

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

1. PURPOSE

To provide a procedure for classifying, packing, labeling and shipping infectious agents to be delivered via courier to or from any study site that collaborates with the Naval Health Research Center Department of Respiratory Diseases Research (NHRC DRDR).

2. SCOPE

This SOP is applicable to all personnel who ship specimens out from NHRC.

3. GENERAL CONSIDERATIONS

This document is provided as a guideline for the classification, packaging, labeling, and shipping of infectious specimens. For a list of infectious substances forbidden as Biological Substance Category B specimens, please reference Attachment 7.5 (HHS and USDA Select Agents and Toxins, 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). Penalties for non-compliance are significant and could result in fines or imprisonment.

For shipment of Biological Select Agents and Toxins (BSAT), refer to SOP # BSL3-0.326 'Intra-Entity and Inter-Entity Transfer of Biological Select Agents and Toxins' for handling procedures.

Before a new collaborating laboratory elects to ship specimens to NHRC DRDR, it must first be determined if the laboratory has adequate shipping materials to prepare specimen shipments. All shipping materials shown in the attachments section of this SOP can be provided by the NHRC DRDR shipping department, if requested.

3.1. PPE

Laboratory Biosafety Level 2 PPE at a minimum requires non-latex gloves, clean laboratory coats, and safety glasses or face shield if not working in a BSC. Refer to HMIG decals and/or MSDS for additional PPE requirements for chemicals.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

4. DEFINITIONS

BSC:	Biological Safety Cabinet
CFR:	Code of Federal Regulations
Consignee:	The person who is receiving a specimen shipment.
Courier:	FedEx, DHL, UPS, World Courier, USPS
HMIG:	Hazardous Material Identification Guidelines
IATA:	International Air Transport Association
Infectious Specimen:	Any specimen type that falls under 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. See Attachment 7.5
MSDS:	Material Safety Data Sheet
NHRC DRDR:	Naval Health Research Center Department of Respiratory Diseases Research
PPE:	Personal Protective Equipment
QA:	Quality Assurance
SOP:	Standard Operating Procedure
UN:	United Nations

5. RESPONSIBILITIES

5.1. LABORATORY SECTION SUPERVISOR

The Laboratory Supervisor is responsible for ensuring compliance to this SOP and ensuring that the Shipper is appropriately qualified and trained to safely and properly handle specimens for shipping purposes.

5.2. DESIGNATED SHIPPER OF INFECTIOUS SPECIMENS

The Shipper is responsible for:

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

- Complying with this SOP and ensuring they meet training requirements including bloodborne pathogen training certification.
- Ensuring that the proper procedures are followed when classifying, identifying, packing, labeling and shipping infectious specimens.

6. PROCEDURES

6.1. PACKAGING INFECTIOUS SPECIMENS

Proper packaging of infectious specimens includes four basic requirements: watertight primary containers, absorbent material, watertight secondary containers, and sturdy outer packaging. These requirements must meet the standards for packing instruction 602 under 49 CFR 173.196 and 49 CFR 137.199.

6.1.1. USE WATERTIGHT PRIMARY CONTAINERS

All primary containers must have positive closures (such as screw-on, snap-on, or push-on lids) and must be reinforced by adhesive tape.

To prevent contact between multiple fragile primary containers, each primary unit should be individually wrapped with absorbent material.

Primary containers must be leak proof to accommodate liquid specimens or sift proof to accommodate solid specimens.

Depending on the type of infectious substance, it must first be determined whether it is permissible to ship the substance by "Passenger and Cargo Aircraft" or by "Cargo Aircraft" only.

For shipping liquid or solid infectious substances by Passenger and Cargo Aircraft, primary containers should contain no more than 50ml or 50g, respectively.

For shipping liquid or solid infectious substances by Cargo Aircraft Only, primary containers should contain no more than 4L or 4Kg, respectively.

When determining the volume of infectious specimens, be sure to include any transport media to the total volume of the specimen. The entire contents of the primary containers are considered the infectious specimen.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

Primary containers may be made of plastic or metal. See attachment 7.1.

6.1.2. USE ABSORBENT MATERIAL

Place absorbent material between the primary and secondary containers, making sure that multiple primary containers are individually wrapped to prevent contact.

Use enough absorbent material to absorb the entire content of all primary containers.

Absorbent material may include any of the examples shown in attachment 7.2.

6.1.3. USE WATERTIGHT SECONDARY CONTAINERS

Secondary containers can be any watertight packaging. See attachment 7.3.

6.1.4. USE STURDY OUTER PACKAGING

Sturdy outer packaging must consist of corrugated fiberboard, wood, metal, or rigid plastic and be appropriately sized for content.

The minimum package size that couriers will accept is 7" x 4" x 2". For smaller packages that do not contain dry ice, insert the entire package (meeting all 4 basic requirements) into an appropriate clinical shipping pack.

Each completed package must be able to withstand a 4' drop (as outlined in IATA 6.6.1).

Some examples of unacceptable forms of outer packaging are styrofoam boxes, plastic bags, paper envelopes, banker's boxes, tubes, packs, or envelopes.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

6.2. FILL OUT A LABORATORY REQUISITION FORM

A Laboratory Requisition Form # QA-4.40 and Specimen Log(s) Form # 4.50 should be filled out according to SOP # QA-0.315 Preparation of Laboratory Requisition Forms. The Specimen Log(s) should contain an accurate description of each specimen within the shipment.

Each specimen will have a label that matches the description written in the Specimen Log, per SOP # QA-0.315 Preparation of Laboratory Requisition Forms.

This Laboratory Requisition Form # QA-4.40 should be placed inside the shipment between the watertight secondary container and the sturdy outer packaging.

6.3. LABEL THE OUTER BOX OF THE INFECTIOUS SPECIMEN SHIPMENT

To avoid delays of shipments, all packages must be labeled correctly. Infectious specimen shipments must have all the following labels securely affixed to the outer packaging: (see attachment 7.4).

Package must have the Proper Shipping Name(s) of the inner contents, supplemented with the technical name(s) if appropriate, and the corresponding UN number(s) or ID number(s) preceded by the letters "UN" or "ID" as applicable. Following the UN number or ID number, it must be specified in parenthesis whether the specimen is a solid or a liquid.

- Fully infectious specimens (liquid or solid) that affect humans shall be designated UN2814.
- Fully infectious specimens (liquid or solid) that affect animals shall be designated UN2900.

Full name and address of the shipper and consignee.

Net quantity and gross weight (in metric units) of dangerous goods contained in each package must be shown, affixed next to the label with the Proper Shipping name of the inner contents.

Name and telephone number of a responsible person, listed for emergencies.

Complete Shipper and Consignee information.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

6.4. COMPLETE A SHIPPER'S DECLARATION FOR DANGEROUS GOODS

A Shipper's Declaration for Dangerous Goods must be completed when shipping a category A infectious substance with UN2814 or UN2900. A declaration is not required for shipments in which dry ice is the only hazardous material or for biological category B UN3373 substances.

Declarations must be typewritten or computer-generated. Handwritten declarations are not acceptable.

Declarations must be printed in color to show the red-striped border.

Blank Declaration forms can be found on the FedEx website:

<http://www.fedex.com/us/services/options/express/dangerousgoods/declarationforms.html>

Complete the required information on the Shipper's Declaration form:

- Shipper: Enter full name, address and telephone number.
- Consignee: Enter full name and address of recipient. When shipping infectious substances, include the phone number of a responsible point of contact.
- Air waybill No.: This number will be the same as your FedEx tracking number. See section 6.5 to generate a tracking number.
- Pages: Enter the total number of pages of the shipper's declaration.
- Transport Details: Indicate whether the shipment is restricted to "Cargo Aircraft Only" or "Passenger and Cargo".
- Airport of Departure: If shipping infectious specimens from NHRC DRDR, type in "San Diego, CA". If shipping infectious specimens to NHRC DRDR, type in the city where the nearest airport is located.
- Shipment Type: Cross out the word "radioactive".
- UN or ID Number: Enter appropriate UN number as found in section 6.3.
- Proper Shipping Name: Enter the proper shipping name of the infectious pathogen (scientific name).
- Class or Division: Enter hazard class 6.2 in this section.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

- Packing Group: For dry ice, enter “III” in this section. Biological materials are not assigned packing group numbers.
- Quantity and Type of Packaging: Enter the number of packages and what the package is made of (ex: 1 fiberboard box).
- Packing Instruction: Enter instruction “602” in this section.
- Emergency Telephone Number: Enter the name and telephone number of an emergency contact who can be reached 24 hours a day.
- Name/Title of Signatory: Enter the name of the document preparer. Note: This person must be trained to ship infectious substances prior to preparing a shipment.
- Place and Date: Enter the consignee information and date the shipment was prepared.
- Signature: An original signature in black ink is required for all Shipper’s Declarations.

If an error is made, cross out the error with a straight line and write the correct information in the appropriate section. All corrections must be in black ink and followed with an original signature from the person who prepared the declaration.

Print out at least 4 copies of the shipper’s declaration: 3 copies for the courier, 1 copy for the shipper’s records.

It is required that all shipper’s declaration records be maintained for a minimum of 2 years.

6.5. PREPARING SHIPMENT DOCUMENTS/ TO SCHEDULE PACKAGE PICK UP

Go online to the website www.fedex.com.

Click on the “Ship” tab at the top of the page.

Click on “Prepare and Manage Shipments”.

Enter User ID and password to login. To obtain this information, please contact the NHRC DRDR designated shipping technician.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

Complete recipient/consignee information.

Shipments should be billed to NHRC. To obtain account information, please contact the NHRC DRDR designated shipping technician using the shipper information list provided in Attachment 7.7 NHRC DRDR Consignee Information List.

- If shipping from NHRC, choose bill to sender.
- If shipping to NHRC, choose bill to recipient.

Select appropriate package and shipment details. Always ship infectious specimens for "Priority Overnight" delivery.

Complete the FedEx ShipAlert[®] as necessary.

Enter ship date (this will usually be "today").

Under "Shipment Details", click on the "Go To Options" button.

Under "Special Services" click on the box labeled "Dangerous Goods".

- A Disclaimer screen will appear describing the marking and labeling requirements for Dangerous Goods/Hazardous Material. After reading, click OK to select the class of your Dangerous Good.
- Dangerous goods are classified as "Accessible" or "Inaccessible" on the FedEx website. Infectious substances fall under the "Inaccessible" genre.

Click "Continue".

Print 2 copies of the air waybill – one to send and one for the shipper to file for reference in the designated filing area.

Click "Go To Next Steps".

Click "Schedule a pickup".

Follow the instructions to schedule a pickup.

Use ship to address:

Naval Health Research Center

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

US Military Base, Point Loma

ATTN: Laboratory/ 619-553-9105

McClelland Rd. & Patterson Rd.

Gate 4, Barracks Building 330

San Diego, CA 92152

6.6. SHIPMENT EXCEPTIONS

FedEx cannot pick up or deliver shipments directly to or from shipboard locations.

Shipboard sites that wish to ship specimens to NHRC DRDR must first determine their domestic shipping point from where all shipboard packages are routed.

The shipper can send the specimens to their domestic shipping point and arrange for a FedEx pick up at that location using the NHRC DRDR account. Shipments intended for ships can be arranged by an NHRC DRDR Shipboard Study Coordinator.

The NHRC DRDR FedEx account cannot be used for importing or exporting specimens from other countries. Shipping requirements vary from country to country.

NHRC DRDR uses a World Courier account to accommodate international shipping and handling requirements. Please use the main contacts on the Consignee Information List for more details on how to use the World Courier account for international shipments (see attachment 7.7.).

All required documentation for shipping infectious specimens still applies when using the World Courier account.

6.7. INFECTIOUS SHIPPING TRAINING

All sites that intend to ship specimens to NHRC DRDR are responsible for properly packaging and labeling their infectious shipments.

NHRC DRDR uses the SafTPak training program to properly train employees on how to ship infectious specimens.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

The SafTPak training program includes a comprehensive test after all training modules are complete. The passing score for this comprehensive test is 80% or higher.

NHRC DRDR employees are not permitted to ship infectious specimens until SafTPak training and tests are complete.

Upon completion of the comprehensive exam, a certificate will be automatically generated, as proof of training. This record of training will be signed and maintained by QA.

Refresher training for shipping infectious specimens is provided and maintained by NHRC DRDR on an annual basis. Please contact Safety and Logistics to obtain annual refresher training or to begin new training or certification.

NHRC DRDR can provide the SafTPak training CD upon request.

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

7. ATTACHMENTS

7.1. EXAMPLES OF PRIMARY CONTAINERS

7.2. EXAMPLES OF ABSORBENT MATERIAL

7.3. EXAMPLES OF SECONDARY CONTAINERS

7.4. EXAMPLES OF OUTER FIBERBOARD LABELS

7.5. REGULATORY REFERENCES 7 CFR PART 331, 9 CFR PART 121, 42 CFR PART 73 LIST OF HHS AND USDA SELECT AGENTS AND TOXINS OF HHS AND USDA SELECT AGENTS AND TOXINS

7.6. SHIPPER'S DECLARATION FORM

7.7. NHRC DRDR CONSIGNEE INFORMATION LIST

8. REFERENCES

Federal Express Pointers on shipping: clinical samples, diagnostic specimens, and environmental test samples. Available at: http://fedex.com/us/services/pdf/PKG_Pointers_Specimens.pdf?link=4. Accessed April 21, 2004.

IATA Dangerous Goods Regulations 2006, 47th Edition

Part 602 under 49 CFR 173.196 and 49 CFR 137.199

HHS and USDA Select Agents and Toxins, 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

SOP # QA-0.315 Preparation of Laboratory Requisition Forms

Form # QA-4.40 Laboratory Requisition Form

Form #QA-4.50 General Specimen Log Sheet

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

SOP # BSL3-0.326 Intra-Entity and Inter-Entity Transfer of Biological Select Agents and Toxins

9. REVISION HISTORY

Version	Brief general description and justification of changes	Effective Date
A	New SOP	5/21/07
B	Updated to current department title. Removed Fuller; Replaced Ellorin. Removed Russell; Replaced Blair. Deleted 'day 14 expiration date' throughout SOP. Change 'NHRC DRDR' to 'NHRC DRDR' throughout SOP. Change 'lab' to 'laboratory' throughout SOP. Removed information about Adenovirus Trail throughout SOP. 7.: Added attachments 7.5, 7.6 and 7.7 to the list. Updated REGULATORY REFERENCES 7 CFR Part 331, 9 CFR Part 121, 42 CFR part 73 lists of HHS and USDA Select agents and Toxins List to most current information. 8.: Added reference SOP # BSL3-0.326.	05.05.2010
C	4.: Added MSDS, PPE and QA to this section. 5.2.: Combined shipper responsibility of complying with SOP and ensure meeting all training requirements including Bloodborne pathogen. 6.1.: Added another basic requirement for proper packaging of infectious specimens (sturdy outer packaging). Deleted section 6.5.1. and made that particular section a part of section 6.5 first sentence. 6.7.: Changed 'safety department' to 'safety and logistics'. 7.1. attachment: added note on sealed plastic bag. 7.7. attachment: corrected phone number/building number for main NHRC contacts; added Virology contact number. Verified account information is omitted, updated ship-to address throughout SOP. Corrected grammatical, punctuation and spelling errors throughout SOP. Added 'reference' watermark on document.	03.17.2011

ATTACHMENT 7.1. Examples of Primary Containers



* Used sealed sterile plastic bags as primary containers for tissues only.

ATTACHMENT 7.2. Examples of Absorbent Material

Approved: 03.16.2011

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

ATTACHMENT 7.3. Examples of Secondary Containers



Screw-Cap Can Container



Sealed Styrofoam™ Container
(minimum of 1" thick)



Sealed Plastic Bag



Plastic



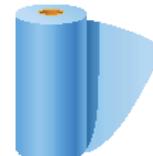
Super Absorbent Packet Towels



Cellulose Wadding



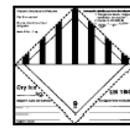
Cotton Balls



Paper

**ATTACHME
NT 7.4.
Examples
of Outer
Fiberboard
Labels**

Class 6 — Infectious Substances
(Division 6.2)



FedEx Dry Ice Label

ATTACHMENT 7.5. REGULATORY

CRF Part 331, 9 CFR Part 121, 42 CFR part 73 list of HHS and USDA Select agents and Toxins

REFERENCES 7

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

<u>HHS Select Agents AND TOXINS</u>	<u>OVERLAP Select Agents AND TOXINS</u>
Abrin	<i>Bacillus anthracis</i>
Botulinum neurotoxins	<i>Brucella abortus</i>
Botulinum neurotoxin producing species of <i>Clostridium</i>	<i>Brucella melitensis</i>
Cercopithecine herpesvirus 1 (Herpes B virus)	<i>Brucella suis</i>
<i>Clostridium perfringens epsilon toxin</i>	<i>Burkholderia mallei</i> (formerly <i>Pseudomonas mallei</i>)
<i>Coccidioides posadasii/Coccidioides immitis</i>	<i>Burkholderia pseudomallei</i> (formerly <i>Pseudomonas pseudomallei</i>)
Conotoxins	Hendra virus
<i>Coxiella burnetii</i>	Nipah virus
Crimean-Congo haemorrhagic fever virus	Rift Valley fever virus
Diacetoxyscirpenol	Venezuelan Equine Encephalitis virus
Eastern Equine Encephalitis virus	<u>USDA Select Agents AND TOXINS</u>
Ebola virus	African horse sickness virus
<i>Francisella tularensis</i>	African swine fever virus
Lassa fever virus	Akabane virus
Marburg virus	Avian influenza virus (highly pathogenic)
Monkeypox virus	Bluetongue virus (exotic)
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	Bovine spongiform encephalopathy agent
Ricin	Camel pox virus
<i>Rickettsia prowazekii</i>	Classical swine fever virus
<i>Rickettsia rickettsii</i>	<i>Ehrlichia ruminantium</i> (Heartwater)
Saxitoxin	Foot-and-mouth disease virus
Shiga-like ribosome inactivating proteins	Goat pox virus
	Japanese encephalitis virus
	Lumpy skin disease virus
	Malignant catarrhal fever virus

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

<p>Shigatoxin</p> <p>South American Haemorrhagic Fever viruses Flexal Guanarito Junin Machupo Sabia</p> <p>Staphylococcal enterotoxins</p> <p>T-2 toxin</p> <p>Tetrodotoxin</p> <p>Tick-borne encephalitis complex (flavi) viruses Central European Tick-borne encephalitis Far Eastern Tick-borne encephalitis Kyasanur Forest disease Omsk Hemorrhagic Fever Russian Spring and Summer encephalitis</p> <p>Variola major virus (Smallpox virus)</p> <p>Variola minor virus (Alastrim)</p> <p><i>Yersinia pestis</i></p>	<p>(Alcelaphine herpesvirus type 1)</p> <p>Menangle virus</p> <p><i>Mycoplasma capricolum</i> subspecies <i>capripneumoniae</i> (contagious caprine pleuropneumonia)</p> <p><i>Mycoplasma mycoides</i> subspecies <i>mycoides</i> small colony (Mmm SC) (contagious bovine pleuropneumonia)</p> <p>Peste des petits ruminants virus</p> <p>Rinderpest virus</p> <p>Sheep pox virus</p> <p>Swine vesicular disease virus</p> <p>Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3</p> <p>Virulent Newcastle disease virus 1</p> <p><u>USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents AND TOXINS</u></p> <p><i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)</p> <p><i>Phoma glycinicola</i> (formerly <i>Pyrenochaeta glycines</i>)</p> <p><i>Ralstonia solanacearum</i> race 3, biovar 2</p> <p><i>Rathayibacter toxicus</i></p> <p><i>Sclerophthora rayssiae var zaeae</i></p> <p><i>Synchytrium endobioticum</i></p> <p><i>Xanthomonas oryzae</i></p> <p><i>Xylella fastidiosa</i> (citrus variegated chlorosis strain)</p>
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8/31/2009

**NHRC DEPARTMENT OF RESPIRATORY
DISEASES RESEARCH**
How to Package, Label and Ship Infectious Specimens

ATTACHMENT 7.6. Sample of Shipper's Declaration Form

NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

How to Package, Label and Ship Infectious Specimens

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least three copies to the airline.)

Shipper: _____

Consignee: _____

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

TRANSPORT DETAILS

Flight number: _____ Date of departure: _____
 (Route not applicable)

ESSENTIAL AIRCRAFT ONLY DANGEROUS AIRCRAFT ONLY

Shipper's Destination: _____

Statement by: _____
 Signature: _____

FedEx Express

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.

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification

UN or ID No.	Proper Shipping Name	Pkg. or Instr. No.	Pkg. or Instr. Qty.	Quantity and type of packaging	Packing Inst.	Authorization

Additional Handling Information: _____

Emergency Telephone Number: _____

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.

Signature of Shipper: _____
 Name and Date: _____
 Signature (see item above): _____

ON ADDITIONAL MAJOR SHIPPER'S DECLARATIONS FOR DANGEROUS GOODS, THE SHIPPER CONTAINS RADIOACTIVE MATERIALS INTENDED FOR USE IN OR OUTSIDE OF RESEARCH, MEDICAL DIAGNOSIS OR TREATMENT.

ATTACHMENT 7.7. NHRC DRDR Consignee Information List

Naval Health Research Center
 Department of Respiratory Diseases Research
 Shipper and Consignee Information Sheet
 NHRC DRDR

Shipping Address:

Approved: 03.16.2011

**NHRC DEPARTMENT OF RESPIRATORY
DISEASES RESEARCH**
How to Package, Label and Ship Infectious Specimens

Naval Health Research Center
ATTN: Larivhie Dela Cruz / 619-553-9105
McClelland and Patterson Roads,
Gate 4, Barracks Building 330
San Diego, CA 92152

Main Contacts:

NHRC Main Phone: 619-553-7027
Shipping Dept.: Larivhie Dela Cruz, 619-553-9105
Email: larivhie.delacruz@med.navy.mil
Laboratory Director: CDR Patrick Blair, 619-767-4842
Microbiology Office 330: 619-553-5558
Virology Laboratory 330: 619-553-6384
Bacteriology Laboratory 330: 619-553-8770
Molecular Office 335: 619-553-0573

Other Contacts:

FedEx Dangerous Goods Department: 901-344-3000
FedEx U.S. Customer Service: 800-463-3339