AIDS CLINICAL TRIALS NETWORK* (ACTN) INSTRUCTIONS FOR OVERNIGHT SHIPMENTS

1.0 Determine type of shipment: (see <u>https://www.actgnetwork.org/lab_resources/shipping_guidelines.aspx</u> ACTN GUIDELINES FOR SHIPMENT AND RECEIPT OF CATEGORY B BIOLOGICAL SUBSTANCE SPECIMENS or Category A Biological Substances (INFECTIOUS SPECIMENS) AND OTHER DANGEROUS GOODS section 3.6, 3.7, and 3.8)

- 1.1 ____Category B Biological Substance -ambient (complete section 5.1)
- 1.2 ____Category B Biological Substance -dry ice (complete section 5.2)
- 1.3 ____Category A Biological Substance --dry ice (complete section 5.3)
- 1.4 <u>Category B Biological substance</u> Approved LN2 shipper (Such as MVE Cryoshipper) complete section 5.4)
- 2.0 Use Packaging appropriate for shipment type: (See <u>https://www.actgnetwork.org/lab_resources/shipping_guidelines.aspx</u> ACTN GUIDELINES FOR SHIPMENT AND RECEIPT OF CATEGORY B BIOLOGICAL SUBSTANCE SPECIMENS or CATEGORY A BIOLOGICAL SUBSTANCE SPECIMENS AND OTHER DANGEROUS GOODS section 4.0, 5.0 AND 6.0)
 - 2.1 Category B Biological Substance Shipper (e.g., STP210, 230, 250, 308, 309, 320)
 - 2.2 <u>Category A Biological Substance Shipper (e.g., STP100, 110, 130, 100/300, 310, 370)</u>
 - 2.3 ____Repository "Suitcase" (STP350)
 - 2.4 _____Air/Sea Shippers
 - 2.5 Approved LN2 shipper (Such as MVE Cryoshipper)
 - 2.6 ____Other (must conform to IATA regulations for shipment type)
- 3.0 Paperwork (See Guidelines sections 1.6-1.12)
 - 3.1 _____ Provide an LDMS Diskette or CD (place in disk/CD mailer)
 - 3.2 Provide an LDMS shipping manifest for all boxes. Shipping manifest(s) must exactly match the label information and order in the associated shipment, including the global specimen IDs.
 - 3.3 ____Provide an LDMS Box map for all boxes. Box maps must exactly match the label information and order in the associated shipment, including the global specimen IDs.
 - 3.4 ____Provide any relevant CRFs. Confirm with receiving lab if CRFs are required. Do NOT send CRFs to the Repository.
- 4.0 Courier Information and Notification: (See Guidelines section 2.0)
 - 4.1 _____Record Courier Service on ACTN Specimen Shipment Notice.
 - 4.2 _____Record Courier Airbill number on ACTN Specimen Shipment Notice.
 - 4.3 _____Advance Notification of shipment must be made to the recipient.
 - 4.3.1 FAX or email notification using a properly completed ACTN Specimen Shipment Notice document is the preferred method of notification

*Participating Networks are defined on the sign-off page (p.9)

- 4.3.2 If FAX is not possible, email notification is allowed. Request return email to confirm recipient did receive the notification. Record the email address used. If return email is not received, continued efforts to contact the recipient are required.
- 4.3.3 If Fax and email notifications are not possible, direct phone conversation is the next recommended option. Record the name of the lab contact.
- 4.3.4 If you are not able to communicate with the recipient/consignee, contact the ACTN Operations Office for assistance. Do NOT ship if you are unable to send the advance notification.
- 4.3.5 Retain a copy of the completed ACTN Specimen Shipment Notice for every outgoing shipment for at least one year.
- 5.0 Packing Instructions (complete the checklist for the packaging that applies to your shipment type)
 - 5.1 Ambient Category B Biological Substance Specimens (See Guidelines sections 1.6-1.12)
 - 5.1.1 Confirm you are using the correct packaging! NOTE: STP210, 230, 250 or equivalent are acceptable examples. Do not mix components from different shippers or manufacturers. Infectious shippers may be used for Category B Biological Substance shipments, but outside labels and markings <u>must</u> be modified to satisfy requirements for Category B Biological Substance shipments.
 - 5.1.2 <u>Make sure primary container (e.g. Vacutainer) is correctly labeled</u> with PID, Date, Protocol, and VID.
 - 5.1.3 _____Place primary tube in a leak proof secondary receptacle with sufficient absorbent material to contain the contents in the event of breakage. Multiple primary containers must be separated using bags, bubble wrap, cardboard grid or absorbent material to prevent breakage during transit.
 - 5.1.4 _____Place the secondary receptacle into a strong outer fiberboard container (minimum dimension of one rigid side is 4"/ 10.16 cm).
 - 5.1.5 ____Place paperwork (CRF, manifest, etc) and shipping diskette/CD (if provided) in the box such that it will not be destroyed in the event of breakage.
 - 5.1.6 _____Seal the fiberboard box and label the outside of the box with the following:

5.1.6.1 _____Sender and Recipient address labels with phone numbers

5.1.6.2 _____Responsible Person label

5.1.6.3 UN3373 Biological Substance Category B label

5.1.6.4 Completed airbill placed in transparent pouch. If shipping

to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill

- 5.2 Category B Biological Substance Specimens on Dry Ice. (see Guidelines sections 5.0-7.0)
 - 5.2.1 ____Confirm you are using the correct packaging NOTE: STP309, 308, 320 or equivalent are acceptable examples. Do not mix components from different shippers or manufacturers._Infectious shippers may be used for Category B Biological Substance shipments, but outside labels and markings <u>must</u> be modified to satisfy requirements for Category B Biological Substance shipments.
 - 5.2.2 Make sure primary containers (e.g. cryovials) are correctly labeled with a LDMS generated label (Global Spec. I.D., PID, Date, Protocol, VID, Primary/Additive/Derivative) and sorted appropriately in a 2" fiberboard box with column/row delineations.
 - 5.2.3 _____Record LDMS Shipment Number (batch number), box number (if more than one box in batch), Lab or Clinic Site #, and orientation mark on the top and bottom of each box.
 - 5.2.4 _____Place one rubber band around each specimen box.
 - 5.2.5 ____Place one absorbent sheet around each specimen box and secure with a second rubber band.
 - 5.2.6 _____Place each box in a leak proof secondary receptacle.
 - 5.2.7 _____Place the secondary receptacle into a strong outer container.
 - 5.2.8 _____Add sufficient dry ice to fill the space between the secondary container and the outer box. Do not add dry ice to the secondary container. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated. IATA packing instruction 650.
 - 5.2.9 Place paperwork (CRF, manifest, etc) and shipping diskette (if provided) between the Styrofoam lid and outer box lid such that it will not be destroyed in the event of breakage.
 - 5.2.10 _____Seal the outer box and label with the following:
 - 5.2.10.1 _____Sender and Recipient address labels with phone numbers
 - 5.2.10.2 _____Responsible Person label
 - 5.2.10.3 _____UN3373 Biological Substance Category B label
 - 5.2.10.4 _____Dry Ice, Class 9 miscellaneous label (diamond-shaped) and UN1845 label with weight in kg.
 - 5.2.10.5 _____Completed airway bill placed in transparent pouch
 - 5.2.10.6 _____If shipping to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill.
- 5.3 Infectious Specimens (Category A, e.g. cultured viral isolates) on Dry Ice (see Guidelines sections 5.0-8.0)
 - 5.3.1 Confirm you are using the correct packaging. NOTE: STP100/300, 310, 350, 370 or equivalent are acceptable examples. The outer box must be labeled by the manufacturer to show that it is certified (i.e. UN4G/Class 6.2/99). Do not mix components from different shippers or

manufacturers. Packaging that is specific for Category B Biological Substance shipments <u>MAY NOT</u> be used for infectious shipments.

- 5.3.2 ____Make sure primary containers (e.g. cryovials) are correctly labeled with a LDMS generated label (Global Spec. I.D., PID, Date, Protocol, VID, Primary/Additive/Derivative) and sorted appropriately in a 2" fiberboard box with column/row delineations.
- 5.3.3 _____Record LDMS Shipment Number (batch number), box number l(if more than one box in batch), Lab or Clinic Site #, and orientation mark on the top and bottom of each box.
- 5.3.4 _____Place one rubber band around each specimen box.
- 5.3.5 ____Place one absorbent sheet around each specimen box and secure with a second rubber band.
- 5.3.6 _____Place each box in a leak proof secondary receptacle
- 5.3.7 _____Place the secondary receptacle into a strong outer container
- 5.3.8 Add sufficient dry ice to fill the space between the secondary container and the outer box. Do not add dry ice to the secondary container. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated. IATA packing instruction 602.
- 5.3.9 ____Place paperwork (CRF, manifest, etc) and shipping diskette between the Styrofoam lid and outer box lid such that it will not be destroyed in the event of breakage
- 5.3.10 _____Seal the outer box and label with the following:
 - 5.3.10.1_____ Sender and Recipient address labels with phone numbers
 - 5.3.10.2 Responsible Person label
 - 5.3.10.3 _____ Directional arrow labels on two opposite sides of box.

5.3.10.4____Dry ice, Class 9 miscellaneous label (diamond-shaped) and UN1845 label with weight in Kg

5.3.10.5 Completed airway bill placed in transparent pouch 5.3.10.6 If shipping to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill 5.3.10.7 UN2814 label with volume (mls) or weight (g), and class

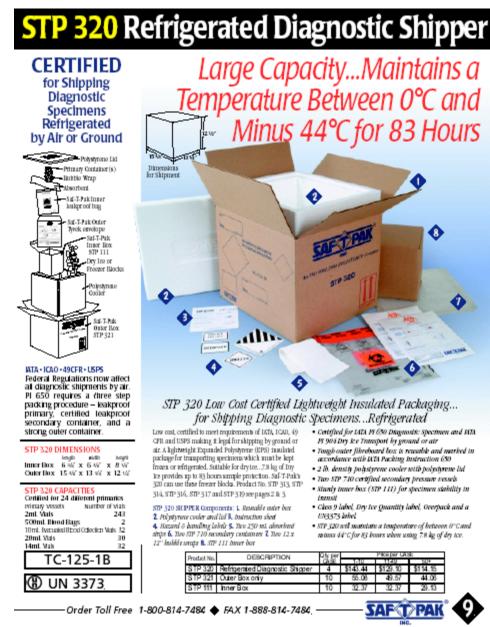
6.2 label (diamond-shaped).

5.3.10.8 Completed original Shipper's Declaration with 3 copies

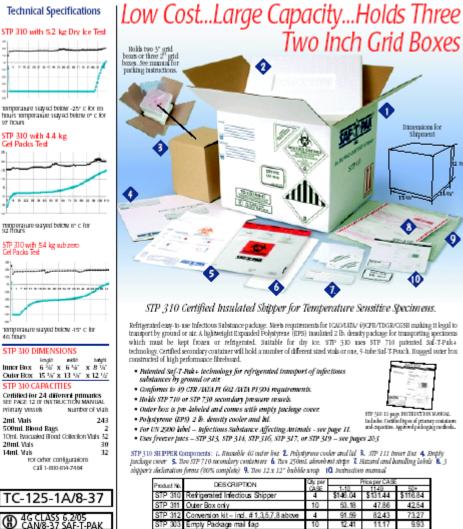
- 5.4 Category B biological substance Specimens in an LN2 Shipper. <u>NOTE: Do not</u> <u>mix components from different shippers or manufacturers.</u> Perform the fill times <u>as outlined by the manufacturer.</u>
 - 5.4.1 ____Begin this procedure with sufficient time prior to the planned time of shipping in order to complete the required fill times.
 - 5.4.2 _____Remove the secondary container when filling LN2 into the shipper
 - 5.4.3 _____Fill the unit to the bottom of the neck and allow the LN2 to absorb. Record Time of fill on the ACTN Specimen Shipment Notice.
 - 5.4.4 _____Perform the first repeat fill to the same level as outlined by the manufacturer. Record Time of fill on the ACTN Specimen Shipment Notice.

- 5.4.5 _____ Perform the second repeat fill to the same level as outlined by the manufacturer. Record time of fill on the ACTN Specimen Shipment Notice.
- 5.4.6 Perform the final repeat fill to the same level as outlined by the manufacturer. Record time of removal on the ACTN Specimen Shipment Notice. Do not pour out the excess LN2 until you are ready to load the shipper with specimen boxes. There should be no liquid left inside the shipping container.
- 5.4.7 (If possible) Weigh the shipper to ensure that the full capacity of liquid has been absorbed. Determine if the final weight indicates that an appropriate volume of LN2 has been absorbed. Contact the LN2 shipper provider (i.e. BRI) or manufacturer if the appropriate weight has not been achieved.
- 5.4.8 _____Pre-cool the secondary container in LN2 vapor phase or -70°C before placing fibreboard specimen boxes inside.
- 5.4.9 <u>Make sure primary containers (e.g. cryovials) are correctly labeled</u> with a LDMS generated label (PID, Date, Protocol, VID, Primary/Additive/Derivative) and sorted appropriately in a 2" fiberboard box with column/row delineations.
- 5.4.10 _____Place one rubber band around each specimen box.
- 5.4.11 _____Place one absorbent sheet around each specimen box and secure with a second rubber band.
- 5.4.12 _____Place the boxes (maximum 4) inside the secondary container. Do not put dry ice or LN2 inside the secondary container. Seal the lid with all six screws.
- 5.4.13 _____Place the secondary container inside the shipper and place the lid on the shipper. Secure the lid.
- 5.4.14 _____Place paperwork (CRF, manifest, etc) and shipping diskette (if provided) in the plastic bag and tape it to the top of the metal lid
- 5.4.15 _____ Close the lid and buckle the outer plastic shipping container Label the container with the appropriate labels as follows:
 - 5.4.15.1 _____Sender and Recipient address labels with phone numbers
 - 5.4.15.2 _____ Responsible Person label
 - 5.4.15.3 ____UN3373 Biological Substance Category B label
 - 5.4.15.4 ____Completed airway bill placed in transparent pouch
 - 5.4.15.5 _____If shipping to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill
 - 5.4.15.6 _____ (optional) Add label to indicate "Temperature Sensitive Material: Please Expedite Delivery but Store at 2-8C if Delayed".

Attachment I: Examples of Approved Shippers



STP 310 Refrigerated Infectious Shipper



Refurbishment Inner Box only

STP 111 Order Toll Free 1-800-814-7484 🔶 FAX 1-888-814-7484.



10



Procedure: ACTN Checklist for Overnight Shipments

Prepared by: <u>ACTN Laboratory Technologist Committee</u>

Preparation Date: 10 July 2006,

Date Implemented into the Laboratory: _____

Updated on:

<u>02 May 2008</u>

Reviewed by:

Date:

Linda K. Lambrecht, M.S_____ 02 May 2008____

ACTN Laboratory Technologists Cpommittee 02 May 2008

Participating Networks:

ACTG IMPAACT