Utah Department of
Health & Human Services
Utah Public Health Laboratory

Submitting Samples to UPHL for Ebola or Marburg Virus Disease Testing

Key Points

- Utah Public Health Laboratory (UPHL) will accept specimens for Ebola or Marburg virus testing after consultation with the State Epidemiologist and CDC.
- Immediately report suspect cases to your local health department and the Utah Department of Health and Human Services (UDHHS). Call 1-888-374-8824 to reach the UDHHS epidemiologist on call.
- Ruling in or ruling out Ebola or Marburg in persons arriving in the U.S. from affected countries requires careful consideration of clinical, epidemiological and laboratory data by persons familiar with Ebola Virus Disease (EVD) or Marburg Virus Disease (MVD). **Consultation with CDC (and a CDC PUI case number) is therefore required for every case tested with the LRN deployed assay. UDHHS will facilitate this consultation.**
- Call 801-965-2561 (M-F) or 801-560-6586 (24/7) to contact a UPHL BT Team member and initiate required sample submission paperwork.
- Sample requirements:
    - 2 plastic EDTA (lavender/purple top) tubes each containing a minimum of 4 mL of blood, bagged separately
    - Packaged and transported to UPHL as Category A Infectious Substance. (Both tubes may be packaged and transported to UPHL in the same Category A shipper.)

INTENDED USE STATEMENT

The FilmArray® NGDS Warrior Panel is a qualitative, multiplexed, nucleic acid-based in vitro diagnostic test intended for use with the FilmArray 2.0 system. The FilmArray NGDS Warrior Panel detects and identifies Ebola virus, Marburg virus, *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis,* and *Coxiella burnetii* nucleic acids directly from human whole blood (EDTA). The FilmArray NGDS Warrior Panel is intended to test individuals with signs and symptoms of infection from biothreat agents and/or individuals who are at risk for exposure or may have been exposed to these agents.

The FilmArray NGDS Warrior Panel is indicated as an aid in the diagnosis of the hemorrhagic fevers caused by Ebola and Marburg virus as well as anthrax, plague, tularemia, and Q fever in response to a suspected or confirmed bioterrorism event or outbreaks. It is for diagnostic use in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the appropriate Department of Defense and public health authorities.

Results are for the presumptive identification of Ebola virus, Marburg virus, *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, and *Coxiella burnetii*. The definitive identification of Ebola virus, Marburg virus, *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, and *Coxiella burnetii* requires additional testing and confirmation procedures in consultation with the appropriate Department of Defense and public health

authorities for whom reports may be necessary. Negative results do not preclude infection with these biothreat agents and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

The FilmArray NGDS Warrior Panel is solely for use by United States Department of Defense laboratories and laboratories designated by the Department of Defense.

Communication/Reporting to Public Health Reminder

It is ***critical*** for health care providers to first contact Local and State public health for consultation if they have a PUI. If further communication with CDC is necessary, that contact should be initiated through the Utah Department of Health. A delay in public health knowing about a patient first may cause a loss of valuable time and resources in ensuring that the patient and contacts are managed properly and testing is expedited.

When Should Specimens be Collected for Ebola or Marburg Testing at UPHL?

Ebola and Marburg virus are 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 from 3-10 days after symptoms appear.

Specimens should be taken as soon as possible after a symptomatic patient reports to a health care facility and is suspected of having an Ebola or Marburg exposure. If the first test is negative, a second test should be performed at 72 hours after the onset of symptoms to rule out Ebola or Marburg. All positive assay results must be confirmed by the CDC.

Preferred Specimens for Ebola or Marburg Testing

For each test, collect two (2) plastic EDTA (lavender/purple top) tubes each containing a minimum of 4 mL of blood. Label each specimen with patient's name or ID number, specimen ID number, and date of collection (testing cannot be performed if specimens are not labeled). One specimen will be tested at UPHL and the other will forwarded by UPHL to the CDC for confirmatory testing. Each institution should develop protocols to safely collect, handle and transport specimens to the institution's laboratory. These protocols should include details on how the guidance below (based on CDC guidance at http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html) will be implemented in the institution. It is advisable that the institution's personnel who will be participating in these procedures in the clinical setting and in the laboratory conduct drills to ensure proficiency.

Specimens collected for Ebola or Marburg testing at UPHL/CDC should be packaged and shipped without attempting to open collection tubes or aliquot specimens. If additional testing is to be performed at your institution, please collect separate specimens for that testing.

Bag each tube separately.

Do not submit specimens in glass containers or in heparinized tubes.

Specimens should be immediately stored and/or transported at 2-8°C on cold-packs.

Improper collection, storage, or transport of specimens may lead to false negative results.

All laboratorians and other health care personnel collecting or handling specimens must follow established standards compliant with the OSHA bloodborne pathogens standards (https://www.osha.gov/SLTC/bloodbornepathogens/standards.html), which includes blood and other potentially infectious materials. These standards include wearing appropriate personal protective equipment (PPE) and following all safety rules for all specimens regardless of whether they are identified as being infectious.

Recommendations for specimen collection by staff: Any person collecting specimens from a patient with a case of suspected Ebola virus disease (EVD) or Marburg virus disease (MVD) should wear gloves, fluid-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth. **Additional PPE may be required in certain situations** (see http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html).

Transporting Specimens within the Hospital/Institution

In compliance with 29 CFR 1910.1030, specimens should be placed in a durable, leak-proof secondary container for transport within a facility. To reduce the risk of breakage or leaks, do not use any pneumatic tube system for transporting suspected Ebola or Marburg virus specimens.

Spill Clean-up

In the case of a spill in the laboratory, the basic principles for blood or body substance spill management are outlined in the OSHA bloodborne pathogens standards (see above link). There are no disinfection products with specific label claims against the Ebola or Marburg virus. Enveloped viruses such as Ebola and Marburg are susceptible to a broad range of hospital disinfectants used to disinfect hard, non-porous surfaces. In contrast, non-enveloped viruses are more resistant to disinfectants. As an added precaution, use a disinfectant with a higher potency than what is normally required for an enveloped virus to disinfect potentially Ebola- or Marburg-contaminated surfaces. EPA-registered hospital disinfectants with label claims against non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, poliovirus) are broadly antiviral and capable of inactivating both enveloped and non-enveloped viruses.

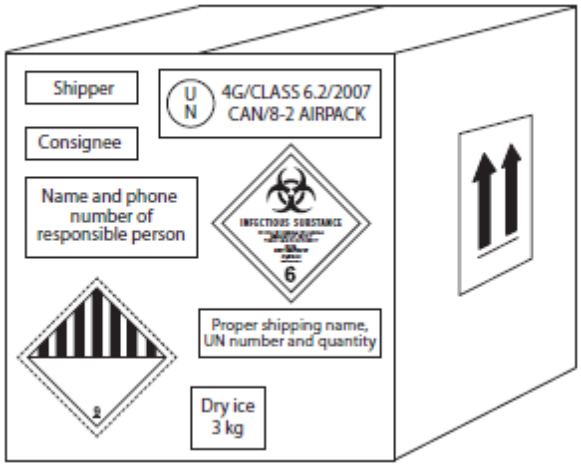
See the Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus (http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html) for recommendations regarding the cleaning and disinfection of patient care area surfaces including the management of blood and body fluid spills. These recommendations also apply to cleaning and disinfecting in a laboratory where specimens are being processed from persons under investigation, or with probable or confirmed Ebola or Marburg virus infections.

Packaging and Transporting Specimens to UPHL

It is the responsibility of the institution submitting samples, as shipper, to correctly package and label specimens to meet shipping regulations. Individuals packaging and shipping specimens for Ebola or Marburg testing should use packing instruction 620, International Air Transport Association (IATA) guidelines for Category A, which utilizes a triple packaging system. A trained and certified individual is required to package specimens using Category A guidelines. Please follow these steps:

- Check that the primary specimen tube cap is securely closed.
- Ensure patient's name and second identifier are on the specimen tube and match information on the specimen submission form.
- Place tube in a Biohazard bag with absorbent material.
- Follow exactly all packing instructions provided by the manufacturer of the insulated Category A shipper you are using.
- Place both copies of CDC Form 50.34 in the box before folding the box flaps down and securing them with sealing tape. Do not put paperwork in the same bag as the specimens.
- Mark and label (or mark out, as appropriate) the outside of the shipper appropriately. Markings and labels must include:
    - Shipper's and consignee's name and addresses
    - Responsible person – name and telephone number of someone at your facility who can answer questions about the shipment.
    - A Class 6 diamond-shaped "Infectious Substance" label.
    - A label with proper shipping name and UN number (UN2814, Infectious Substance, Affecting Humans).
    - If the package contains more than 50 mL of a liquid or frozen liquid, it must have orientation marks – arrows on opposite sides of the package.
    - Category A outer packages also must have a "UN" label (from the manufacturer).
- Fill out a Shipper's Declaration for Dangerous Goods form and include it with the package (specific instructions for filling out this form may be found at the end of this document).
- Packages transported by courier should also be accompanied by written emergency response information.

FIGURE 4. A completely labeled outer package. The primary container inside contains a liquid Category A infectious substance and is packed according to PI 620



Abbreviation: PI = packing instructions.

Test Turn-around-time

Test results should normally be available within six (6) hours after specimens are received by the UPHL BT Team.

Results Reporting

Specimens that test **positive** using this assay will be reported as "Ebola virus detected" and/or "Marburg virus detected." Definitive identification requires additional testing and confirmation procedures in consultation with the appropriate Department of Defense and public health authorities for whom reports may be necessary.

Specimens that test **negative** will be reported as "Ebola virus not detected" and/or "Marburg virus not detected." If fever or symptoms have been present for less than 72 hours, a repeat test may be required to rule out Ebola or Marburg virus infection. Negative results do not preclude infections with these biothreat agents and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Important information about Ebola and Marburg virus testing

- A negative test result for Ebola or Marburg virus from a blood specimen collected less than 72 hours after onset of symptoms **does not necessarily rule out Ebola or Marburg virus infection** and should not be the sole basis of a patient treatment/management decision.
    - If the patient is still symptomatic after 72 hours, the test should be repeated.
    - If the patient has recovered from the illness that brought them to medical attention, a repeat test is not required.
- A negative test result for Ebola or Marburg virus from a blood specimen collected more than 72 hours after symptom onset rules out Ebola or Marburg virus infection.
- Positive Ebola or Marburg virus results are considered **presumptive** until confirmed by CDC.
- False positive results may occur from cross-contamination by target organisms, their nucleic acids or amplified product.
- Improper collection, storage, or transport of specimens may lead to false negative results.
- Specimens from patients who have received therapeutics or vaccines based on nucleic acid sequences derived from Ebola or Marburg virus may exhibit false positive or other confounding test results.

Testing When Public Health Officials Determine It Is Not Indicated

Testing performed on individuals who do not meet the intended use criteria as defined in FDA labeling or without consultation with public health is not advisable and carries inherent risk.

- Testing outside the approved parameters of the EUA is considered to be a test modification and the laboratory performing the testing is responsible for establishing and assuring the safety and efficacy of the test in the patient population being tested (e.g. asymptomatic individuals). **UPHL will not perform testing outside the approved parameters of the EUA.**
- A positive result in a patient who is at low risk for EVD or MVD may be a false positive and can cause undue public health concern.

- Patients without symptoms but with risk factors for EVD or MVD who are tested outside the recommended parameters of the assay may be overly assured by a negative result and not comply with federal or state Movement and Monitoring requirements or seek medical care if symptoms develop.

- Individuals with a travel history to West Africa may be at risk for other infectious diseases, including malaria and Lassa Fever. All risk factors must be assessed and testing for other conditions should be considered.

Procedure for Submitting Samples to UPHL

1. **Immediately report suspect cases to your local health department and Utah Department of Health and Human Services (UDHHS). Call 1-888-374-8824 to reach the UDHHS epidemiologist on call.**

2. **Collect two 4 mL EDTA blood tubes (lavender/purple top). Bag each tube separately. Collect, prepare, and store specimen(s) according to the above guidance and CDC's interim guidance (**http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html**).**

3. **Contact a UPHL BT Team member at 801-965-2561 (office) or 801-560-6586 (24/7 BT phone*) for a CDC Specimen Submission Form 50.34, which is required for specimen submission. This person will be your UPHL Contact for this process. This person will provide you their contact information. Please provide a valid email address for the point of contact at your institution.**

   *NOTE: 801-560-6586 is a 24/7 number that is often forwarded to one of the BT Team's personal phones (Kim, Annette, Jenni, and Courtney). If you get voicemail when calling one of the above numbers, please leave a message with your contact information before calling the next number. You may also call Kim's cell 801-560-6816.

4. **UPHL will fill out the following sections of Form 50.34:**

   STATE PHL Info
   LABORATORY EXAMINATION REQUIRED
   - **→Test order Code**
   - **→Test order name**
   - **→Suspected agent**
   - **→At CDC, bring to the Attention of**

   PATIENT INFORMATION
   - **→Patient Name**
   - **→Birthdate**
   - **→Age**
   - **→Age Units**
   - **→Sex**

5. **UPHL will then log the sample in their database, assign a UPHL accession number, and email the CDC Specimen Submission Form 50.34 to you.**

6. **You will fill out the following sections (online, please – CDC will not accept hand-written forms):**
   LABORATORY EXAMINATION REQUIRED
   - **→Date sent to CDC**

   PATIENT INFORMATION
   - **→Clinical Diagnosis**
   - **→Date of Onset**
   - **→Fatal/Date of Death**

SPECIMEN INFORMATION
ORIGINAL SUBMITTER
→Including Specimen ID
INTERMEDIATE SUBMITTER (→if needed)
PATIENT HISTORY
→Brief Clinical History
→State of Illness
→Type of infection
→Therapeutic Agent(s) During Illness
EPIDEMIOLOGICAL DATA
→Extent
→Travel History
→Exposure History
→Relevant Immunization History
PREVIOUS LABORATORY RESULTS/COMMENTS (as available)

7. **Email the completed CDC Form 50.34 back to your UPHL Contact (and to kchriste@utah.gov) for their records and print two (2) copies of the form to send with your specimen (barcodes will be generated on the form upon printing).**
8. **UPHL will fill out the Viral Special Pathogens Branch (VSPB) form.**
9. **Follow UPHL instructions for packaging, marking, labeling, and transporting the sample to UPHL.**

For additional resources regarding Ebola and Marburg virus, including disease reporting requirements, investigative guidelines, and additional links to the CDC, visit the CDC Ebola Information Page or the CDC Marburg Information page at http://www.cdc.gov/vhf/ebola/ or https://www.cdc.gov/vhf/marburg/.

Dangerous Goods Shipper's Declaration

How to fill out the declaration of dangerous goods form, 11-19-2014

A fillable form can be found at http://www.iata.org/whatwedo/cargo/dgr/Documents/Shippers-Declaration-Column-Format-Fillable.pdf

1. **Shipper:** Enter the full name and address of the shipper.
2. **Consignee:** Enter the full name and address of the consignee.

   Utah Public Health Laboratory
   4431 South 2700 West
   Taylorsville, UT 84129

3. **Air Waybill number:** Enter the number of the air waybill. If transporting by courier, leave this blank.
4. **Page of pages:** Enter the page number and the total number of pages.

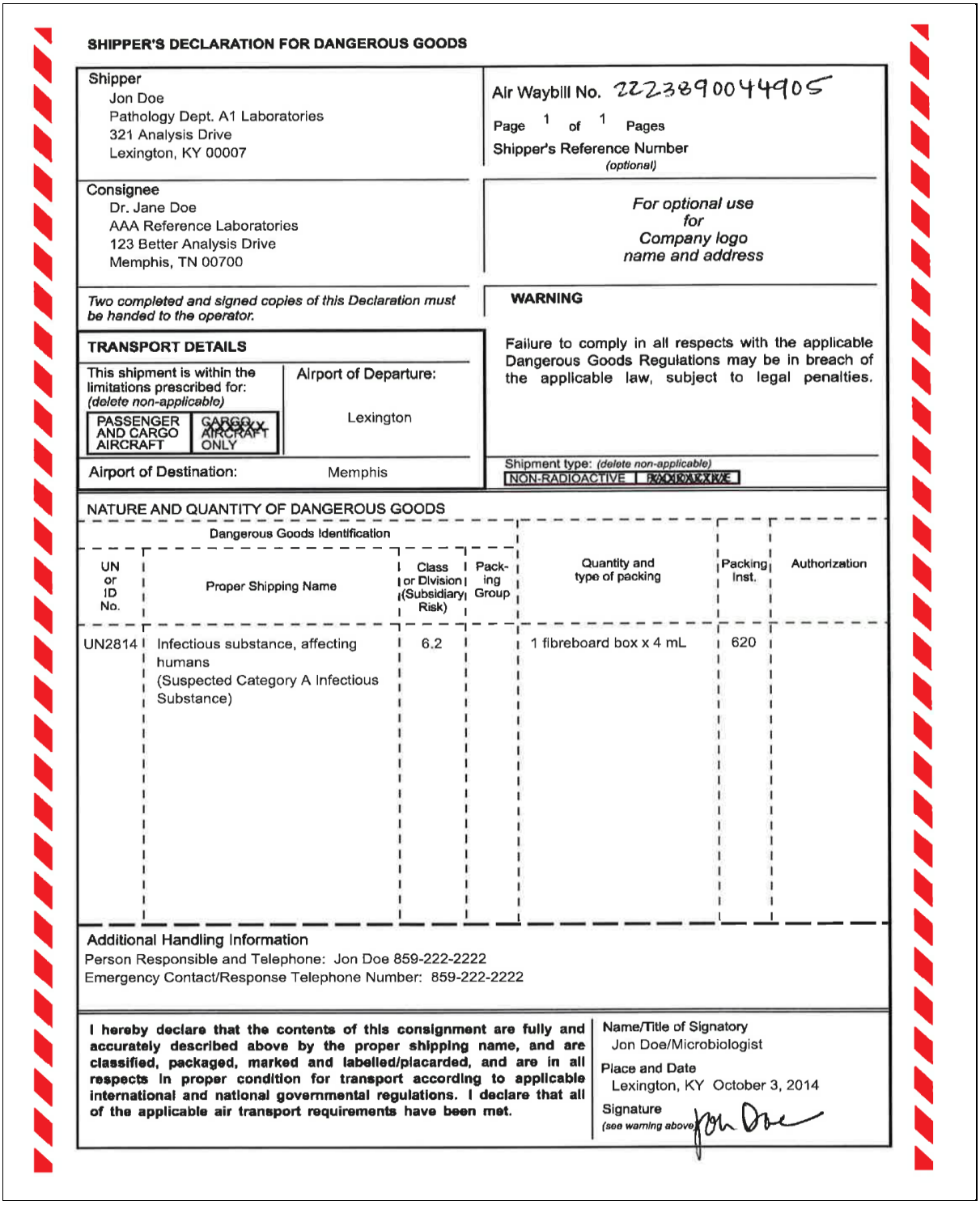
5. **Airport of departure:** Enter the full name of the city or airport of departure. Do not use the three-letter airport code. If transporting by courier, leave this blank.
6. **Airport of destination:** Enter the full name of the city or airport of destination. Do not use the three-letter airport code. If transporting by courier, leave this blank.
7. **Nature and quantity of dangerous goods:** The following should be included in this section:
    - **UN or ID no.:** Enter **UN2814** for the specimens.
    - **Proper shipping name:** Enter **Infectious Substance, Affecting Humans** with the technical name **(Suspected Category A Infectious Substance)**. Do not enter any other technical name (genus or species):

      Infectious Substance, Affecting Humans (Suspected Category A Infectious Substance)

    - **Class or division:** Enter the number **6.2** for the infectious substance.
    - **Packing group:** Leave this blank.
    - **Quantity and type of packing:** Enter the total volume (not number) of specimens within the shipping container and the appropriate package type.
    - **Packing instruction:** Enter the number **620**.
    - **Authorization:** Leave blank.
    - **Additional handling information:** A telephone number answered by a person 24 hours per day seven days per week must be provided. This person must be knowledgeable of what is being shipped and must be available during the entire time the package is in transit.

    If you are including dry ice in your shipment, add the following on an additional line.
    - **UN or ID no.:** Enter **UN1845** for dry ice.
    - **Proper shipping name:** Enter **Dry Ice** or **Carbon dioxide, solid**.
    - **Class or division:** Enter the number **9** for the dry ice.
    - **Packing group:** Leave this blank.
    - **Quantity and type of packing:** Enter the total volume of specimens within the shipping container and the appropriate package type.
    - **Packing instruction:** Enter the number **954**.
    - **Authorization:** Leave blank.
    - **Additional handling information:** A telephone number answered by a person 24 hours per day seven days per week must be provided. This person must be knowledgeable of what is being shipped and must be available during the entire time the package is in transit.
8. **Name and title of signatory:** Enter the name and title of the person who is signing the declaration. This information may be printed or stamped (on all copies). Enter the date and the location where the declaration form is signed. The shipper must sign the declaration, and the signature must be written by hand and not typed.
9. **Place and Date:** Enter the place from where the item is being shipped. Enter the date.
10. If shipping with FedEx: Four (**4)** copies of the Shipper's Declaration for Dangerous Goods should be printed in **COLOR**. Forms must have red diagonal hatch marks on the sides. Three (**3)** copies should be sent with the shipment and the last copy of the Shipper's Declaration of Dangerous Goods should be kept with a copy of the air waybill for two years. If transporting by courier, two (**2**) copies of the

Shipper's Declaration for Dangerous Goods should be printed (color is optional). Send one copy with the shipment and keep one copy for your records.



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper
Jon Doe
Pathology Dept. A1 Laboratories
321 Analysis Drive
Lexington, KY 00007

Air Waybill No. 222389004490 5

Page 1 of 1 Pages

Shipper's Reference Number *(optional)*

Consignee
Dr. Jane Doe
AAA Reference Laboratories
123 Better Analysis Drive
Memphis, TN 00700

For optional use for Company logo name and address

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*
PASSENGER AND CARGO AIRCRAFT | ~~CARGO AIRCRAFT ONLY~~

Airport of Departure: Lexington

Airport of Destination: Memphis

Shipment type: *(delete non-applicable)*
NON-RADIOACTIVE | ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
UN2814	Infectious substance, affecting humans (Suspected Category A Infectious Substance)	6.2		1 fibreboard box x 4 mL	620	

Additional Handling Information
Person Responsible and Telephone: Jon Doe 859-222-2222
Emergency Contact/Response Telephone Number: 859-222-2222

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory
Jon Doe/Microbiologist

Place and Date
Lexington, KY October 3, 2014

Signature *(see warning above)* Jon Doe