

Department of Respiratory Diseases Research Naval Health Research Center

140 Sylvester Road • San Diego, CA 92106 • Tel (619) 553-9105
Fax (619) 553-7601 • email: nhrc-fri@med.navy.mil



Diagnostic Specimen Shipping Instructions

1. Package specimen according to appendix 1 (Shipping SOP).
2. All shipments must include four basic requirements:
 - watertight primary containers
 - absorbent material
 - watertight secondary containers
 - sturdy outer packaging
3. Upon request, shipping materials are available from NHRC.
4. A lab requisition form and a specimen log must be included in your specimen shipment. Refer to appendices 2 and 3 (lab requisition form and specimen log).
5. When choosing a courier to ship, use the following guidelines:
 - Shipped in CONUS – use FedEx
 - Shipped OCONUS – use World Courier
6. The outside of all packages must have the following information:
 - Label UN1845 - dry ice (indicating the number of kilograms of dry ice in the package)
 - Label UN3373 – Biological Substance Class B (both must be present)
7. All packages should be shipped to the following address:

Naval Health Research Center
McClelland Rd. and Patterson Rd.
Gate 4, Building 315
ATTN: Laboratory
San Diego, CA 92152
8. For detailed instructions, please consult appendix 1 (shipping SOP).
9. For any questions please contact us at:

nhrc-fri@med.navy.mil
Phone (619) 553-9105

Appendices:

1. Shipping SOP
2. Lab requisition form
3. Specimen log

DEPARTMENT OF RESPIRATORY DISEASES RESEARCH

DIAGNOSTIC SPECIMENS: HOW TO PACKAGE, LABEL, AND SHIP

SOP #: QA-0.309	Effective Date: 1/23/08	Version: F	Page: 1 of 8

1. PURPOSE

To provide a procedure for packing, labeling and shipping preserved diagnostic specimens to be delivered via courier to or from any collaborating study site.

2. SCOPE

The scope of this procedure is to provide instructions on how to package, label and ship specimens that will be delivered to or from Naval Health Research Center (NHRC) by any applicable courier, in compliance with applicable regulations.

3. GENERAL CONSIDERATIONS

In accordance with changes in IATA and FedEx® shipping regulations, all domestic and international specimens routinely shipped and received by the NHRC Department of Respiratory Diseases Research (NHRC DRDR), are now classified as DIAGNOSTIC SPECIMENS (IATA Code UN3373). This document is provided as a guideline for the packaging, labeling, and shipping of diagnostic specimens. For a list of infectious substances forbidden as diagnostic specimens, please see Table 7.5 - HHS and USDA Select Agents and Toxins, 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

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 section 7 of this SOP can be provided by the NHRC DRDR shipping department, if requested.

4. RESPONSIBILITIES

4.1 The Laboratory Supervisor is responsible for:

- 4.1.1 Distributing the SOP to all collaborating sections for compliance.
- 4.1.2 Ensuring that the Shipper is appropriately qualified and trained to safely and properly handle specimens for shipping purposes.

4.2 The Shipper is responsible for:

- 4.2.2 Ensuring that the proper procedures are followed when packing, labeling and shipping diagnostic specimens.

4.3 The Courier or Transporter is responsible for:

- 4.3.1 Ensuring that samples are properly packed and labeled prior to acceptance for transport
- 4.3.2 Ensuring that samples are stored in a suitable secondary container while in transport

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4.3.3 Ensuring that secondary containers are adequately secured while in a transport vehicle.

5. DEFINITIONS

- 5.1 IATA- International Air Transport Association
- 5.2 UN- United Nations
- 5.3 Courier- FEDEX, DHL, UPS, World Courier, USPS, other transport carriers as applicable.
- 5.4 DRDR: Department of Respiratory Diseases Research
- 5.5 SOP- Standard Operating Procedure
- 5.6 Diagnostic Specimen- Any specimen type that does not fall under 7 Code of Federal Regulations Part 331, 9 Code of Federal Regulations, Part 121, and 42 Code of Federal Regulations Part 73. See Attachment following this SOP.
- 5.7 DOT: Department of Transportation

6. PROCEDURES

- 6.1 Packaging Diagnostic Specimens
 - 6.1.1 Proper packaging of diagnostic specimens includes four basic requirements: watertight primary containers, absorbent material, watertight secondary containers, and sturdy outer packaging. See attachments in part 7, per this SOP.
 - 6.1.2 Use Watertight Primary Containers
 - 6.1.2.1 All primary containers must have positive closures (such as screw-on, snap-on, or push-on lids) and must be reinforced by adhesive tape.
 - 6.1.2.2 To prevent contact between multiple fragile primary containers, each primary unit should be individually wrapped.
 - 6.1.2.3 Primary containers must be leak proof (liquid specimens) or sift proof (solid specimens).
 - 6.1.2.4 Primary containers cannot contain more than 500ml or 500g for liquid or solid specimens, respectively.
 - 6.1.2.5 When determining the volume of diagnostic specimens, be sure to include any transport media as well. The entire contents of the primary containers are considered the diagnostic specimen.
 - 6.1.2.6 Primary containers may be plastic, or metal. See Figure 7.1.

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RESEARCH**

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6.1.3 Use Absorbent Material

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

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

6.1.3.3 Absorbent material may include any of the following in Figure 7.2.

6.1.4 Use Watertight Secondary Containers

6.1.4.1 Secondary containers can be any watertight packaging. See figure 7.3.

6.1.5 Use Sturdy Outer Packaging

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

6.1.5.2 The outer packaging cannot contain more than 4L or 4Kg for liquid or solid shipments, respectively.

6.1.5.3 The minimum package size that FedEx® can accept is 7" x 4" x 2." For smaller packages that do not contain dry ice, insert entire package (meeting all 4 basic requirements) into a FedEx® Clinical Pak.

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

6.1.5.5 Some examples of unacceptable forms of outer packaging are Styrofoam™ boxes, plastic bags, paper envelopes, and FedEx® boxes, tubes, packs, or envelopes.

6.2 Fill out a Laboratory Requisition Form

6.2.1 A Laboratory Requisition Form and Specimen Log should be filled out, per the SOP for Preparation of Laboratory Requisition Forms. The specimen log should contain an accurate description of each specimen within the shipment.

6.2.2 Each specimen will have a label that matches the description written in the specimen log, per the SOP for Preparation of Laboratory Requisition Forms.

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6.2.3 This Laboratory Requisition Form should be placed inside the shipment between the watertight secondary container and the sturdy outer packaging.

6.3 Label the Outer Box of the Diagnostic Specimen Shipment

6.3.1 To avoid delays of shipments, all packages must be labeled correctly. Diagnostic specimen shipments should have the following labels securely affixed to the outer packaging. See Figure 7.4

6.3.1.1 Temperature Requirements: For specimens that need to be stored in specific temperature conditions, dry ice or ice gel packs may be placed within the watertight secondary container.

6.3.1.2 Temperature specification will be determined based on the requirements of the laboratory test protocol. Dry Ice Label may not be required for shipments, when applicable.

6.3.2 "INNER PACKAGING COMPLIES WITH PRESCRIBED SPECIFICATIONS" should only be used if the inner packaging actually does include all four of the basic requirements (watertight primary container, absorbent material, watertight secondary container, and sturdy outer packaging).

6.3.3 The outer shipping box must be labeled with the name and phone number of the person shipping the package, as well as the name and phone number of the person receiving the package.

6.4 Shipping Diagnostic Specimens

6.4.1 Go online to website www.fedex.com

6.4.2 Click on the "Ship" tab at the top of the page

6.4.3 Click on "Prepare and Manage Shipments"

6.4.4 Enter User ID and password to Login

6.4.4.1 User ID: contact NHRC DRDR

6.4.4.2 Password: contact NHRC DRDR

6.4.5 Fill out recipient information

6.4.6 Shipments should be billed to NHRC

6.4.6.1 If shipping from NHRC, choose bill to sender

6.4.6.2 If shipping to NHRC, choose bill to recipient

6.4.6.3 If another party requests to be billed for a shipment, that party must provide their account number to NHRC, and billing options adjusted when appropriate.

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- 6.4.7 Select appropriate package and shipment details, Always ship specimens “Priority Overnight”
- 6.4.8 Complete the FedEx ShipAlert® as necessary
- 6.4.9 Enter ship date (this will usually be “today”)
- 6.4.10 Under “Shipment Details”, click on the “Go To Options” button.
- 6.4.11 Under Special Services click on the box labeled “Dangerous Goods”
 - 6.4.11.1 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.
 - 6.4.11.2 Dangerous goods are classified as “Accessible” or “Inaccessible” on the FEDex website. Infections substances fall under the “Inaccessible” genre.
- 6.4.12 Click “Continue”
- 6.4.13 Print 2 copies of the Air waybill – one to send, and one for the shipper to file for reference purposes in the designated filing area.
- 6.4.14 Click “Go To Next Steps”
- 6.4.15 Click “Schedule a pickup”
- 6.4.16 Follow the instructions to schedule a pick-up
- 6.4.17 Use ship to address:
 - 6.4.17.1 Naval Health Research Center
US Military Base, Point Loma
ATTN: Laboratory
McClelland Rd. & Patterson Rd.
Gate 4, Barracks Building 315
San Diego, CA 92152

6.5 Acceptance and Transport of Diagnostic Specimens

- 6.5.1 Transport personnel are responsible for ensuring that diagnostic specimen shipments meet all packing and documentation requirements prior to accepting and transporting a package.

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6.5.1.1 While in transit, all packages are subject to random inspection at any time.

- 6.5.2 If a package is suspected of not meeting the above requirements, the courier or transport personnel must reject the package and notify the shipper of the error. The package should not be accepted or transported until all errors and missing information have been corrected.
- 6.5.3 Specimens must be secured in a secondary container, and held in the designated areas of the transport vehicle while in transit.
- 6.5.4 In the event of an accident while in transit, the courier must notify the shipper and the consignee. In the event of a biological spill, special handling precautions must be taken, per IATA and DOT regulations.

7 ATTACHMENT

7.1 Examples of Primary Containers



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

7.2 Examples of Absorbent Material

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Super Absorbent Packet



Cellulose Wadding



Cotton Balls



Paper Towels

7.3 Examples of Secondary Containers



Screw-Cap Can



Sealed Styrofoam™ Container
(minimum of 1" thick)

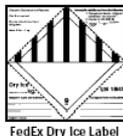


Sealed Plastic Bag



Plastic Container

7.4 Examples of Outer Fiberboard Labels



FedEx Dry Ice Label

**BIOLOGICAL
SUBSTANCE
CATEGORY B**

UN3373

7.5 7 CFR Part 331, 9 CFR Part 121, 42 CFR part 73 list of HHS and USDA Select agents and Toxins (See attached)

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8 REFERENCES

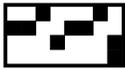
8.1 Federal Express. Pointers on shipping: clinical samples, diagnostic specimens, and environmental test samples. Available at http://fedex.com/us/services/pdf/PKG_Pointers_Specimens.pdf?link=4. Accessed April 21, 2004.

8.2 Consignment of diagnostic specimens. Available at http://www.iata.org/NR/ContentConnector/CS2000/SiteInterface/pdf/cargo/dg/Consignment_diagnostic_specimens_2003.pdf. Accessed April 23, 2004.

9 REVISION HISTORY

Change History				
Version	SOP #	Description	Originator	Effective Date
E	QA-0.309	Updated format and added new procedures to 6.3 and 6.4		3/5/2007
F	QA-0.309	Added new responsibility section for couriers, added new procedures for accepting specimen shipments		1/23/08

SOP Approved: 1/22/08



52241

Laboratory Request

Naval Health Research Center
Dept. of Respiratory Disease Research
McClelland & Patterson Rds. Gate 4
Building 315
San Diego, California 92152
Microbiology Section: 619-553-8771
Molecular Section: 619-553-0755

Laboratory Director:

CAP# 6928701
CLIP# DOD9215201

(Lab Use Only) Date Received:

Request ID:

Study Name:

Site Information/ Site ID#:

Name:
Address:

Point of
Contact:

SELECT TESTS BY CHECKING BOX

Atypical Pneumonia Multiplex PCR*

- *M. pneumoniae*
- *C. pneumoniae*
- *B. pertussis*
- *L. pneumophila*

Coronavirus

- RT-PCR OC43, 229E & NL63*
- SARS PCR by LightCycler*

Respiratory Viral Culture Panel

- Influenza A / Influenza B
- Adenovirus
- Parainfluenza 1, 2 & 3
- RSV
- Herpes Simplex 1 & 2
- Enterovirus

Influenza

- Subtyping HAI
- RT-PCR
- RT-PCR by Light Cycler*
- LRN H5
- Molecular Typing*

Adenovirus

- Culture Identification
- Serotyping (microneutralization)*
- PCR
- PCR by Light Cycler*
- Adenovirus - 36 Serology*
- Adenovirus - 4 & 7 Serology*
- Multiplex PCR for Adenovirus Typing (Specify)

Human Metapneumovirus

- RT-PCR*
- Bacteriology Culture***

B. pertussis

- Culture Identification
- PCR*

C. pneumoniae

- Serology IgM and IgG*
- PCR*

M. catarrhalis

- PCR*

M. pneumoniae

- Culture Identification
- Serology IgM and IgG
- PCR*

N. meningitidis

- PCR*
- Culture Identification
- Antibiotic Sensitivity Test (E-Test)
- Serogrouping

H. influenzae

- Culture Identification
- Antibiotic Sensitivity Test (E-test)
- PCR*

S. aureus

- Culture Identification
- Antibiotic Sensitivity Test

S. pneumoniae

- Culture Identification
- Antibiotic Sensitivity Test
- Serotyping*
- Pneumococcal pneumolysin PCR*
- PCR*

S. pyogenes

- Culture Identification
- Antibiotic Sensitivity Test
- Emm Typing*
- Spe B PCR*
- Serogrouping

Misc.

- Enterovirus PCR*
- RSV PCR*
- Rhinovirus RT-PCR*
- Storage Only

Other (Specify Lab Section and Test)

- Microbiology
- Molecular

Number of Specimens

Record all specimen information on specimen log.

Page of

Requesting Clinician or Designee (Print Name):

Sign Name:

Date:

/ /
M M D D Y Y Y Y

* research only test



5324

Laboratory Specimen Log

(For Office Use Only)

Request ID:

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Instructions for Completing Specimen Log Form QA-4.50

1. Specimen Logs must be accompanied with a laboratory requisition, form 4.40
2. Use one sheet per specimen/ media type.
3. For serum specimens, enter media type as "None".
4. Specimen collector's initials required for serum samples only.

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Specimen Type

- Quality Control/ Blank
- Aspirate
- Body Fluid
- Body Tissue
- Bronchial
- Bronchial Wash
- Cerebral Spinal Fluid
- Homogenate
- Isolate
- ITCF
- Other: _____
- Lyophilized
- Nasal/Throat Combination
- Nasal Swab
- Serum, Acute
- Serum, Convalescent
- Sputum
- Stool
- Throat Swab
- Whole Blood

Media Type

- None
- A549
- RMK
- Plate
- Slant
- SP4 Broth
- TSB Buffer
- TE Buffer
- UTM
- VTM
- Unknown
- Other: _____

Date Collected MM / DD / YYYY	1st Identifier	2nd Identifier	Comments	Specimen collector initials											
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