

ACTG/ IMPAACT Biological Substance, Category B SHIPMENTS Checklist

Refer to the ACTG/ IMPAACT Network Guidelines for Shipping and Receiving Biological Substance, Category B Specimens for shipping instructions:

<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>

1.0 Determine type of shipment:

- 1.1 Category B Biological Substance -ambient (complete section 5.1)
- 1.2 Category B Biological Substance -refrigerated (complete section 5.2)
- 1.3 Category B Biological Substance - dry ice (complete section 5.3)
- 1.4 Category B Biological substance - approved LN2 dry shipper (e.g. MVE Cryoshipper Extra Capacity-VSS IATA Dry Shipper. Complete section 5.4)

2.0 Use Packaging appropriate for shipment type:

- 2.1 Category B Biological Substance Shipper or equivalent (e.g., STP-200, STP-210, STP-250,STP-270, STP-302, STP- 308, STP-309, STP-320, STP-340)
- 2.2 Repository "Suitcase"
- 2.3 Approved LN2 dry shipper (e.g. MVE CryoShipper Extra Capacity-VSS IATA Dry Shipper)

3.0 Paperwork

- 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 required CRFs. Confirm with the receiving lab if CRFs are required. Do NOT send CRFs to the Repository.

4.0 Courier Information and Notification:

- 4.1 Record Courier Service on [ACTG/ IMPAACT Specimen Shipment Notice](#).
- 4.2 Record Courier Airbill number on [ACTG/ IMPAACT 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 [ACTG/ IMPAACT Specimen Shipment Notice document](#).

- 4.3.2 If a FAX notification is not possible, then email notification is allowed, if pre-approved by the recipient. It is advised that your laboratory request a return e-mail to confirm receipt as these e-mails are not automatically returned. If return email is not received, continued efforts to contact the recipient are required.
- 4.3.3 Packages should not be shipped if advanced notification is not possible. Refer to the LPC for additional contact information.
- 4.3.4 Completed ACTG/ IMPAACT Specimen Shipment Records must be maintained for at least two years.

5.0 Packing Instructions

5.1 Ambient Biological Substance, Category B Specimens

- 5.1.1 Confirm you are using the correct packaging [NOTE: STP-200, STP-210, STP-250, STP-270, STP-302, STP-308, STP-309, STP-320, STP-340 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 must be modified to satisfy requirements for Category B Biological Substance shipments.

Note: if the shipment will be exposed to extreme temperature conditions, use an insulated shipper or overpack.
- 5.1.2 Make sure primary container (e.g. Vacutainer or vial) is correctly labeled with PID, Date, Protocol, and VID.
- 5.1.3 Place primary containers 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 contact between primary containers during transit.
- 5.1.4 Place the secondary receptacle into a strong outer fibreboard container (minimum dimension of one rigid side is 3.94" or 10.0 cm).
- 5.1.5 Place paperwork (CRF, manifest, etc) and shipping diskette/CD (if provided) between the secondary and outer packaging such that it will not be destroyed in the event of breakage.
- 5.1.6 Seal the fibreboard 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, import permit, and commercial invoice document must be placed in transparent pouch on outside of packaging. Multiple copies of documents may be required for international shipments.

5.2 Refrigerated Biological Substance, Category B Specimens

- 5.2.1 Confirm you are using the correct packaging [NOTE: STP-302, STP- 308, STP-309, STP-320, STP-340 or equivalent] are acceptable examples. Do not mix components from different shippers or manufacturers. Category A Infectious shippers may be used for Biological Substance, Category B shipments, but outside labels and markings must be modified to satisfy requirements for Biological Substance, Category B shipments.
- 5.2.2 Make sure primary containers (e.g. cryovials) are correctly labeled with a LDMS generated label (PID , Global Specimen ID (for specimen dates after September 1, 2005; not required for hand-written specimen labels) , Protocol Number (s) , Specimen Date , Primary/Additive/Derivative/Sub-Add-Der , Specimen Time (24 hour) , Two-dimensional LDMS-generated Barcode (for specimen dates after October 1, 2008)) and sorted appropriately in a 2" or 3" fibreboard 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 with sufficient absorbent material to contain the contents in the event of breakage..
- 5.2.5 Place each box in a leak proof secondary receptacle.
- 5.2.6 Place the secondary receptacle into a strong outer container.
- 5.2.7 Add sufficient refrigerated/frozen gel packs to fill the space between the secondary container and the outer box. Interior support must be provided to secure the secondary packages in the original position (IATA packing instruction 650).
- 5.2.8 Place paperwork (CRF if required, shipping manifest, box report) and protected shipping diskette (if provided) in a paper or plastic envelope between the Styrofoam lid and outer box lid such that it will not be destroyed in the event of breakage.
- 5.2.9 Tape the outer box closed with packing tape and label with the following:
 - 5.2.9.1 Sender and Recipient address labels with phone numbers
 - 5.2.9.2 Responsible Person label
 - 5.2.9.3 UN3373 Biological Substance, Category B label
 - 5.2.9.4 Completed airway bill placed in transparent pouch
 - 5.2.9.5 If shipping to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill.

5.3 Biological Substance, Category B Specimens on Dry Ice. (see Guidelines sections 5.0-7.0)

- 5.3.1 Confirm you are using the correct packaging [NOTE: STP-320, STP-340 or equivalent] are acceptable examples. Do not mix components from different shippers or manufacturers. Biological Substance, Category A (STP-310) shippers, may be used for Biological Substance, Category B shipments, but outside labels and markings must be modified to satisfy requirements for Biological Substance, Category B shipments (IATA packing instructions 650).
- 5.3.2 Make sure primary containers (e.g. cryovials) are correctly labeled with a LDMS generated label ((PID , Global Specimen ID (for specimen dates after September 1, 2005; not required for hand-written specimen labels), Protocol Number(s), Specimen Date, Primary/Additive/Derivative/Sub-Add-Der, Specimen Time (24 hour), Two-dimensional LDMS-generated Barcode (for specimen dates after October 1, 2008) and sorted appropriately in a 2" or 3" fibreboard box with column/row delineations.
- 5.3.3 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.
- 5.3.4 Place one absorbent sheet around each specimen box and secure with a rubber band.
- 5.3.5 Place each box in a leak proof secondary receptacle.
- 5.3.6 Place the secondary receptacle into a strong outer container.
- 5.3.7 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).
- 5.3.8 Place paperwork (CRF if required, shipping manifest, box report) and protected shipping diskette (if provided) between the Styrofoam lid and outer box lid such that it will not be destroyed in the event of breakage.
- 5.3.9 Seal the outer box and label with the following:
 - 5.3.9.1 Sender and Recipient address labels with phone numbers
 - 5.3.9.2 Responsible Person label
 - 5.3.9.3 UN3373 Biological Substance Category B label
 - 5.3.9.4 Dry Ice, Class 9 miscellaneous label (currently acceptable diamond-shaped labels) and UN1845 label with dry ice weight in kg.
 - 5.3.9.5 Completed airway bill placed in transparent pouch
 - 5.3.9.6 If shipping to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill.

5.4 Category B biological substance Specimens in an LN2 dry shipper.

NOTE: Do not mix components from different shippers or manufacturers. Refer to LN2 dry shipper charging instructions provided by the network repository. LN2 Dry shipper charging process should be started at least 24 hours prior to shipping.

Liquid Nitrogen Dry Shippers are exempted from packaging, marking, labeling and documentation requirements for liquid nitrogen shipping but the words "Not Restricted and A152" are printed on the airbill. This indicates that the shipper meets the requirements of Special Provision A152.

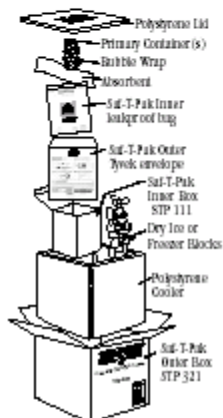
- 5.4.1 Remove the secondary container when filling liquid nitrogen into the shipper. Pre-cool the secondary container in liquid nitrogen vapor phase or -70°C mechanical freezer.
- 5.4.2 Fill the unit to the bottom of the neck and allow the liquid nitrogen to absorb.
- 5.4.3 Four hours later, repeat with another fill to the same level.
- 5.4.4 Four hours later (i.e. 8 hours from initial fill) repeat with another fill.
- 5.4.5 At least 16 hours later (i.e. 24 hours after initial fill) and just prior to shipping, pour out the excess liquid nitrogen. Do not pour out the liquid nitrogen until you are ready to load the shipper with the specimen boxes. There should be no liquid left inside the shipping container.
- 5.4.6 To insure that the vapor shipper has absorbed the full capacity of liquid, it is necessary to weigh the shipper. The empty weight of the unit without the outer plastic container and inner secondary container is 30 lbs. The full weight should be 47-50 lbs. This will allow the shipper to hold the maximum number of days in the vapor phase.
- 5.4.7 Make sure primary containers (e.g. cryovials) are correctly labeled with a LDMS generated label (PID, Date, Protocol, VID, Primary/Additive/Derivative) and sorted appropriately in a 2" fibreboard box with column/row delineations.
- 5.4.8 Place one absorbent sheet around each specimen box and secure with a rubber band.
- 5.4.9 Place the boxes (maximum 4) inside the secondary container. Do not force boxes into metal container. Please contact BRI for further instructions if boxes are too big. Do not put liquid nitrogen inside the secondary container. Do not use plastic biohazard bag or envelope. They are not required.
- 5.4.10 Seal the lid with all six screws using the wrench provided. Do not over-tighten.
- 5.4.11 Place the secondary container inside the shipper and place lid on shipper. Secure lid with twist tie.
- 5.4.12 Place paperwork (CRF if required, shipping manifest, box report) and protected shipping diskette (if provided) inside the plastic bag and tape to the metal lid.
- 5.4.13 Buckle the outer plastic shipping container and place tape over the buckles.
- 5.4.14 Close the lid and buckle the outer plastic shipping container Label the container with the appropriate labels as follows:

- 5.4.15 Sender and Recipient address labels with phone numbers
 - 5.4.15.1 Responsible Person label
 - 5.4.15.2 UN3373 Biological Substance, Category B label
 - 5.4.15.3 Completed airway bill placed in transparent pouch
 - 5.4.15.4 If shipping to USA from international sites, copy of CDC import permit and commercial invoice in transparent pouch with airway bill
 - 5.4.15.5 “Dry Shipper Not –restricted” Label. See Appendix B

Attachment A: Examples of Approved Shippers

STP 320 Refrigerated Diagnostic Shipper

CERTIFIED
for Shipping
Diagnostic
Specimens
Refrigerated
by Air or Ground



ATA • ICAO • 49CFR • USPS
Federal Regulations now affect all diagnostic shipments by air. PI 650 requires a three step packing procedure – leakproof primary, certified leakproof secondary container, and a strong outer container.

STP 320 DIMENSIONS
length width height
Inner Box 6 1/2" x 6 1/2" x 8 1/2"
Cooler Box 15 1/2" x 13 1/2" x 12 1/2"

STP 320 CAPACITIES
Certified for 24 different primaries
primary vessels number of vials
20ml Vials 243
500ml Blood Bags 2
100ml Recapped Blood Collector Mats 32
20ml Vials 30
14ml Mats 32

TC-125-1B
UN 3373

*Large Capacity...Maintains a
Temperature Between 0°C and
Minus 44°C for 83 Hours*



*STP 320 Low Cost Certified Lightweight Insulated Packaging...
for Shipping Diagnostic Specimens...Refrigerated*

Low cost, certified to meet requirements of IATA, ICAO, 49 CFR and USPS making it legal for shipping by ground or air. A lightweight Expanded Polystyrene (EPS) insulated package for transporting specimens which must be kept frozen or refrigerated. Suitable for dry ice...7.8 kg of dry ice provides up to 83 hours sample protection. Saf-T-Pak's 320 can use these freezer blocks. Product No. STP 313, STP 314, STP 316, STP 317 and STP 319 see pages 2 & 3.

STP 320 SHIPPER Components: 1. Reusable outer box
2. Polystyrene cooler and lid & instruction sheet
3. Hazard & handling labels
4. Two 250 ml absorbent strips
5. Two STP 710 secondary containers
6. Two 12 x 12" bubble wrap
7. STP 111 inner box

- Certified for IATA PI 650 Diagnostic Specimen and IATA PI 903 Dry Ice Transport by ground or air
- Tough outer fibreboard box is reusable and marked in accordance with IATA Packing Instruction 650
- 2 lb. density polystyrene cooler with polystyrene lid
- Two STP 710 certified secondary pressure vessels
- Sturdy inner box (STP 111) for specimen stability in transit
- Class 9 label, Dry Ice Quantity label, Overpack and a UN3375 label
- STP 320 will maintain a temperature of between 0°C and minus 44°C for 83 hours when using 7.8 kg of dry ice.

Product No.	DESCRIPTION	Qty per case	Pricer Base		
			1-10	11-20	21+
STP 320	Refrigerated Diagnostic Shipper	4	\$143.44	\$129.90	\$134.95
STP 321	Outer Box only	10	55.00	49.57	44.06
STP 111	inner box	10	32.37	32.37	29.13

Order Toll Free 1-800-814-7484 ♦ FAX 1-888-814-7484.



STP 310 Refrigerated Infectious Shipper

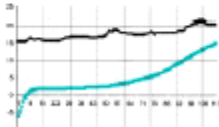
Technical Specifications

STP 310 with 5.2 kg Dry Ice Test



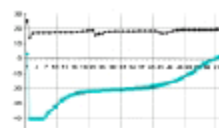
temperature stayed below -25° c for 10 hours
temperature stayed below 0° c for 10 hours

STP 310 with 4.4 kg Gel Packs Test



temperature stayed below 0° c for 10 hours

STP 310 with 5.4 kg subzero Gel Packs Test



temperature stayed below -15° c for 46 hours

STP 310 DIMENSIONS

length width height
Inner Box 6 5/8" x 6 1/4" x 8 1/8"
Outer Box 15 1/4" x 13 1/4" x 12 1/2"

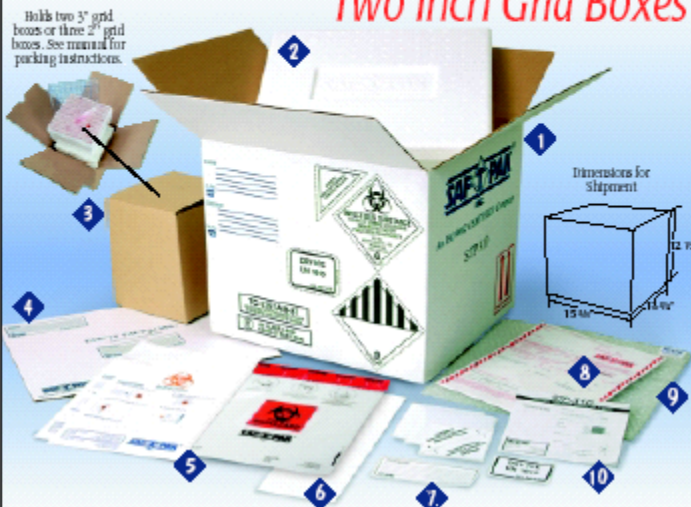
STP 310 CAPACITIES

Certified for 24 different primaries
SEE PAGE 12 OF INSTRUCTION MANUAL
Primary vessels Number of vials
2ml Vials 243
500ml Blood Bags 2
10ml. Recapped Blood Collection Vials 32
20ml Vials 30
14ml Vials 32
for other configurations
CALL 1-800-814-7484

TC-125-1A/8-37

4G CLASS 6.205
CAN/8-37 SAFT-PAK

Low Cost...Large Capacity...Holds Three Two Inch Grid Boxes



STP 310 Certified Insulated Shipper for Temperature Sensitive Specimens.

Refrigerated easy-to-use Infectious Substance package. Meets requirements for ICA/MATA/49CFR/TDGR/CGSB making it legal to transport by ground or air. A lightweight Expanded Polystyrene (EPS) insulated 2 lb. density package for transporting specimens which must be kept frozen or refrigerated. Suitable for dry ice. STP 310 uses STP 710 patented Saf-T-Pak+ technology. Certified secondary container will hold a number of different sized vials or one, 5-tube Saf-T-Pouch. Rugged outer box constructed of high performance fibreglass.

- Patented Saf-T-Pak+ technology for refrigerated transport of infectious substances by ground or air.
- Conforms to 49 CFR /ATA PI 602 /ATA PI 504 requirements.
- Holds STP 710 or STP 730 secondary pressure vessels.
- Outer box is pre-labeled and comes with empty package cover.
- Polystyrene (EPS) 2 lb. density cooler and lid.
- For UN 2800 label - Infectious Substance Affecting Animals - see page 11.
- Uses freezer packs - STP 313, STP 314, STP 316, STP 317, or STP 319 - see pages 263



STP 310 10-page INSTRUCTION MANUAL.
Includes: Certified types of primary containers and capacities. Appointed packaging methods.

STP 310 SHIPPER Components: 1. Reusable 4G outer box 2. Polystyrene cooler and lid 3. STP 111 inner box 4. Empty package cover 5. Two STP 710 secondary containers 6. Two 250ml absorbent strips 7. Hazard and handling labels 8. 3 shipper's declaration forms (80% complete) 9. Two 12 x 12" bubble wrap 10. Instruction manual

Product No.	DESCRIPTION	Qty per CASE	Price per CASE		
			1-10	11-20	20+
STP 310	Refrigerated Infectious Shipper	4	\$146.04	\$131.44	\$116.84
STP 311	Outer Box only	10	63.98	47.86	42.54
STP 312	Conversion kit - incl. # 1, 3, 5, 7, 8 above	4	91.69	82.43	73.27
STP 303	Empty Package mail flap	10	12.41	11.17	9.93
STP 111	Refrurbishment Inner Box only	10	32.37	32.37	29.13

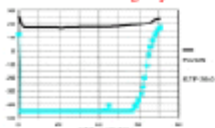
Order Toll Free 1-800-814-7484 ♦ FAX 1-888-814-7484.



STP 350 Refrigerated Infectious Shipper

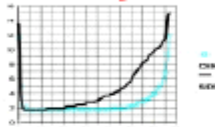
Technical Specifications

STP 350 with 9.5 kg Dry Ice Test



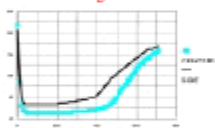
Temperature for the center container remained between 0° C and -5° C for 70 hours.

STP 350 with 5 kg Wet Ice Test



Temperature for the center container remained between 0° and 10° C for 60 hours and temperature for the side container remained between 0° and 10° C for 50 hours.

STP 350 with 4 kg Gel Pack Test



Temperature of the center container remained between 0° and 10° C for 60 hours. Temperature of the side container remained between 0° and 10° C for 48 hours.

STP 350 DIMENSIONS

	length	width	height
Outside	24	20 1/2	12 1/4
Inside	19	15	7

STP 350 CAPACITIES

Certified for 24 different primaries FOR STP 104 Grid Page 18

PRIMARY VESSEL	number of vials
25mL Vials	24
2mL Vials	456
14mL Vials	152
10mL Vials	40
7mL Vials	40
500mL Blood Bag	8

FOR STP 352

requires 2 mL grid boxes at 60 vials per box. Total of 972 solutions. For Other Configurations Call 1-800-881-3744

TC-125-1A/8-14

4H2 CLASS 6.205 CAN/8-14 SAF-T-PAK



SAFTPAK
INC.

Order on the INTERNET ♦ www.saftpak.com

Hi Capacity Saf-T-Case... Certified for 4 Litre Shipments... Under IATA Special Provision A 81



Dimensions for Shipment



STP 350-11 page INSTRUCTIONS MANUAL includes:

- A. Certified types of primary containers, container capacities and number of containers per package.
- B. Directions for approved packaging methods.
- C. Directions for marking and labeling.

STP 350 Certified to Hold up to 972 two mL Vials (see STP 352 below)

- Certified for up to 4 litres on Passenger and Cargo Aircraft using IATA special provision A 81.
- Meets IATA P1 602 (Infectious Substances), IATA P1 650 (Diagnostic Specimens), IATA P1 904 (Dry Ice)
- Meets Transport Canada TC-125-1A Requirements.
- Certified for STP 710 technology. See page 12

Durable, HDPE Saf-T-Case with an insulated polystyrene EPS liner, has convenient carrying handle and hinged lid that meet requirements of ICAO/IATA Packing Instruction 602 (Infectious Substances), IATA P1 650 Diagnostic Specimens, Packing Instruction 904 (Dry Ice).

STP 350 SHIPPER Components: 1. Durable HDPE case 2. Expanded Polystyrene insulated liner 3. Retaining labels 4. Instruction manual 5. Hazard labels



STP 352 Grid Box Insert for Saf-T-Case

Certified for STP 710 secondary pressure vessel system to use with STP 350 case above. Grid box insert holds up to twelve 2mL grid boxes at 60 vials per box for a total of 972 specimens. Meets requirements 602 Infectious and 650 Diagnostic Specimen refrigerated transport.

STP 352 Contains: • Retainer • 12 STP 710 secondary pressure vessels • Twelve 250 mL absorbent strips • Instruction sheet

Product No.	DESCRIPTION	Qty per CASE	Price per CASE		
			1-10	11-40	50+
STP 350	Refrigerated Saf-T-Case	1 each	\$376.85	\$338.99	\$301.32
STP 351	Replacement Polystyrene Liner	1 each	111.40	100.26	89.12
STP 352	Grid Box Retainer & Pressure Vessels	12	40.35	40.35	36.32

Attachment B: Shipping Material examples

Gel Pack:



MVE Shipper



“Dry Shipper Not Restricted”, Labels, UN3373 diamond label, recipient name and address, shippers name and address, responsible person name and phone number.



Attachment C: STP-310 Packing Instructions



STP-310

Packing Instructions

