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# INSTRUCTIONS

## SAMPLE COLLECTION, PREPARATION AND SHIPMENT

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### INTRODUCTION

This manual contains information and step-by-step procedures for preparing and shipping samples to ViroMed to be tested under the Navy HIV Testing Contract (N00140-03-D-N800).

### INTENDED USERS

This manual is intended for any personnel responsible for drawing, labeling, packing and shipping specimens to be tested under the Navy HIV Testing Contract.

### BEFORE YOU BEGIN

Read this manual in its entirety before proceeding.

Assemble all supplies required before you begin so that you are aware of any missing components. [See page 2-3 for a complete listing of all supplies provided under this contract.]

### HOW THIS MANUAL IS ORGANIZED

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*For questions, please contact ViroMed Client Services at 800.582.0077*

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# Supplies Provided By ViroMed

- Supplies will be shipped to the SAs on a quarterly basis.
- Requests for supplemental supply shipments should be directed to ViroMed Client Services at 800-582-0077.

- **Primary Serum Separator Tubes (SST)** – 7ml, plastic, double-gel serum separator tubes. Brand name is Vacuette. To be used for all blood draws sent to ViroMed.



- **5ml screw top serum transfer tubes** – 5ml, white, plastic, round-bottom screw top transfer tube. To be used to pour off serum if unable to draw or send blood samples in the Vacuette tubes.



- **Foam tube holders** – Dimensions = 9 1/2" x 3 3/4" x 3 15/16". 1 1/2# foam block drilled with 40 slots to hold both the SSTs and the 5ml screw top transfer tubes.



- **Ziplock bags** – Clear, plastic bag with a ziplock closure. Dimensions = 15 1/2" x 12". Each ziplock bag will hold one tube holder.

[Ziplock bags not pictured]

- **Small shipping box** – Dimensions = 10 1/8" x 8 5/8" x 5". Printed with an "up" arrow on both sides. This box will hold two foam tube holders.

[Small shipping box not pictured]

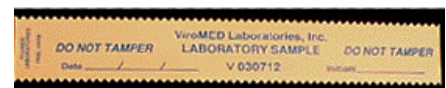
- **Medium shipping box** – Dimensions = 19 5/8" x 8 5/8" x 5". Printed with an "up" arrow on both sides. This box will hold four foam tube holders.

[Medium shipping box not pictured]

- **OCONUS shipping system** – medium shipping box, insulation and refrigerant packs.
  - Shipping box – Dimensions = 19 5/8" x 8 5/8" x 5". Printed with an arrow on both sides. This box is to be used in conjunction with the foam insulation and refrigerant packs. It will hold a maximum of three foam tube holders.
  - Insulation – A complete set consists of six pieces of white foam insulation to be placed inside the OCONUS shipping box.
  - Refrigerant Packs – Reusable Polar Packs to be frozen at the OCONUS sites and used with the OCONUS shipping box and the foam insulation.



- **Tamper-proof stickers** – Serial-numbered stickers to be applied to the closure of each ziplock bag containing samples. When using a tamper-proof sticker, you must initial and date it before you place the sticker on the ziplock.



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- **Shipping tape** – Each roll of shipping tape can be used with the dispenser.



- **Pre-printed barcode labels** – Self-adhesive labels coded with a unique 10-digit barcode number. See Page 6 for specific instructions on placing these labels on sample tubes.



- **Pre-printed airbills** – FedEx airbills are pre-printed with the receiver's address (ViroMed). One airbill should be used for each box sent to ViroMed.

Examples of airbills are located on pages 9 and 10 of this section

- **CDC Permit** – Biomedical Materials, Etiological Agents or Vectors (OCONUS). A copy of the CDC permit must be placed on all packages being sent to ViroMed from OCONUS sites.

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# Sample Collection

- Collect blood samples using the 7ml, plastic, double-gel serum separator tubes (SSTs) provided by ViroMed. Submit blood samples to ViroMed in the SST.
- Using a vacutainer-type needle system, draw blood samples into the SST until the tube is full.



- Allow samples to sit at room temperature for up to 30 minutes. **Do not refrigerate tubes prior to centrifugation.**
- Once the samples have clotted, centrifuge tube immediately at 1100 – 1300 g for a minimum of 10 minutes and maximum of 2 hours to complete serum separation.

- Samples may be stored in the SST at 2 - 8°C for up to seven (7) days.
- Samples that will not arrive at ViroMed within seven (7) days from the date drawn must be poured off and frozen until transshipment. Transfer the serum to the 5ml screw cap serum transfer tubes provided by ViroMed and freeze at -20°C or colder.



- If unable to collect blood samples in the SST provided by ViroMed, submit serum samples to ViroMed by pouring off into the 5ml screw cap transfer tube provided by ViroMed. **Do not inject serum into the SSTs.**
  - Do not submit samples in any tube other than those provided by ViroMed. Samples submitted in tubes other than the 7ml SST or the 5ml screw cap transfer tube will be rejected. Examples of unacceptable tube types are:
    - Glass tubes of any kind
    - Serum transfer tubes with flat bottoms
    - Serum transfer tubes larger than 5ml (21mm x 75mm)
    - Serum transfer tubes with snap caps rather than screw caps

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# Sample Rejection Issues

Samples found to be unacceptable for testing will be rejected at ViroMed using the deficiency codes indicated below.

<b>Deficiency Code</b>	<b>Description</b>	<b>Action</b>
D-1	No Record Received	Hold
D-2	No Specimen Received	Hold
D-3	Deficiency (Duplicate Barcode)	Hold
D-4	Other Problem (invalid submission/date drawn.	Reject/Resubmit Sample
D-5	Data Mismatch	Reject/Resubmit Sample
D-6	No Specimen Barcode	Reject/Resubmit Sample
D-7	Grossly Hemolyzed	Reject/Resubmit Sample
D-8	Quantity Not Sufficient	Reject/Resubmit Sample
D-9	Individual Specimen Contamination or Gross Leakage	Reject/Resubmit Sample

- Samples that are rejected using codes D-4 through D-9 will NOT be tested. The sample MUST be resubmitted.
- Samples whose barcode labels are not correctly attached to the SST tube (see Page 6 for details) or have barcodes that cannot be scanned will be rejected as D-4. During the routine testing process, samples are diluted using automated equipment. If the dilutor cannot scan the barcode label, the tube cannot continue through the testing process. Quality standards prevent ViroMed staff from typing in barcode numbers by hand.
- Samples that leak in transit will contaminate other samples contained within that ziplock bag. The possibility that the leaked sample may contain any bloodborne pathogen prevents us from:
  - Opening the package and putting our laboratory personnel at risk for exposure.
  - Testing samples that have even a remote possibility of being contaminated.
- ViroMed understands that it is not always easy (and in some cases impossible) to recollect samples. Therefore, you must carefully examine all samples collected so that you can immediately correct a submission format error or redraw an inappropriate sample. If you have questions as to the quality of a sample or the specific ViroMed rejection criteria CALL VIROMED. We can work together to avoid major problems!

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# Labeling Sample Tubes

## **DO Place Label Starting at the Top of the Tube**

- **All barcode labels must be applied starting at the top of the sample tube** (the end closest to the cap). The barcode must be placed on the tube in a vertical position.



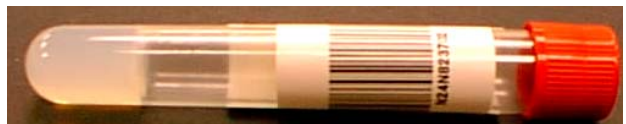
## **Never Place Labels at the Bottom of the Tube**

- **No labels of any kind can be placed on the bottom portion of the sample tube.** Samples received with labels covering the bottom half inch of the samples tube will be rejected.



## **Never Place Labels Horizontally on the Tube**

- **Barcode labels must be placed vertically.** Barcodes placed on tubes horizontally will be rejected.



## **No Wrinkles, Folds or Tears in Labels**

- **Barcode labels must be placed on the tube so that there are no wrinkles, folds or tears on the barcode itself.** Samples received with damaged barcodes will be rejected.



## **No Incomplete or Illegible Labels**

- **Barcode labels must be complete and legible and have no blanks or smudges.** Samples with barcodes that cannot be read by the barcode scanner will be rejected.



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# Packaging Instructions

- Place centrifuged, barcoded SSTs or 5ml screw cap serum transport tubes upright in the foam tube holder.
- Place the filled tube holder into a ziplock bag (provided by ViroMed). Release all air from the ziplock and seal the bag.
- With the tubes sitting upright on a flat surface, fold the two top corners of the bag in toward the middle. Then (with the corners tucked in) fold the top of the bag over until it is flush with the tube holder.
- Initial and Date the tamper proof sticker. Place the ViroMed-provided tamper proof sticker across the entire folded end of the bag, wrapping excess label around to the sides.

**NOTE: The tamper proof sticker must cover and seal the entire bag opening.**



- Place the sealed tube holder into the shipping box.
  - Two tube holders fit into the small box.
  - Three tube holders fit into the OCONUS box system.
  - Four tube holders fit into the medium box.
  - If you are shipping a box that is not completely full, you must fill the empty space with either an empty tube holder or other suitable materials (i.e., crumpled newspaper – please *do not* use shredded paper or Styrofoam peanuts).
- Tape the box shut and place a FedEx airbill on the top of the outside of the box. [See page 9 for instructions on completing this airbill.]

**NOTE: Each individual box must have its own completed airbill. Do not utilize the same airbill for more than one box. It is unacceptable to tape boxes together for shipment.**



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# Packaging Instructions for OCONUS Sites

- After the shipping box has been assembled, place the foam insulation into place. Each insulation set consists of 6 pieces.
- Place the sealed tube holder(s) into the OCONUS shipping box. Three tube holders will fit into a box.
- Place the foam refrigerant packs along the sides of the box.
- If you are shipping a box that is not completely full, you must fill the empty space with either an empty tube holder or other suitable material (i.e., crumpled newspaper).
- After the box has been filled, place the last piece of foam on top of the tube holders and seal the box. Place the FedEx International Air Waybill and a CDC Permit (Biomedical Materials, Etiological Agents or Vectors) on the top of the outside of the box. [See Page 10 for instructions on completing the airbill.]



**NOTE: Each individual box must have its own completed airbill. Do not utilize the same airbill for more than one box. It is unacceptable to tape boxes together for shipment.**



# FedEx USA Airbill

## Label A – For shipments sent Saturday through Thursday

- Peel off the lower portion of the label and apply to package. (1)
- Upper label (tab) to be used for the site’s record keeping. (2)

*Hint: Write actual date shipped on upper tab. The shipping date listed is the date the label was created.*

*Note: Weight will be listed as 3 lbs. Fed Ex will adjust the weight once they pick up the package.*

*The airway bills will indicate “Bill Sender.” ViroMed will be charged for the shipment.*

2 →

1 →

Invoice : Customer : Phone # : Dept :	Date : 05/24/2006 Weigh : 3.0 COD : DV :	Shipping : Special : Handling : Total :	0.00 0.00 0.00
Svcs: PRIORITY OVERNIGHT HLD TRK#: 7384 1865 3750		Ship Date: 24MAY06	
ORIGIN ID: BBBA (301) 295-6590 NAVY CENTRAL HIV PROGRAM (NCHP) NATIONAL NAVY MEDICAL CENTER 8901 WISCONSIN AVE BLDG 11, ROOM 116 BETHESDA, MD 20889 UNITED STATES US		Actual Mgt: 3.0 LB MGN System#: 0748008/CAFE2286 Account: S *****	
TO VIROMED LABS - GOVERNMENT LAB (952) 563-3300		FedEx Express	
6101 BLUE CIRCLE DR HOPKINS, MN 553439108		E	
REF:		Delivery Address Barcode	
BILL SENDER			

## Label B – For shipments sent Friday

- Peel off the lower portion of both labels and apply to package. (1)
- Upper label (tab) to be used for the site’s record keeping. (2)

*Hint: Write actual date shipped on upper tab. The shipping date listed is the date the label was created.*

PRIORITY OVERNIGHT	THU
TRK# 7384 1865 3750	Deliver By: 25MAY06
55343 -MN-US	MSP A1
HLD	78 BBBA
BILL SENDER	

Label A

Invoice : Customer : Phone # : Dept :	Date : 05/26/2006 Weigh : 3.0 COD : DV :	Shipping : Special : Handling : Total :	0.00 0.00 0.00
Svcs: PRIORITY SATURDAY HLD TRK#: 7384 1865 3760		Ship Date: 26MAY06	
ORIGIN ID: BBBA (301) 295-6590 NAVY CENTRAL HIV PROGRAM (NCHP) NATIONAL NAVY MEDICAL CENTER 8901 WISCONSIN AVE BLDG 11, ROOM 116 BETHESDA, MD 20889 UNITED STATES US		Actual Mgt: 3.0 LB MGN System#: 0748008/CAFE2286 Account: S *****	
TO VIROMED LABS - GOVERNMENT LAB (952) 563-3300		FedEx Express	
6101 BLUE CIRCLE DR HOPKINS, MN 553439108		E	
REF:		Delivery Address Barcode	
BILL SENDER			

← 2

← 1 →

ORIGIN ID: BBBA (301) 295-6590 NAVY CENTRAL HIV PROGRAM (NCHP) NATIONAL NAVY MEDICAL CENTER 8901 WISCONSIN AVE BLDG 11, ROOM 116 BETHESDA, MD 20889 UNITED STATES US	Ship Date: 26MAY06 Actual Mgt: 3.0 LB MGN System#: 0748008/CAFE2286
TO VIROMED LABS - GOVERNMENT LAB (952) 563-3300	
6101 BLUE CIRCLE DR HOPKINS, MN 553439108 (US)	
E	
TRK# 7384 1865 3760	
PRIORITY SATURDAY	
6101 BLUE CIRCLE DR	

### PRIORITY SATURDAY ###	Deliver By: 27MAY06
TRK# 7384 1865 3760	Form 0221
55343 -MN-US	MSP A1
HLD	7P BBBA
BILL SENDER	

Label B

PLACE THIS LABEL ON PACKAGE  
NEXT TO THE SHIPPING LABEL

# Filling out the FedEx International Air Waybill

- Pre-printed FedEx International Air Waybills are provided to all OCONUS sites. The following sections have been completed for the sender:
  - Receiver address
  - Service
  - Packaging
  - Special Handling
  - Payment – The air waybills are marked for Receiver Billing (for both the transportation charges and the duties and taxes), with ViroMed’s account number.

The image shows a FedEx International Air Waybill form with several sections highlighted by red arrows. The form is filled out with the following information:

- Section 1: From (please print and press hard)**
  - Date: MM/DD/YY
  - Sender's FedEx Account Number: 8062 8242 0395
  - Sender's Name: YOUR COMPANY
  - Address: YOUR ADDRESS
  - City: YOUR CITY
  - Country: YOUR COUNTRY
- Section 2: Your Internal Billing Reference Information**
  - Recipient's Name: ATTN: GOVERNMENT LAB
  - Company: VIROMED LABORATORIES, INC.
  - Address: HOLD AT FEDEX (HAL)
  - City: ST. LOUIS PARK, MN
  - Country: USA
- Section 4: Shipment Information**
  - Total Packages: 1
  - Total Weight: 20.00
  - Commodity Description: DIAGNOSTIC SPECIMENS
  - Total Declared Value For Carriage: 20.00
  - Total Value For Customs: 20.00
- Section 5: Broker Selection**
  - Broker's Name: [Blank]
- Section 9a: Payment - TRANSPORTATION CHARGES PAID BY**
  - Payment Method: Recipient
- Section 10: Required Signature**
  - Sender's Signature: [Blank]
  - Date: [Blank]

Additional details on the form include: FedEx Tracking Number 8062 8242 0395, Form ID No. 0400, and a FedEx logo on the right side.

- The **sender must complete** the following fields on the pre-printed FedEx International Air Waybill:
  - Section 1: Date
  - Section 1: Sender’s Address
  - Section 1: Sender’s Name
  - Section 4: Total Packages
  - Section 4: Total Weight
  - Section 10: Sender’s Signature and Date

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# Arranging for A FedEx Pick-Up

- Call FedEx at 1-800-463-3339 (1-800-GO-FEDEX).
- Press '0' to talk to a Customer Service Agent and request a shipment pick-up.
- Have the following information ready when you place the call:
  - Facility name, address and phone number
  - Number of packages and approximate weight
  - What time the package(s) will be ready
  - How late your facility will be open for the pick-up
- It is recommended that submitting activities establish a scheduled pick-up with FedEx if they have routine or daily pick-ups.

## Ordering Additional Pre-Printed Airbills

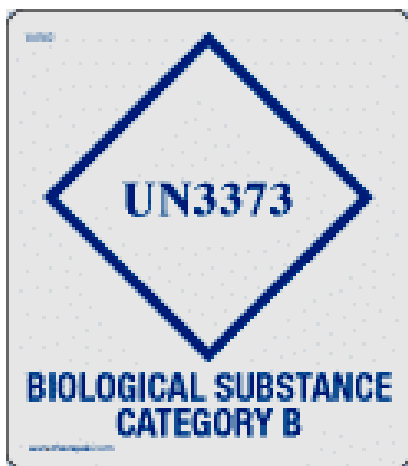
- Call ViroMed Client Services at 1.800.582.0077.
- Tell the Client Service Representative that you need to order additional pre-printed airbills under the Navy HIV Testing Contract.
- Provide the Representative with the following information:
  - Site Identification Code from the "Company" line of your airbill
  - Site name and address
  - Type of airbill needed (next day delivery, Saturday delivery, or international)
  - Quantity needed
- Your supply of pre-printed airbills will be delivered within 7-10 working days.

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# Packaging Infectious Substances

- **Follow standard specimen packing instructions (please refer to page 7):**
  - *Place centrifuged, barcoded SST or 5ml screw cap serum transport tube upright in the foam tube holder*
  - *Place the filled foam tube holder into a ziplock bag (provided by ViroMed) Release all air from the ziplock bag and seal the bag.*
  - *With the tubes sitting upright on a flat surface, fold the two top corners of the bag in towards the middle. Then (with the corners tucked in), fold the top of the bag over until it is flush with the tube holder.*
  - *Initial and date the tamper proof sticker. Place the ViroMed-provided tamper proof sticker across the entire folded end of the bag, wrapping excess label around the sides.*
- **Place redraw specimen in a separate shipping box.**
- **Place the appropriate Federal Express shipping label on box.**
- **Place UN3373 Biological Substance Category B sticker on the box. (Label C)**



**Label C**