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

1.0 Determine type of shipment: (see https://www.actgnetwork.org/lab_resources/shipping_guidelines.aspx 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 _____Category B Biological substance - Approved LN2 shipper (Such as MVE Cryoshipper) - complete section 5.4)

2.0 Use Packaging appropriate for shipment type:
(See https://www.actgnetwork.org/lab_resources/shipping_guidelines.aspx 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 _____ Category A Biological Substance Shipper (e.g., STP100, 110, 130, 100/300, 310, 370)
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 must be modified to satisfy requirements for Category B Biological Substance shipments.

5.1.2 _____Make sure primary container (e.g. Vacutainer) is correctly labeled 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 must 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 **MAY NOT** 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. NOTE: Do not mix components from different shippers or manufacturers. Perform the fill times as outlined by the manufacturer.

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 -70ºC before placing fibreboard specimen boxes inside.

5.4.9 _____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" 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

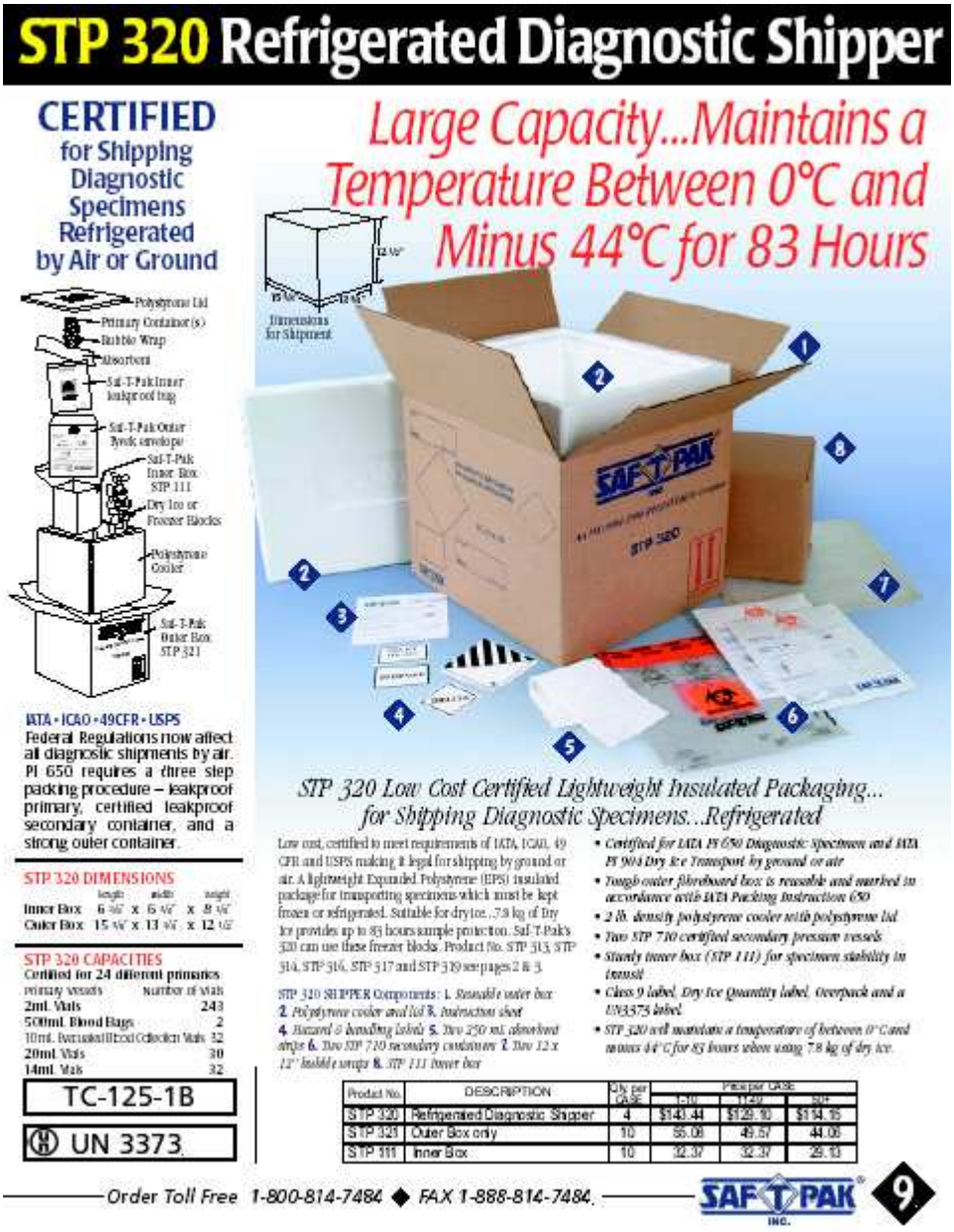
5.4.15.3 _____UN3373 Biological Substance Category B label

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 320 Refrigerated Diagnostic Shipper

CERTIFIED for Shipping Diagnostic Specimens Refrigerated by Air or Ground

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

IATA • 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 ¼"	x 6 ¼"	x 8 ¼"
Outer Box	15 ¼"	x 13 ¼"	x 12 ½"

STP 320 CAPACITIES

Certified for 24 different primaries

Primary Vessels	Number of Vials
2ml. Vials	243
500ml. Blood Bags	2
10ml. Evacuated Blood Collection Vials	32
20ml. Vials	30
14ml. Vials	32

TC-125-1B

UN 3373

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...7.9 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* 3. *Instruction sheet* 4. *Hazard & handling labels* 5. *Two 250 ml. absorbent strips* 6. *Two STP 710 secondary containers* 7. *Two 12 x 12" bubble wraps* 8. *STP 111 Inner box*

- *Certified for IATA PI 650 Diagnostic Specimen and IATA PI 904 Dry Ice Transport by ground or air*
- *Tough outer fiberboard 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 UN3373 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	Price per CASE 1-20	21-49	50+
STP 320	Refrigerated Diagnostic Shipper	4	$140.44	$129.10	$114.15
STP 321	Outer Box only	10	55.00	49.57	44.00
STP 111	Inner Box	10	32.37	32.37	29.13

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

SAF-T-PAK INC.

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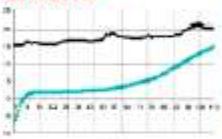
STP 310 Refrigerated Infectious Shipper

Technical Specifications

STP 310 with 5.2 kg Dry Ice Test

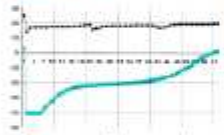
temperature stayed below -25° C for 60 hours. temperature stayed below 0° C for 97 hours

STP 310 with 4.4 kg Gel Packs Test



temperature stayed below 8° C for 52 hours

STP 310 with 5.4 kg sub zero Gel Packs Test



temperature stayed below -15° C for 46 hours

STP 310 DIMENSIONS

	length	width	height
Inner Box	6 7/8"	x 6 1/4"	x 8 1/4"
Outer Box	15 3/4"	x 13 3/4"	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 Evacuated 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 6.2/05
CAN/8-37 SAF-T-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 ICAO/IATA/ 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 fibreboard.

- *Patented Saf-T-Pak+ technology for refrigerated transport of infectious substances by ground or air.*
- *Conforms to 49 CFR /IATA PI 602 /IATA PI 650 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 2900 label – Infectious Substance Affecting Animals - see page 11.*
- *Uses freezer packs – STP 313, STP 314, STP 316, STP 317, or STP 319 – see pages 253*

STP 310 12 page INSTRUCTION MANUAL Includes: Certified types of primary containers and capacities. Approved 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 (100% complete) 9. Two 12 x 12" bubble wrap 10. Instruction manual

Product No.	DESCRIPTION	Qty. per CASE	Price per CASE 1-10	11-49	50+
STP 310	Refrigerated Infectious Shipper	4	$140.04	$131.44	$116.84
STP 311	Outer Box only	10	53.18	47.86	42.54
STP 312	Conversion kit – incl. # 1,3,5,7,8 above	4	91.99	82.43	73.27
STP 303	Empty Package mail flap	10	12.41	11.17	9.93
STP 111	Refurbishment Inner Box only	10	32.37	32.37	29.13

Order Toll Free 1-800-814-7484 ◆ FAX 1-888-814-7484

SAF-T-PAK INC.

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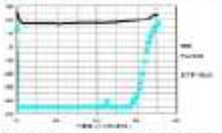
STP 350 Refrigerated Infectious Shipper

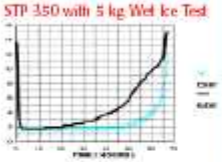
Technical Specifications

STP 350 with 9.5 kg Dry Ice Test



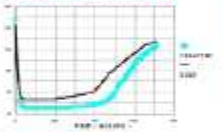
Temperature for secondary container remained between 0° C and -10° C for 70 hours.

STP 350 with 5 kg Wet Ice Test



Temperature for the cooler container remained between 0° and 10° C for 60 hours and temperature for the side container remained between 0° and 10° C for 54 hours.

STP 350 with 4 kg Gel Pack Test



Temperature of the cooler container remained between 0° and 10° C for 55 hours. Temperature of the side container remained between 0° and 10° C for 48 hours.

STP 350 DIMENSIONS

	length		width		height
Outside	24	x	20 ½	x	12 ½"
Inside	19	x	15	x	7"

STP 350 CAPACITIES

Certified for 24 different primaries
FOR STP 104 On Page 18.

primary vessels	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
PACKING 2 ea. grid boxes or 19 Vials per box...total of 972 specimens.
For Other Configurations Call 1-800-814-7801

TC-125-1A/8-14

4H2 CLASS 6.2/05 CAN/8-14 SAF-T-PAK

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

Dimensions for Shipment

STP 350 11 page INSTRUCTION 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 PI 602 (Infectious Substances), IATA PI 650 (Diagnostic Specimens), IATA PI 904 (Dry Ice)*
- *Meets Transport Canada TC-125-1A Requirements.*
- *Certified for STP 710 Technology. See page 12.*

Durable, HDPP 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 PI 650 Diagnostic Specimens, Packing Instruction 904 (Dry Ice).

STP 350 SHIPPER Components: *1. Durable HDPP case 2. Expanded Polystyrene insulated liner 3. Handling 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 81 vials per box for a total of 972 specimens. Meets requirements 602 Infectious and 650 Diagnostic Specimen refrigerated transport.

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

Product No.	DESCRIPTION	Qty per CASE	Price per CASE 1-10	11-49	50+
STP 350	Refrigerated Saf-T-Case	1 each	$378.65	$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

20 SAF-T-PAK INC. — Order on the INTERNET ◆ www.saftpak.com

Procedure: ACTN Checklist for Overnight Shipments

Prepared by: ACTN Laboratory Technologist Committee

Preparation Date: 10 July 2006,

Date Implemented into the Laboratory: _____

Updated on:

_02 May 2008_____

_____

Reviewed by: Date:

___Linda K. Lambrecht, M.S_____ _ 02 May 2008__

___ACTN Laboratory Technologists Cpommittee _02 May 2008_

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Participating Networks:

ACTG
IMPAACT