

7. STORAGE AND SHIPMENT OF SPECIMENS

7.1 Storage at the Field Center Laboratory

All blood and urine specimens that are drawn for the HAPO Follow-Up Study will be stored in the field center laboratory prior to shipment to the Laboratory Coordinating Center in Chicago. This includes cryovials and the plastic purple top tubes containing DNA samples. All vials and tubes must be frozen immediately after processing. The freezer temperature must be -20° C, or colder if available.

The freezer must have a backup power supply in the event of a power outage. The temperature of the freezer should be checked with sufficient frequency to determine whether the temperature varies significantly. A freezer must be utilized that is **not** the automatic defrost type. These freezers pass through a warm cycle to prevent the build up of frost on the inside. In doing so, this warm cycle may actually thaw the specimens contained therein. **Note: It is very important that blood and urine specimens not be thawed following initial freezing.** The first thawing should occur at the Laboratory Coordinating Center in Chicago when specimens are processed for analysis.

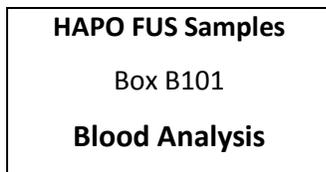
Note: Cryovials without white inserts are designated as 'Analysis' samples, while cryovials with white inserts are considered 'Backup' samples.

'Analysis' samples are stored in the field center laboratory in plastic freezer boxes at -20° C or colder prior to shipment on dry ice to the Laboratory Coordinating Center every 4 weeks. The plastic freezer boxes will also be used to hold the specimens when they are shipped to the Laboratory Coordinating Center. 'Backup' samples are stored temporarily (prior to shipment to the Laboratory Coordinating Center), for approximately one month, in the field center laboratory in separate plastic freezer boxes at -20° C or colder. The plastic purple top tubes containing blood for DNA analysis are stored in cardboard freezer boxes at -20° C or colder, prior to shipment. **Note:** Freezer boxes should be placed in the field center laboratory freezer, so that cryovials and the purple top tubes containing DNA blood samples are in the upright position in the freezer.

7.1.1 Storage Labels

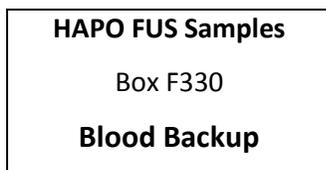
The Data Coordinating Center will provide Box Identification Labels to each field center for identifying freezer boxes and for attachment to the Shipping Grid associated with each freezer box. The Box Identification Label identifies the samples in each freezer box as HAPO samples. This label also contains the field center code and the specific box number. The Box Identification Label also identifies the type of samples contained in the box. There are 5 different types of Box Identification Labels: 1. Analysis blood samples – box numbers 000 – 299; 2. Backup blood samples – box numbers 300 – 599; 3. Urine analysis samples – box numbers 600 -699; Urine backup samples – box numbers 700 – 799; and 5. DNA blood samples – box numbers 800 – 899. Examples of the 5 types of Box Identification Label are shown below:

1. Analysis blood samples

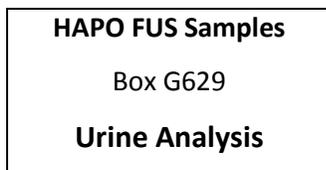


The Box Identification Label indicates that this is box “101” in center “B”.

2. Backup blood samples



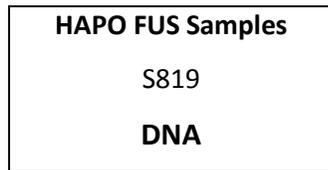
3. Urine analysis samples



4. Urine backup samples



5. DNA blood samples



When the first cryovial or DNA sample tube is placed in a freezer box, laboratory staff should locate the next available set of Box labels corresponding to the type of sample. In selecting the appropriate set of Box Identification Labels:

- Select the next set of 'Blood Analysis' box labels, if this is a plastic freezer box containing blood sample cryovials without white inserts.
- Select the next set of 'Blood Backup' box labels, if this is a plastic freezer box containing blood sample cryovials with white inserts.
- Select the next set of 'DNA' box labels, if this is a cardboard freezer box containing purple top tubes for DNA analysis.
- Select the next set of 'Urine Analysis' box labels, if the plastic freezer box contains urine sample cryovials without white inserts.
- Select the next set of 'Urine Backup' box labels, if the plastic freezer box contains urine sample cryovials with white inserts.

There will be a set of 4 identical Box Identification Labels for each freezer box. One Box Identification Label should be placed on the back left corner of the lid of the freezer box. A second Box Identification Label containing the same box number should be placed on the right side of the lower portion of the front side of the box. When the first cryovial or DNA sample tube is placed in a freezer box, laboratory staff should start a Shipping Grid for the freezer box by

placing the two remaining Box Identification Labels on the top of pages 1 and 2 of the forms that constitute the Shipping Grid.

7.1.2 The Shipping Grid

The Shipping Grid is used to record the location of each cryovial or DNA sample tube in each freezer box. When the first cryovial or DNA sample tube is placed in the freezer box, the date should be written after “Start Date” at the top of page 1 of the Shipping Grid using year/month/day format, entering only the last digit of the year. When the last cryovial or DNA sample is placed in the freezer box, the date should be written after “End Date” on page 2 of the Shipping Grid, again using year/month/day format. **Note:** When an ‘Analysis’ freezer box is shipped, the date it was shipped should be recorded on the Shipping Grid for its backup freezer box. The backup freezer box should not be shipped until after the analysis freezer box has been shipped.

The Shipping Grid for a specific freezer box should be updated each time a cryovial or DNA sample tube is placed in that freezer box. As each cryovial or DNA sample tube is placed in the freezer box, the identical HAPO Bar-code label should be affixed to the corresponding location on the freezer box’s Shipping Grid. Each page of the Shipping Grid contains 10 rows and 5 columns. Page 1 corresponds to the locations on the left side of the freezer box, while page 2 corresponds to the locations on the right side of the box. Freezer boxes should be filled from the back to the front beginning with the left most slot in the back of the box.

A separate Shipping Grid should be completed for each freezer box. Shipping Grids should be stored in a loose leaf binder for easy access by field center staff. Shipping Grids for DNA samples and ‘Urine Analysis’ and ‘Urine Backup’ cryovials should be stored separately from those for ‘Blood Analysis’ and ‘Blood Backup’ samples. Whenever a freezer box is shipped to the Laboratory Coordinating Center, the original Shipping Grid should be sent with the box. Prior to shipment, a photocopy of the Shipping Grid should be made and stored locally.

HAPO Study – Shipping Grid

Box Identification Label

Start Date: 201_ / _ / _
Year Month Day

	1	2	3	4	5
A					
B					
C					
D					
E					
F					
G					
H					
I					
J					

If this is a 'Backup' Sample Box: Date 'Analysis' Box Shipped: 201_/_/_ (year/month/day)

HAPO Study - Shipping Grid

Box Identification Label

End Date: 201 / /
Year Month Day

6	7	8	9	10	
					A
					B
					C
					D
					E
					F
					G
					H
					I
					J

Date Shipped: 201 / /
Year Month Day

7.1.3 Storage of Cryovials for Laboratory Coordinating Center Analysis

Cryovials without white inserts are the samples that are to be sent to the Laboratory Coordinating Center for analysis or storage. Blood sample cryovials are to be stored in plastic freezer boxes identified on the Box Identification Labels as 'Blood Analysis' samples, while urine sample cryovials are to be stored in freezer boxes identified as 'Urine Analysis' samples. When the first 'Analysis' sample is placed in a freezer box, the appropriate set of Box Identification Labels should be located, and the labels attached to the box and to the Shipping Grid. The freezer box should then be filled with the side containing the Box Identification Label facing you.

Within a plastic freezer box, place the samples in order of the date drawn, filling the box from back to front, beginning with the top most row of the box. (**Note:** The top most row corresponds to row A on pages 1 and 2 of the Shipping Grid.) An example of the layout of the plastic freezer boxes is shown in Figure 1. Place the first cryovial in the slot in the back left hand corner of the box beneath the Box Identification label on the lid, i.e., slot A1. Place the next cryovial in slot A2. When slots A1 through A10 have been filled, proceed to slot B1 and then to B2. (The shaded area in Figure 1 illustrates that slots A1-A10 followed by B1 and B2 have been filled.) As each cryovial is placed in the freezer box, make sure that an identical HAPO Bar-code label is attached to the Shipping Grid in the space corresponding to the sample's position in the box. **Note:** Store the freezer boxes so that the samples which are stored first are the first to be shipped. **Note:** Boxes should be filled sequentially even if samples from a specific participant are split across rows or boxes.

Figure 1. Layout of Plastic Freezer Boxes

	Left				Back		Right			
	1	2	3	4	5	6	7	8	9	10
A	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10
B	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
C	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10
D	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
E	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10
F	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
G	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10
H	H1	H2	H3	H4	H5	H6	H7	H8	H9	H10
I	I1	I2	I3	I4	I5	I6	I7	I8	I9	I10
J	J1	J2	J3	J4	J5	J6	J7	J8	J9	J10
	Left				Front		Right			

7.1.4 Storage of Backup Cryovials

Cryovials with white inserts are 'Backup' samples. 'Backup' sample cryovials should be stored in separate plastic freezer boxes (backup blood sample cryovials should be stored separately from backup urine sample cryovials) and placed temporarily in the freezer at -20° C or colder. For these samples, the Box Identification Labels should be identified as 'Blood Backup' samples, or 'Urine Backup' samples. 'Backup' samples should be shipped to the Laboratory Coordinating Center approximately one month after the shipment of the corresponding 'Analysis' samples. The 'Backup' sample plastic freezer boxes should be filled and the Shipping Grid completed in the same way as for 'Analysis' samples. **Note:** The backup samples should be stored so that these samples are also shipped in the order in which they were stored.

7.1.5 Placement of Blood Samples

*Blood sample cryovials should be placed into the plastic freezer boxes according to the layout on the next page. If all OGTT blood samples are collected from a mother/child pair, that would yield a total of 18 cryovials for both the Blood Analysis box and the Blood Backup box. The Shipping Grid on the next 2 pages shows which samples for a given pair should go where. For example, samples from the first mother/child pair should go into slots A1 – B8. The maternal samples should go into slots A1 – A7. The child samples should then go into slots A8 – B8. The slots are numbered sequentially according to the type of sample, e.g. fasting maternal glucose has a barcode ending in digits "700". The last 2 slots B9 and B10 will not contain any samples from this pair and so they are labeled "X". Samples for the next pair should go into slots C1 – D8, and so on. If a sample is not obtained, please put a cross over the number on the slot where the sample should have been. Placement of samples into a specific Blood Backup box should be the mirror image of the sample placement into the Blood Analysis box. One plastic freezer box has enough slots to hold all of the blood samples for 5 mother/child pairs. **Note:** This Shipping Grid should only be used for Blood Analysis and Blood Backup freezer boxes.*

Box Identification Label

HAPO Study – Shipping Grid

Start Date: 201 / /
 Year Month Day

	1	2	3	4	5
A	700	701	702	703	705
B	603	605	650	651	610
C	700	701	702	703	705
D	603	605	650	651	610
E	700	701	702	703	705
F	603	605	650	651	610
G	700	701	702	703	705
H	603	605	650	651	610
I	700	701	702	703	705
J	603	605	650	651	610

If this is a 'Backup' Sample Box: Date 'Analysis' Box Shipped: 201 / / (year/month/day)

HAPO Study - Shipping Grid

Box Identification Label

End Date: 201 / /
Year Month Day

6	7	8	9	10	
720	723	600	601	602	A
611	620	621	X	X	B
720	723	600	601	602	C
611	620	621	X	X	D
720	723	600	601	602	E
611	620	621	X	X	F
720	723	600	601	602	G
611	620	621	X	X	H
720	723	600	601	602	I
611	620	621	X	X	J

Date Shipped: 201 / /
Year Month Day

7.1.6 Storage of DNA Samples

The purple top tubes containing blood for DNA analysis should be stored upright in the field center laboratory freezer at -20° C or colder in cardboard freezer boxes. For these boxes, the Box Identification Labels should be labeled as 'DNA' samples. The Shipping Grids for boxes containing DNA samples should be stored separately from those for freezer boxes containing 'Analysis' and 'Backup' blood and urine samples. DNA sample tubes should be placed in every other slot in the box. For example, the first tube should be placed in the back left hand corner of the box in slot A1. The next tube should be placed in the third slot, i.e., slot A3. The third tube should be placed in slot A5, the fourth in slot A7, and the fifth in slot A9. The next tube should then be placed in slot B2, followed by B4, B6, and so on. After slot B10 has been filled, place the next tube in slot C1, followed by C3, and so on. The shaded area in Figure 2 (below) depicts a cardboard freezer box where these slots have been filled. As each DNA sample tube is placed in the freezer box, the identical HAPO Bar-code label should be placed on the Shipping Grid in the space corresponding to the location of the tube in the cardboard freezer box. **Note:** The DNA sample tubes should be stored so that the DNA sample tubes are shipped in the order in which they were stored.

freezer boxes or 5 cardboard freezer boxes are included in the shipment. **Note:** A package for shipment to the Laboratory Coordinating Center may contain both blood and urine 'Analysis' and 'Backup' samples; however, there must be at least a 4 week interval between the date the last sample was placed in the backup freezer box and the date of shipment of the 'Backup' freezer box to the Laboratory Coordinating Center. This should ensure that analysis and backup samples for a participant are not included in the same shipment. Field centers should ship all completely filled freezer boxes containing analysis samples that have accumulated since the last shipment. If a partially filled plastic freezer box has at least 50 samples (i.e., the box is half full), it can also be shipped. If a partially filled plastic freezer box has fewer than 50 samples, it should be sent with the next shipment. Plastic freezer boxes containing backup samples may be added to each shipment up to a total of 8 plastic freezer boxes, provided that each backup sample has been stored locally for at least 4 weeks. Plastic and cardboard freezer boxes may be sent in the same shipment.

The packing and labeling instructions provided below are in accordance with the International Standards for Shipping Biohazard Materials as specified by the World Health Organization.

7.2.1.1 Packing Instructions:

The following instructions should be followed for packing samples for shipment to the Laboratory Coordinating Center:

- Check that each freezer box has a Box Identification Label clearly visible on both the top and the lower front side of the box. This label contains information identifying the field center and a number to identify the specific freezer box. Make sure that the box number is the same on both labels on the box. Check that the Box Identification Label number on the box is the same as the Box Identification Label number on both pages of the Shipping Grid.
- At the bottom of the second page of the Shipping Grid for each plastic freezer box being shipped, enter the date the freezer box is being shipped.
- Make sure that all cryovials are firmly in place in the plastic freezer box and that the white inserts in the backup sample cryovials are firmly pressed in.
- Make sure that each plastic freezer box is tightly closed (the clamp is clicked shut).

- Wrap each freezer box with a double layer of absorbent paper such as paper toweling, place it in a zip lock bag, and seal the bag shut.
- Place a layer of dry ice in the bottom of the shipping box. **Note:** Follow the Guidelines for Handling Dry Ice (see Section 7.2.1.2 below).
- Pack up to 8 plastic freezer boxes, or 5 cardboard freezer boxes or a combination of both in the polyurethane shipping box, packing them tightly together but leaving enough room to insert the foam shipping box lid.
- Fill the remaining space with dry ice. **Note:** The dry ice should be **tightly** packed into the polyurethane shipping box and the freezer boxes should be surrounded by dry ice.
- **Note:** Make sure that the chunks of dry ice are large enough that they will stay frozen during shipment but not so large that they take up too much space. Small chips could melt in transit and the specimens **must** stay frozen during shipment. A total of approximately 13-14 kg of dry ice will be needed to assure the samples stay frozen for up to 72 hours during shipment. If fewer than 8 plastic freezer boxes or 5 cardboard freezer boxes are included in the shipment, the weight of the dry ice should be greater.
- Place the foam lid into the top of the shipping box making sure that the top of the foam is flush with the top of the box.
- The total weight will be about 17 kg or 37 lb
- Photocopy the Shipping Grid for each freezer box and keep the copy at the field center.
- Place the original copy (the one with the Bar-code labels) of the Shipping Grid for each of the freezer boxes in a baggie (ziplock bag) and place inside the polyurethane box on top of the dry ice.
- Place an order for the shipment and print the FedEx shipping documents at fedex.com.
- Make a copy of the shipping documents and tape them to the foam lid in case the documents that are placed on the outside of the box get lost or damaged.
- Attach the pre-printed Federal Express documents to the top of the box.
- **Note:** It is very important that the process of packing the samples is completed as quickly as possible so that they do not begin to thaw out. The samples must remain

frozen when they are transferred from the -20° C or colder freezer to the shipping box.

7.2.1.2 Guidelines for Handling Dry Ice

Dry ice (CO₂) should be handled carefully, since the fumes can suffocate you and the dry ice can burn your hands. The following precautions should be taken in handling dry ice:

- Dry ice should be stored in a designated container and labelled as a hazardous material.
- Dry ice should be handled, and the polyurethane box filled, only in a well-ventilated area.
- Protective (insulated) gloves should be worn.
- Obey local safety regulations about the use of dry ice.
- Take care when removing dry ice blocks from storage. Do not attempt to remove them from a deep chest. If removing them involves bending over into the dry ice, suffocation may result.
- Never work alone in a confined space; have someone keep an eye on you.

7.2.1.3 Initial preparation for shipping via FedEx

Before making the first shipment with FedEx, each field center needs to register at fedex.com and create an account with a user ID and password. One account should be created per field center. To create an account:

- Go online to fedex.com.
- Select “create a shipment”
- Select “create an account”
- Select “create a user ID for shipping with an account” and “continue”
- Select “use my account online”
- Enter your registration information
- Mark the checkbox for terms and conditions
- Confirm your selected account option by selecting “use my account online”
- For linking the account number, use account number 245944616-616
- For the billing address:

Lynn Lowe, PhD
Northwestern Univ. Feinberg School of Medicine, Dept Prev Med
680 N Lake Shore Dr., Suite 1400
Chicago, IL 60093 USA
(if a phone # is requested use 312-503-7217)

7.2.1.4 US shipments to the Laboratory Coordinating Center:

For shipments from within the US to the Laboratory Coordinating Center, the following steps should be completed:

- Go to fedex.com and select “ship”
- Enter your user ID and password
- For “1. From” enter your name and address
- For “2. To” enter the following:
 - United States
 - Northwestern Univ. Feinberg School of Medicine
 - Fei Chen
 - Division of Endocrinology, Tarry 15-754
 - 303 E. Chicago Ave.
 - Chicago
 - IL
 - 60611
 - 312-503-1610
- For “3. Package & Shipment Details” select “Overnight Priority”, “Your packaging”, 1 package, 17 kg or 37 lbs, \$1 US dollar
- For “4. Billing Details” enter 24594461-616
- For dimensions indicate 48 x 36 x 56 cm
- For “Special Services” from the drop down box select “dry ice” and if it asks for the weight enter 13 kg or 29 lbs
- For “E-mail Notifications” from the drop down box enter your email address, lpowe@northwestern.edu, and fei-chen@northwestern.edu
- For “5. Complete your Shipment” select “create a shipment profile” (name it Laboratory Coordinating Center) which will automatically store all of the information

that was entered above so that it will be available for all future shipments to the Laboratory Coordinating Center.

- Select the Laboratory Coordinating Center from your shipment profile (when you make your first shipment, at the “Complete your Shipment” step, save the shipment profile for future use as it will automatically populate the required fields) when you are preparing your shipment.
- Print out the shipping label three times. Tape 1 to the foam box cover, affix one to the outside of the shipping box using a FedEx plastic pouch, and store one locally.
- Affix the Information Label to the top of the package which states:
HANDLE WITH CARE
DEGRADABLE GOODS TO BE KEPT AT -20° C
NO COMMERCIAL VALUE
- Affix a Dry Ice label (available from FedEx) to 2 sides of the package (i.e., affix 2 Dry Ice labels per package).
- Advise Lynn Lowe (lplove@northwestern.edu) and Fei Chen (fei-chen@northwestern.edu) of the FedEx tracking number and the box ID number of each freezer box included in the shipment (e.g. Box B105, B106, B107).
- Once the shipment has been transported to or picked up by Federal Express, it can be tracked using the fedex.com website.

7.2.1.5 International shipments to the Laboratory Coordinating Center:

For shipments from outside the US to the Laboratory Coordinating Center, the following steps should be completed:

- Go to fedex.com and select “ship”
- Enter your user ID and password
- For “1. From” enter your name and address
- For “2. To” enter the following:
United States
Northwestern Univ. Feinberg School of Medicine
Fei Chen
Division of Endocrinology, Tarry 15-754
303 E. Chicago Ave.
Chicago, IL

60611

312-503-1610

- For “3. Package & Shipment Details” select “International Priority”, “Your packaging”, enter 1 package, 17 kg or 37 lbs, 48 x 36 x 56 cm, \$1 US dollar, select “Products/Commodities”, select “Commercial”, enter 10.00, select “US Dollars”
- For “4. Billing Details” , Bill transportation to 24594461-616, select “Sender”, enter 24594461-616, reference HAPO
- For “Special Services” from the drop down box select “dry ice” and enter 13 kg or 29 lbs
- For “E-mail Notifications” from the drop down box enter your email address, lplove@northwestern.edu, and fei-chen@northwestern.edu
- For “5. Continue your Shipment” select “Continue”
- For “6. Commodity Information” enter “human blood samples for research purposes only”, enter “10.00”, enter the number of freezer boxes in the shipment, enter 4kg or 9lb, for total shipment weight enter 17 kg or 37 lb, for total carriage value enter 1.0 US Dollars
- For “7. Customs Documentation” select “Commercial Invoice”
- For “8. Electronic Export Information” select “No EEI/SED required”
- For “9. Complete your Shipment” select “save as a new profile in My Shipment Profiles” (name it Laboratory Coordinating Center) which will automatically store all of the information that was entered above so that it will be available for all future shipments to the Laboratory Coordinating Center.
- Select the Laboratory Coordinating Center from your shipment profile (when you make your first shipment, at the “Complete your Shipment” step, save the shipment profile for future use as it will automatically populate the required fields) when you are preparing your shipment.
- Print out the shipping label and the Commercial Invoice (the latter will have 6 pages). Make 2 copies of the shipping label. Tape 1 to the foam box cover, place one along with the Commercial Invoices in the FedEx pouch which you will affix to the outside of the shipping box, and store one locally.
- Affix the Information Label to the top of the package which states:
HANDLE WITH CARE
DEGRADABLE GOODS TO BE KEPT AT -20° C

NO COMMERCIAL VALUE

- Affix a Dry Ice label (available from FedEx) to 2 sides of the package (i.e., affix 2 Dry Ice labels per package).
- Advise Lynn Lowe (lpowe@northwestern.edu) and Fei Chen (fei-chen@northwestern.edu) of the FedEx tracking number and the box ID number of each freezer box included in the shipment (e.g. Box B105, B106, B107).
- Once the shipment has been transported to or picked up by Federal Express, it can be tracked using the fedex.com website.