

HALT-C Shipping Procedures

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I. General Information

A. Contacting and Communicating with BBI Biotech:

- When calling BBI Biotech in reference to this project, please refer to it as the HALT-C Project.
- Normal operating hours for BBI Biotech is from 8:30 AM to 5:00 PM Monday through Friday (Eastern Standard Time). Staff can be reached by phone at (301) 208-8100, by fax at (301) 208-8829 or by email at haltc@bbii.com. For routine messages, when a staff member is not available, a voice mail message may be left. However, if the call is urgent then please instruct the receptionist to page the staff member to the phone.
- In the event of an emergency, if you are unable to reach staff through our main number then call the cell phone and/or pager numbers listed below in Table 1. If you are still unable to reach a HALT-C staff member, then call our company emergency phone number, (301) 208-8296, and the answering service will assist you.

Table 1. Contact information for BBI Biotech.

NAME	PHONE EXTENSION	CELL PHONE NUMBER	EMAIL ADDRESS
Linda Brunson	195	(301) 467-4875	haltc@bbii.com
April Magee	196	(240) 678-8689	haltc@bbii.com

- When communicating with BBI Biotech, please be prepared to state your site number, investigator's name as well as the name of the person initiating the communication (verbal or written) and the name of anyone else involved in clarifying or resolving the problem. If the problem is specific to a given subject, please include the Patient ID or BBI Biotech Sample ID and draw date to help facilitate resolving the problem.

B. Supplies and Supply Shipments:

- Supplies will be shipped from BBI Biotech for one of four different occasions:
 - Mock shipment
 - At the initiation of the study
 - Upon receipt of a shipment at BBI Biotech, and/or
 - When additional supplies have been requested (please refer to the Supply Order Form in Section 4 of this manual).

1. Mock Shipment

There will be one Saf-T-Pak STP-310 shipping kit sent for mock shipment training before the study begins so that all sites can become familiar with the shipping supplies, containers, documentation and specific rules for packaging frozen and fresh specimens. This kit will include the items listed in Table 2 below.

Table 2. Summary of Supplies for a Mock Shipping Kit.

Item Description	Quantity Sent (per STP-310 Kit)
Shipping Containers (STP-310)	1
Brown, Inner Cardboard Box	1
Plastic, Biohazard Bags (STP-711)	3
White, Biohazard Envelopes (STP-710)	3
Bubble Wrap (STP-610)	3
Absorbent Tissue Wraps (STP-152)	3
Cardboard Freezer Boxes	3
Wide Rubber Bands	3
Fax Notification Forms	1
Shippers Declaration of Dangerous Goods	1 for fresh blood shipment 1 for frozen blood shipment
Pre-Printed FedEx Airbill	1
Shipping Container Label Sets ("To," "From," "Emergency Contact," [Pre-labeled on the box, underneath the flap] and blank, white labels to cover Dry Ice when sending fresh shipments)	1 each
Emergency Response Guidelines for all shipments	1
Fed/Ex Clear Pouch for Shipping Paperwork	1

2. Initial Supply Shipment

Once the mock shipment has been received successfully at BBI Biotech, an initial shipment of supplies will be sent which includes the items listed in Table 3 below. These Shipping Kits are to be used for the first four shipments of samples to the repository.

Table 3. Summary of Supplies for Initial Shipping Kit.

Item Description	Quantity Sent (per STP-310 Kit)
Shipping Containers (STP-310)	4
Brown, Inner Cardboard Box	4
Plastic, Biohazard Bags (STP-711)	12
White, Biohazard Envelopes (STP-710)	12
Bubble Wrap (STP-610)	12
Absorbent Tissue Wraps (STP-152)	12
Cardboard Freezer Boxes	12
Wide Rubber Bands	12
Fax Notification Forms	3
Shippers Declaration of Dangerous Goods	4 for fresh blood shipments 4 for frozen blood shipments
Pre-Printed FedEx Airbill	4
Shipping Container Label Sets ("To," "From," "Emergency Contact," [Pre-labeled on the box, underneath the flap] and blank, white labels to cover Dry Ice when sending fresh shipments)	4 each
Emergency Response Guidelines for all shipments	4
Fed/Ex Clear Pouch for Shipping Paperwork	4
Sarstedt™ 1.5 ml Cryovials	2100
Label sets for vials 20 labels per Sample ID (One Sample ID per Patient Visit)	250

3. Standard Shipping Kit

A standard shipping kit will be sent each time a shipment is received at the repository. Table 4 below lists the materials that will be sent in each standard shipping kit.

Table 4. Summary of Supplies for a Standard Shipping Kit.

Item Description	Quantity Sent (per STP-310 Kit)
Shipping Containers (STP-310)	1
Brown, Inner Cardboard Box	1
Plastic, Biohazard Bags (STP-711)	3
White, Biohazard Envelopes (STP-710)	3
Bubble Wrap (STP-610)	3
Absorbant Tissue Wraps (STP-152)	3
Cardboard Freezer Boxes	3
Wide Rubber Bands	3
Pre-Printed FedEx Airbill	1
Shipping Container Label Sets ("To," "From," "Emergency Contact," "Diagnostic Specimens" "Air Eligible" [Pre-labeled on the box, underneath the flap] and blank, white labels to cover Dry Ice when sending fresh shipments)	1 each
Fed/Ex Clear Pouch for Shipping Paperwork	1

4. Ordering of Additional Supplies

When additional supplies are needed that are not included in a standard shipping kit, (i.e., cryovials or cryovial labels). The supply order form should be completed and then faxed to BBI Biotech at (301) 208-8829.

C. Completing the Notification of Shipment Form

Fill out the following information for each shipment on the Shipment Notification Form:

1. Name of Site Principal Investigator: Write in the name of the Principal Investigator for that Site.
2. Site Code: The two numerical digits assigned to the site by NERI.
3. Person Filling Out Form: Your name printed clearly.
4. Contact Number: The telephone number the site can be reached in the event that clarification is needed.
5. Type of Shipment: Indicates whether fresh blood or frozen specimens are being shipped.
6. Date Shipped: The date the specimen is being shipped to BBI Biotech via Federal Express.
7. Federal Express USA Airbill Number*: The tracking number for the shipment.
8. Shipped By: The person preparing the specimen for shipment.
9. Contact Number: The telephone number of the person that prepared the shipment.

If using email notification:

Include all of the above information as well as

1. Batch #
2. Sample ID Range
3. Diagnostic Specimens

NOTE: FAX or email a completed Notification of Shipment Form to April Magee at (301) 208-8829 or haltc@bbii.com the day the shipment is being sent at least one hour prior to the scheduled pickup. If using email notification it must also be sent to bbibiotech@chemtelinc.com.

*NIDDK-LDS Site Only: Send fax notification with the words "Pick-up" in place of the Federal Express Airbill Number.

II. Preparing Fresh Blood For Shipment

A. Packaging Vacutainers:

1. Place up to four vacutainers on the upper half of the sticky bubble wrap (STP-610) and then fold the bottom of the bubble wrap over the top of the vacutainers.
 - a) Use Finalized Manifest to ensure 100% accuracy of contents of shipment. Place the closed bubble wrap with the tubes in the plastic Biohazard Bag provided (STP-710) along with a piece of absorbent material (STP-152). Pull the protective cover off the adhesive flap and seal the flap to the Biohazard Bag.
2. Place the Biohazard Bag in the white Biohazard Envelope provided (STP-710). Pull the protective cover off the adhesive flap and seal the flap to the Biohazard Envelope.
3. Place the white Biohazard Envelope (up to three) in the brown, Inner Cardboard Box and seal the box with tape.
4. Place the Inner Cardboard Box in the slot in the bottom of the Styrofoam Container that is inside of the Saf-T-Pak Box (STP-310) and place the Styrofoam Lid on top.
5. Cut the "Empty Packaging" cardboard return flap (STP-303) from the front of the Saf-T-Pak Box, to expose the address and emergency response labels and place it on top of the Styrofoam Lid before it is sealed.
6. On top of this empty container, place the print-out from the Data Management Program that includes the information pertaining to this specific shipment and then seal the Saf-T-Pak Box with packaging tape along all seams.
7. Use the plain white labels provided in your shipping kit to cover the Class 9 Symbol and the words "Dry Ice".

B. Completing the Federal Express Domestic Airway Bill*:

*To be completed by all sites with the exception of NIDDK-LDS, which will use BBI Biotech Courier Receipt.

(See Section IV of this manual for an example of a completed Federal Express Domestic Airway Bill)

Complete Section 1, Senders Information by adding the appropriate "Shipping Date"

Complete Section 2, by adding Diagnostic Specimens.

Complete Section 6, Under the Section "Does this shipment contain dangerous good?" mark the box that says NO.

Complete Section 7 by adding the weight of the box.

III. Preparing Frozen Specimens for Shipment

A. Packaging of Frozen Cryovials:

1. Place each cryovial in a separate slot within the freezer box. Each box will hold a maximum of 81 cryovials. NOTE that samples for AFP testing and W00 or W20 HCV testing should be put in a separate box from other specimens and marked for "Priority Testing."
 - a) Use Finalized Manifest to ensure 100% accuracy of contents of shipment. Vials should be placed in freezer box in a serpentine fashion according to the order imposed by the Finalized Manifest.
2. Place a rubber band around each freezer box.
3. Place each freezer box in a plastic Biohazard Bag (STP-711) along with a piece of absorbent material (STP-152). Pull the protective cover off the adhesive flap on the Biohazard Bag and seal the flap to the bag.
4. Place each Biohazard Bag in a white Biohazard Envelope (STP-710). Pull the protective cover off the adhesive flap on the Biohazard Envelope and seal the flap to the envelope.
5. Place the White Envelope (up to three) in the inner, brown cardboard box and seal the box with tape.
6. Place the brown, Inner Cardboard Box in the slot in the bottom of the Styrofoam container, which is inside of a Saf-T-Pak STP-310 Box.
7. Surround the Inner Cardboard Box with dry ice, filling the container all the way to the top with dry ice, (18 pounds which equals 9 kilograms should be used).
8. Cut the "Empty Container" cardboard flap (STP-303) off the front of the Saf-T-Pak (STP-310) box, exposing the dry ice, address, diagnostic specimens, air eligible and emergency response labels and place it on top of the Styrofoam Lid.
9. On top of this Styrofoam Lid, place the print-out from the Data Management Program that includes the information pertaining to this specific shipment and then seal the Saf-T-Pak STP-310 box with packaging tape along all seams.
10. Write the weight of the dry ice in Kilograms on the box under the words "Dry Ice."

B. Completing the Federal Express Domestic Airway Bill:

*To be completed by all sites with the exception of NIDDK-LDS which will use BBI Biotech Courier Receipt.

(See Section IV of this manual for an example of a completed Federal Express Domestic Airway Bill)

1. Complete Section 1/From by adding the appropriate "Shipping Date."
2. Complete Section 2 by adding Diagnostic Specimens
3. In Section 6/Special Handling, Under the words "Does this shipment contain dangerous goods?" check the box YES Shipper's Declaration not required. Check the box that indicates "Dry Ice" and write in "1" for the number of packages before the "x" and then write the *weight in kilograms of dry ice used* after the "x."
4. Complete Section 7 by writing in the Total Weight of the box.

IV. Forms

A. Notification of Shipment Form

HALT-C TRIAL REPOSITORY

Notification of Shipment Form

Name of Site Principal Investigator	
Site Code (2 numerical digits)	___ ___
Person Filling Out Form (Please Print Name)	
Contact Telephone Number (The telephone number the Site can be reached in the event that clarification is needed.)	()
Type of Shipment	Fresh <input type="checkbox"/> Frozen <input type="checkbox"/>
Date Shipped (MM/DD/YY)	
FedEx USA Airbill Number (Tracking Number)	
Shipped By: (The Person Preparing the Specimens for Shipment)	
Shipper Contact Number (The number of the person that prepared the shipment)	()

FAX Completed Form To: **BBI Biotech, HALT-C Trial**
FAX: (301) 208-8829

Emergency Contact	BBI Biotech Phone # & Ext (Voice Mail)	Cell Phone
Linda Brunson	195	(301) 467-4875
April Magee	196	(240) 678-8689

B. Supply Order Form

BBI BIOTECH SUPPLY ORDER FORM *For* THE HALT-C Trial

From: Site Number: _____

Complete Shipping Address: _____

Site Investigator: _____

Name of the Individual Ordering: _____

Phone Number of Ordering Individual: _____

Date of Request: _____

Date Supplies Are Needed: _____

**FAX COMPLETED FORM TO BBI BIOTECH (301-208-8829)
 TWO WEEKS IN ADVANCE OF NEEDING ADDITIONAL SUPPLIES**

Item Description	Quantity of Each Item Requested
White, Biohazard Envelopes (STP-310)	
Bubble Wrap (STP-710)	
Absorbent Tissue Wraps (STP-152)	
Cardboard Freezer Boxes	
Sarstedt™ 1.5 ml Cryovials	
Pre-Printed Labels for Sample Vials	
Plastic, Biohazard Bags (STP-311)	
Wide Rubber Bands	
Shipping Container Label Sets (“To,” “From,” “Diagnostic Specimens,” “Air Eligible” and “Emergency Contact”)	
Pre-printed FedEx Airbills	
Shipping Containers (STP-310)	

Make as many copies of this page as needed.

C. Information Update Form

INFORMATION UPDATE FORM *for* HALT-C Trial

Please FAX Any Change in Site-Related Information to 301-208-8829

**BBI BIOTECH, A Division of SeraCare Life Sciences
 217 PERRY PARKWAY
 GAITHERSBURG, MARYLAND 20877**

INFORMATION	CURRENT	NEW/UPDATED
Site #		
Investigator		
Telephone #		
FAX #		
Email Address		
Site Contact		
Telephone #		
FAX #		
Email Address		
Address		

PREPARED BY: _____

DATE: _____

D. Shipment Discrepancy Report

SHIPMENT DISCREPANCY FORM *for* HALT-C TRIAL REPOSITORY

A Discrepancy Report is a form that is generated by BBI Biotech. It documents: a) when a shipment does not arrive as expected, b) missing information in an ADEPT file, and c) mismatched information on a vial that does not match the finalized manifest or vice-versa.

Procedure Overview:

- BBI Biotech will generate a Discrepancy Report and send it to NERI.
 - NERI will contact the site for confirmation of discrepant information.
 - After BBI Biotech and NERI make necessary revisions to the vials and/or databases, a finalized Discrepancy Report will be sent to NERI and the sites.
 - An Example of the Discrepancy Report form can be found on the following page.
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217 Perry Parkway, Gaithersburg, MD 20877
Phone (301)208-8100 Fax (301)208-8829

BBI Biotech Contact: April Magee
Phone: 301-208-8100 ext. 196
E-Mail: amagee@bbii.com
DateGenerated:

5107 Pegasus Court, Frederick, MD 21704
Phone (301)668-8100 Fax (301)668-3416

INCOMING SHIPMENT INVENTORY DISCREPANCY FORM

Study Center/Site:

Site Contact:

Phone:

Fax/E-mail:

Project: Halt C

Study ID:

Shipment/Batch#

Date Shipped:

Date Received:

Type of Shipment: Dry Ice LN2 Dry Shipper Other (specify): _____

Person Receiving Shipment:

Personnel Performing Inventory:

Total # of Vials Rec'd:

Total # of Vials with Discrepancies:

Total # of Discrepancies:

of ID Discrepancies:

of Visit/Date Discrepancies:

of Volume Discrepancies:

of Material Discrepancies:

PART I					PART II			Part III	
Description of Discrepancy					Recommended Corrective Action			Corrective Action Taken	
Primary ID on Manifest	Subject ID	Material	Data on Manifest	Discrepancy	Description	Suggested By/Date	Approved By	Description	Performed By/Date