the medical center and that of PH?*
- **A:** Your responsibilities as an infectious substance shipper are to ensure you have:
 - Appropriate materials on hand to package the shipment;
 - Appropriate staff currently trained to ship infectious substances;
 - Have plans for your transport options.
- Public Health's role in this Ebola scenario is to provide technical assistance, guidance and support

Previously Submitted Questions

- *Q: Should two specimens be sent?*
- **A:** When indicated, yes. The CDC has the capability to conduct additional more extensive laboratory testing including tests for other hemorrhagic fever viruses and serology studies. The CDC and designated LRN testing laboratory will make the determination and will communicate any requests for more than one sample to be sent.

Previously Submitted Questions

- **Q:** *What value does the LRN provide in performing testing if all specimens are being sent to CDC for testing?*
- **A:** The DoD EUA assay was primarily deployed to assist health departments and healthcare facilities in timely care and management of individuals presenting in the U.S. who are at risk of Ebola virus infection. Ruling in or out Ebola in persons arriving from affected areas requires careful consideration of clinical, epidemiological and laboratory data by persons familiar with Ebola virus disease. CDC consultation is required for every case tested with the LRN deployed assay.

Previously Submitted Questions

- **Q:** *What about the use of newly FDA approved Ebola detection tests?*
- **A:** Clinical laboratories considering implementation these must remember the importance of connecting with Public Health authorities whenever Ebola Virus Disease is suspected
- All suspected cases of Ebola virus must be immediately reported to the State Health Department
- All confirmatory testing must be conducted at CDC.
- The currently used EUA Department of Defense (DoD)/LRN test being conducted at CDC designated LRN Public Health Laboratories is supported by the CDC, which provides standardized reagents and protocols, as well as technical support assistance to all designated testing labs

New FDA Test Question Continued

- **A:** Prior to implementing any assay, laboratories should conduct a Biosafety Risk Assessment to identify sources of risk and implement safety measures to mitigate them.
- Laboratories may be required to perform a verification before reporting any patient results to clinicians
- **The current guidance from CDC is for testing to occur at the pre-determined 24 LRN Public Health Lab's**

Webinar Participant Questions



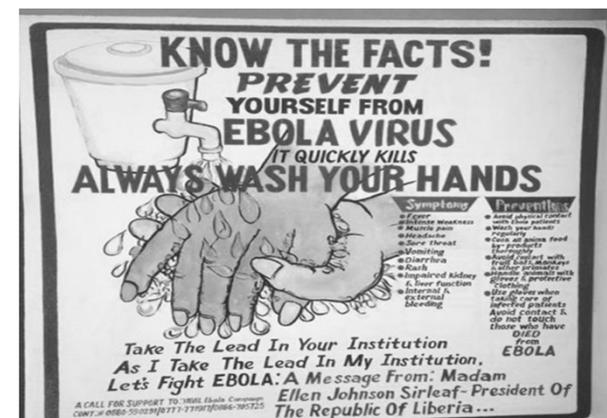
*Please use the question/chat box
feature to ask a question*

What Can You Do To Prepare?

- Maintain appropriate supplies
 - i.e., shipping materials, PPE
- Have appropriate personnel trained in Division 6.2 infectious substance packaging and shipping
- Have written plans and policies in place to address handling a suspected Ebola virus patient
- Review and update existing plans as necessary
- Review current biosafety procedures
 - i.e., PPE donning and doffing, use of primary and secondary safety containment devices, disinfection and decontamination practices, contact notifications

What Can You Do To Prepare?

- Discuss your transport options
- Conduct a tabletop or drill
- PPE familiarization
- Provide and post fact sheets and other guidance materials
- Refresher trainings
- Ensure appropriate staff receive State notifications – i.e., HAN and LRN messages



LRN Notifications

- For questions about the Laboratory Response Network (LRN), Sentinel Laboratories, or registration information for the Oregon State Public Health Laboratory LRN notification system, please contact:

LRN.office@state.or.us or

Robert.E.Nickla@state.or.us

HAN Notifications

- For questions and registration information about the Oregon Health Authority, Health Alert Network (HAN) notifications, please contact:

HAN.Oregon@state.or.us

Ebola Questions?

Have more Ebola questions?

Please contact

ebola.oregon@state.or.us



Thank You

Everyone who participated, and to our
Oregon Health Authority Partners at
Acute and Communicable Disease Prevention
(ACDP) & Health Security Preparedness and
Response (HSPR)

Oregon State Public Health Laboratory
3150 NW 229th Ave Suite 100
Hillsboro, OR 97124
(503) 693-4100