



URMC  
LABS

## Clinical Trials Central Laboratory Manual

Protocol: Coenzyme Q10 (CoQ) in Huntington's Disease  
(HD) (2CARE)

URMC Study Identifier: 2CARE

Manual Version #: 1.00

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## **Section 1. Laboratory Contacts**

Our staff is available to assist the Investigator Sites with requests for supplies, lab reports, changes in demographic and collection information, specimen collection, packaging, and shipping instructions.

To contact the University of Rochester / **URMC Labs** Clinical Trials Central Laboratory, please utilize the following information:

**Mailing Address:** URMC Labs - CTCL  
77 Ridgeland Road  
Attn: Specimen Management  
Rochester, NY 14623

**Toll Free #:** 800-405-1889

**Local Phone #:** 585-350-2670

**Study Support Fax #:** 585-419-6115

**Hours of Operation:** Mon – Fri, 8:00 AM – 6:00 PM EST

**After hours pager #:** 585-220-0757

**Study Support e-mail address:** [LabSRSS@urmc.rochester.edu](mailto:LabSRSS@urmc.rochester.edu)

## Section 2. Laboratory Hours of Operation

URMC Labs operate 24 hours a day / 365 days per year.

Clinical Trials testing is performed Monday – Saturday, unless other arrangements have been made for a specialized courier service to deliver specimens on Sundays for testing.

Federal Express does not offer Sunday delivery service to URMC Labs.

### Holiday Schedules

Based on previous years, FedEx observes the following holidays. These dates are subject to change by FedEx.

#### 2009 - 2010 US Holiday Observations

<b>2009 Dates</b>	<b>Holiday</b>	<b>Observed in U.S.A.</b>
Monday, September 7	Labor Day	X
Thursday, November 26	Thanksgiving	X
Friday, December 25	Christmas	X
<b>2010 Dates</b>	<b>Holiday</b>	<b>Observed in U.S.A.</b>
Friday, Jan 1	New Year's Day	X
Monday, May 31	Memorial Day	X
Monday, September 6	Labor Day	X
Thursday, November 25	Thanksgiving	X
Saturday, December 25	Christmas	X
<b>2011 Dates</b>	<b>Holiday</b>	<b>Observed in U.S.A.</b>
Saturday, Jan 1	New Year's Day	X
Monday, May 30	Memorial Day	X
Monday, July 4	Independence Day	X
Monday, September 5	Labor Day	X
Thursday, November 24	Thanksgiving	X
Sunday, December 25	Christmas	X

## Section 2. Laboratory Hours of Operation (continued)

Should we receive adequate advance notice of a change in schedule, we will provide an updated schedule to your site. However, it is ***strongly recommended*** that you verify your courier's schedule prior to any holiday.

- Ship CAG genotyping (DNA) samples only on Monday or Tuesday to Massachusetts General Hospital.
- Ship frozen samples to URMC labs on Monday – Friday onl. ***Packages shipped to URMC Labs on a Friday must be marked for Saturday Delivery.***
- Avoid collecting ambient specimens for shipment on the day before an observed holiday.
  - If a patient's visit falls on the day before a scheduled holiday, please contact URMC Labs to determine how to best handle the handling of the specimens.

### Section 3. Protocol Laboratory Testing Schedule

Patients will have central laboratory testing according to the following schedule:

Test	Screening	Baseline	Month 3 (V02)	Month 12 (V04)	Month 24 (V06)	Month 36 (V08)	Month 48 (V10)	Month 60/ Early Termination (V12/PW)	Unscheduled
Chemistry Panel	X		X	X	X	X	X	X	X
CBC/Diff	X		X	X	X	X	X	X	X
Urinalysis	X		X	X	X	X	X	X	X
PT/ PTT/ INR	X								X
Pregnancy Test <sup>1</sup>	X	X	X	X	X	X	X	X	X
CoQ plasma	X		X	X	X	X	X	X	X
CAG Genotype		X							

<sup>1</sup>Notes:

- A Urine Pregnancy test will be conducted at all visits for women of childbearing potential.
- Canadian sites must do pregnancy testing for ALL females.
- Duke University must do serum pregnancy testing.

### Section 3. Protocol Laboratory Testing Schedule (continued)

#### Panel Components

Test Name	Component
Urinalysis, Macroscopic	Appearance, UR
Urinalysis, Macroscopic	Blood, UR
Urinalysis, Macroscopic	Leukocyte Esterase, UR
Urinalysis, Macroscopic	Ketones, UR
Urinalysis, Macroscopic	Bilirubin, UR
Urinalysis, Macroscopic	Protein, UR
Urinalysis, Macroscopic	Specific Gravity, UR
Urinalysis, Macroscopic	Glucose, UR
Urinalysis, Macroscopic	Nitrites, UR
Urinalysis, Macroscopic	pH, UR
Urinalysis, Macroscopic	Urobilinogen, UR
Urinalysis, Microscopic	RBC, UR
Urinalysis, Microscopic	WBC, UR
Urinalysis, Microscopic	WBC Clumps, UR
Urinalysis, Microscopic	Bacteria, UR
Urinalysis, Microscopic	Mucus, UR
Urinalysis, Microscopic	Cellular Casts, UR
Urinalysis, Microscopic	Fatty Casts, UR
Urinalysis, Microscopic	Granular Casts, UR
Urinalysis, Microscopic	Hyaline Casts, UR
Urinalysis, Microscopic	Waxy Casts, UR
Urinalysis, Microscopic	Squamous Epithelial Cells, UR
Urinalysis, Microscopic	Renal Tubular Epithelial Cells, UR
Urinalysis, Microscopic	Transitional Epithelial Cells, UR
Urinalysis, Microscopic	Yeast, UR
Urinalysis, Microscopic	Amorphous Crystals, UR
Urinalysis, Microscopic	Calcium Oxalate Crystals, UR
Urinalysis, Microscopic	Cystine Crystals, UR
Urinalysis, Microscopic	Leucine Crystals, UR
Urinalysis, Microscopic	Tyrosine Crystals, UR
Urinalysis, Microscopic	Uric Acid Crystals, UR
Urinalysis, Microscopic	Trichomonas, UR
Urinalysis, Microscopic	Oval Fat Bodies, UR

### Section 3. Protocol Laboratory Testing Schedule (continued)

Test Name	Component
Comprehensive Metabolic	Alkaline Phosphatase
Comprehensive Metabolic	ALT
Comprehensive Metabolic	AST
Comprehensive Metabolic	Bicarbonate
Comprehensive Metabolic	Bilirubin
Comprehensive Metabolic	BUN
Comprehensive Metabolic	Chloride
Comprehensive Metabolic	CPK
Comprehensive Metabolic	Creatinine
Comprehensive Metabolic	Glucose
Comprehensive Metabolic	Potassium
Comprehensive Metabolic	Sodium
Comprehensive Metabolic	Total Protein
Coagulation	Prothrombin Time
Coagulation	INR
Coagulation	PTT
CBC, Platelet, and Diff	WBC
CBC, Platelet, and Diff	RBC
CBC, Platelet, and Diff	Hemoglobin
CBC, Platelet, and Diff	Hematocrit
CBC, Platelet, and Diff	Platelet Count
CBC, Platelet, and Diff	Basophils #
CBC, Platelet, and Diff	Monocytes #
CBC, Platelet, and Diff	Neutrophils #
CBC, Platelet, and Diff	Eosinophils #
CBC, Platelet, and Diff	Lymphocytes #
CBC, Platelet, and Diff	Basophils %
CBC, Platelet, and Diff	Monocytes %
CBC, Platelet, and Diff	Neutrophils %
CBC, Platelet, and Diff	Eosinophils %
CBC, Platelet, and Diff	Lymphocytes %



## **Section 4. Specimen Collection Kits**

Specimen collection kits will be provided to you by URMCLabs with all materials needed for the collection of blood and urine specimens, packaging materials, and shipping labels to send materials back to the URMCLabs.

Each kit will be provided with a set of uniquely numbered labels. The labels included are to be affixed to the test requisition and all the tubes contained in the kit.

In addition, barcode labels for the CAG Genotyping (DNA) will be provided by the CTCC.

Should you have any questions about specimen collection, processing, storage, packaging or shipping, please contact URMCLabs at 800-405-1889.

Additional supplies may be requested by faxing a completed URMCLabs Supply Order Form to 585-419-6115 or emailing to [LabSRSS@urmc.rochester.edu](mailto:LabSRSS@urmc.rochester.edu). See Appendices in Section 13 for the form template. Please allow 5 to 7 business days for supplies to reach your site.

## Section 5. Test Requisitions

Test requisitions have been specifically designed to accurately capture the data elements required for the protocol. Examples of correctly completed test requisitions are included in the Appendices in Section 13 of this manual. Failure to properly complete the test requisition will result in issuance of a data query and may delay the receipt of the results reported to your site.

### Required Elements

- Numbered Labels (see Section 4 above)
- Required Patient Identifiers
  - Subject ID (format: 3 digit site number-XXXX)
  - Subject Date of Birth
  - Subject Initials
  - Subject Gender
- Specimen Collection Date
- Specimen Collection Time
- The initials of the individual that collected the sample

### Documentation Guidelines

The information captured on the test requisition must match the Case Report Form.

In the event that information documented on the test requisition needs to be corrected, place a single line through the incorrect information, clearly write the corrected information, and date and initial the change in accordance with GCP requirements.

Make sure to keep the yellow or pink copies of the test requisitions for your records!

### Canceled Testing / Additional Test Requests

Should a test need to be canceled or a specimen cannot be collected, note the word "Canceled" next to the test / specimen name. Use the comments section at the bottom of the form to provide any additional information regarding the canceled test (Example: "Patient unable to void"). Requests for testing that is not part of the protocol will not be allowed for the 2CARE study.

## Section 6. Specimen Collection and Preparation

(Perform venipuncture per your facility's standard operating procedures.)

**Use Universal Precautions and safety measures when collecting blood samples.**

### Screening Visit (Safety and CoQ Samples)

Order of Draw	Testing	Collection Tube	Processing (see pages 15-16 for detailed instructions)	Packaging and Shipping (see page 18 for detailed Instructions)
1	Comprehensive Metabolic Panel and Serum Pregnancy <sup>1</sup>	1 – 7.5 mL Serum Separator Tube	<ul style="list-style-type: none"> <li>• Gently invert tube 8 - 10 times, allow to clot for 30 minutes</li> <li>• Centrifuge at 1500 x g for 10 minutes</li> <li>• Do not aliquot!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship ambient on day of collection to URMCLabs</li> </ul>
2	CBC/ Diff	1 – 4 mL Lavender Top	<ul style="list-style-type: none"> <li>• Gently invert tube <b>8 - 10</b> times</li> <li>• Do not aliquot!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship ambient on day of collection to URMCLabs</li> </ul>
3	Urinalysis	Specimen Collection Cup	<ul style="list-style-type: none"> <li>• Connect yellow and red marble capped urine tube to the integrated device in the cup lid to transfer urine from the random void</li> </ul>	<ul style="list-style-type: none"> <li>• Ship ambient on day of collection to URMCLabs</li> </ul>
5	PT/INR, PTT	1 – 4.5 mL Blue Top	<ul style="list-style-type: none"> <li>• Gently invert tube <b>8 - 10</b> times</li> <li>• Centrifuge at 1500 x g for 10 minutes</li> <li>• Transfer all the plasma to the 2.0 mL aliquot tube</li> <li>• Freeze immediately!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship frozen on day of collection to URMCLabs</li> </ul>
5	CoQ plasma levels	1 – 10 mL Lavender top	<ul style="list-style-type: none"> <li>• Gently invert tube 8 - 10 times; sit tube upright in an ice bath for 15 minutes</li> <li>• Centrifuge at 1500 x g for 15 minutes in a covered refrigerated centrifuge</li> <li>• Transfer all the plasma to the three 1.5 mL aliquot tubes provided</li> <li>• Freeze immediately!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship 2 of the 3 aliquots to URMCLabs. Store 3<sup>rd</sup> aliquot in pK box provided in deep freezer (-70°C to -80°C)</li> <li>• *If deep freezer is unavailable at the site, ship all 3 aliquots to URMCLabs</li> </ul>

<sup>1</sup>Notes:

- A Urine Pregnancy test will be conducted at all visits for women of childbearing potential.
- Canadian sites must do pregnancy testing for ALL females.
- Duke University must do serum pregnancy testing.
- \*All samples except CoQ3 are shipped same day to URMCLabs

**Section 6. Specimen Collection and Preparation (continued)**

**Baseline Visit (CAG Genotyping/DNA Samples)**

<b>Order of Draw</b>	<b>Testing</b>	<b>Collection Tube</b>	<b>Processing (see page 16 for detailed Instructions)</b>	<b>Packing and Shipping Instructions (see page 18 for detailed Instructions)</b>
1	CAG Genotyping (DNA)	2 – 8.5 mL Yellow Top ACD tubes	<ul style="list-style-type: none"><li>• Label with CTCC-provided barcode label</li><li>• Gently invert tube 8 - 10 times</li><li>• Freeze immediately!</li><li>• Place in plastic bag provided after freezing</li></ul>	<ul style="list-style-type: none"><li>• Ship frozen to Massachusetts General Hospital / Attn: Lakshmi Mysore on a monthly basis if stored in deep freezer (-70°C to -80°C)</li><li>• Ship weekly if stored at -20°C.</li></ul>

**DNA SAMPLES SENT TO Dr. Marcy MacDonald's lab at Massachusetts General Hospital**

**\*\*\*E-MAIL the FedEx Tracking number to LAKSHIMI MYSORE (MGH) AND CARI RAINVILLE (CTCC) TO ALERT THEM OF THE SHIPMENT. \*\*\***

**[mysore@chgr.mgh.harvard.edu](mailto:mysore@chgr.mgh.harvard.edu)**

**[cari.rainville@ctcc.rochester.edu](mailto:cari.rainville@ctcc.rochester.edu)**

**Verify billing reference number on FedEx Airway Bill is 5-25543-2300.  
Do not use this number for any other purposes.**

## Section 6. Specimen Collection and Preparation (continued)

### Follow-Up Visits (V02, V04, V06, V08, V10, V12/PW, and Unscheduled, if applicable) (Safety and CoQ Samples)

Order of Draw	Testing	Collection Tube	Processing	Shipping Instructions
1	Comprehensive Metabolic Panel and Serum Pregnancy <sup>1</sup>	1 – 7.5 mL Serum Separator Tube	<ul style="list-style-type: none"> <li>• Gently invert tube 8 - 10 times, allow to clot for 30 minutes</li> <li>• Centrifuge at 1500 x g for 10 minutes</li> <li>• Do not aliquot!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship ambient on day of collection to URMCLabs</li> </ul>
2	CBC/ Diff	1 – 4 mL Lavender Top	<ul style="list-style-type: none"> <li>• Gently invert tube <b>8 - 10</b> times</li> <li>• Do not aliquot!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship ambient on day of collection to URMCLabs</li> </ul>
3	Urinalysis	Specimen Collection Cup	<ul style="list-style-type: none"> <li>• Connect yellow and red marble capped urine tube to the integrated device in the cup lid to transfer urine from the random void</li> </ul>	<ul style="list-style-type: none"> <li>• Ship ambient on day of collection to URMCLabs</li> </ul>
4	CoQ plasma levels	1 – 10 mL Lavender top	<ul style="list-style-type: none"> <li>• Gently invert tube 8 - 10 times</li> <li>• Centrifuge at 1500 x g for 15 minutes in a dark centrifuge</li> <li>• Transfer all the plasma to the three 1.5 mL aliquot tubes provided</li> <li>• Freeze immediately!</li> </ul>	<ul style="list-style-type: none"> <li>• Ship 2 of the 3 aliquots to URMCLabs. Store 3<sup>rd</sup> aliquot in pK box provided in deep freezer (-70°C to -80°C)</li> <li>• If deep freezer is unavailable at the site, ship all 3 aliquots to URMCLabs.</li> </ul>

#### Notes<sup>1</sup>

- A Urine Pregnancy test will be conducted at all visits for women of childbearing potential.
- Canadian sites must do pregnancy testing for ALL females.
- Duke University must do serum pregnancy testing.
- \*All samples except CoQ3 are shipped same day to URMCLabs

## Section 6. Specimen Collection and Preparation (continued)

### SPECIMEN HANDLING

#### Metal Freezing Block

A *Metal Freezing Block* will be provided to all sites for flash freezing of blood and urine samples. The *Metal Freezing Block* will be stored in the  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer until the time of sample collection. The *Metal Freezing Block* will maintain a temperature of  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  for no longer than 4-5 hours out of the freezer. Remove *Metal Freezing Block* from the freezer before collecting blood and urine samples. Place the *Metal Freezing Block* into the styrofoam carrying box for transporting. The samples will be placed upright in the *Metal Freezing Block* in the slots provided. Following sample collection and flash freezing, samples will be placed into the  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer until shipment. Should your site only have a  $-20^{\circ}\text{C}$  freezer, follow the  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer instructions.

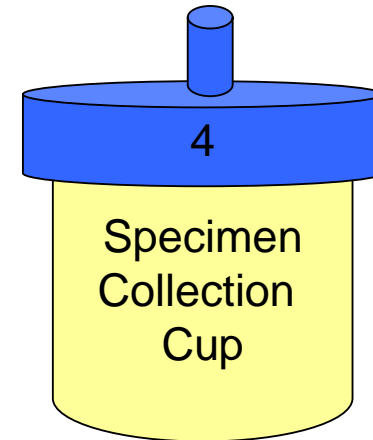
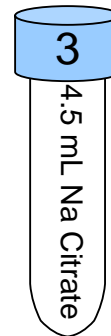
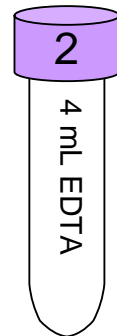
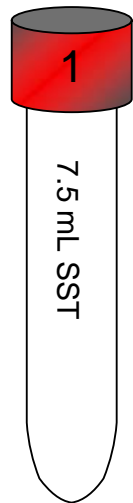
#### STORAGE

Following the blood sample collection and flash freezing of the samples in the *Metal Freezing Block* all samples (CoQ or CAG Genotyping) will be transferred to a freezer storage box and placed in a  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer (if available).

- Maintain samples in a  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer until shipment.
- Samples **must not** be stored in the *Metal Freezing Block* in the freezer.
- Sites with  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer will store the third CoQ plasma sample in a pK box until notified by CTCC.
- CAG genotyping (DNA) samples are to be stored in the  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$  freezer no longer than one month after collection or shipped weekly if stored at  $-20^{\circ}\text{C}$ .

Section 6. Specimen Collection and Preparation (continued)

# Safety Lab Collection Tubes

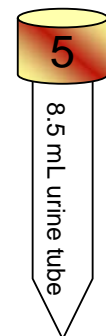


**1.** Collect blood in one red/gray cap 7.5 mL Serum Separator Tube.  
Gently Invert 8-10 times.  
Allow to clot for 30 minutes.  
Centrifuge SST tube at 1500 x g for 10 minutes.  
Do not aliquot.

**2.** Collect blood in one lavender cap 4 mL EDTA tube.  
Gently Invert 8-10 times.  
Do not aliquot.

**3.** Gently invert tube 8 - 10 times  
Centrifuge at 1500 x g for 10 minutes  
Transfer all the plasma to a 2.0 mL aliquot tube  
Freeze immediately!

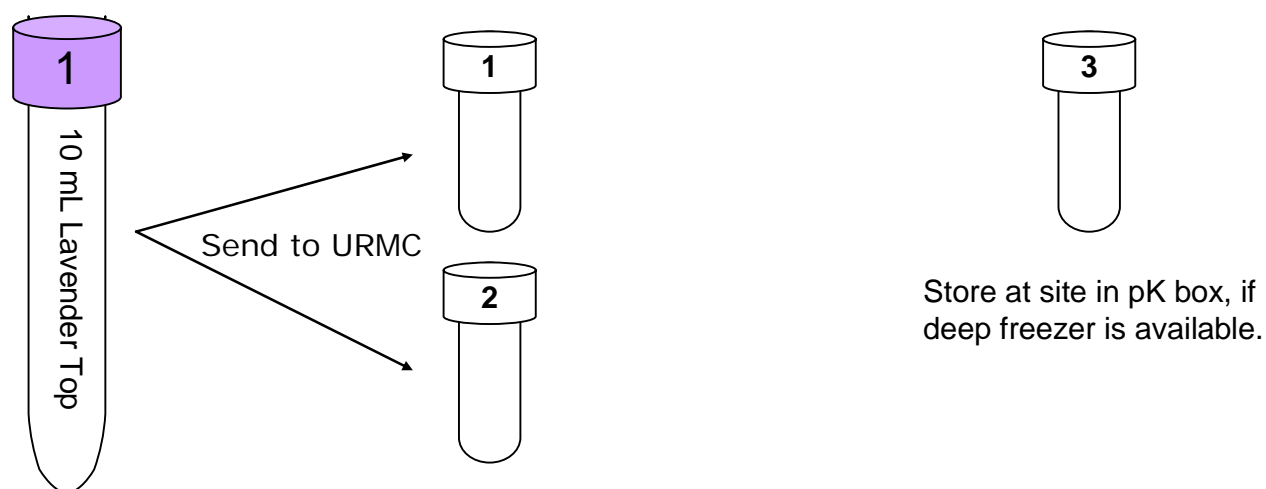
**4.** Collect urine in specimen collection cup.



**5.** Connect yellow and red marbled urine tube to the integrated device in the cup lid to transfer urine from the random void.

## Section 6. Specimen Collection and Preparation (continued)

# CoQ Plasma Collection

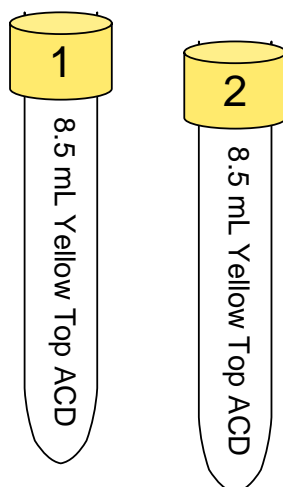


1. Collect blood in one 10 mL lavender top vacutainer.
  - a. Mix immediately by gently inverting the tube at least 8-10 times and allow to sit upright for 15 minutes in an ice bath with a lid or covered in foil (as CoQ is both heat and light sensitive).
2. Centrifuge at 4°C (using a refrigerated centrifuge) at a minimum of 1500 x g for 15 minutes in the dark until cells and plasma are well separated.
  - a. If centrifuging at room temperature is only available, this is acceptable; however, a refrigerated centrifuge is preferable to ensure stability. **Write "RT" on the blood tube label if centrifuged at room temperature.** This information is also captured on the eCRF and test requisition.
3. Transfer all the plasma using the pipette provided into the three (3) 1.8 ml aliquot tubes provided.
4. Flash freeze immediately and store at -70°C or greater until shipment. If your site only has a -20° C freezer, **please write 'frozen at -20° C' on blood tubes.**
5. Ship 2 of the 3 aliquots to URM C Labs. If a deep freezer is unavailable at the site, ship all 3 aliquots to URM C Labs.



## Section 6. Specimen Collection and Preparation (continued)

# CAG Genotyping (DNA)



Barcode labels must be placed on the upper half of tube in the manner shown in the picture or barcodes will be unreadable.

- 1, 2. Collect blood in two 8.5 mL yellow top ACD vacutainers. Gently invert the tube to ensure mixture of the solution in the tube and the blood.**
3. Apply barcode labels provided by the CTCC. **Do not write the subject ID on the blood tube.** Place the remaining barcode label(s) on the DNA Blood Sample Laboratory Requisition. Place the master label containing Subject ID on the DNA label page and file with source documentation.
4. Immediately freeze the tube upright in a  $-70^{\circ}\text{C}$  freezer or greater. Place in small plastic bag provided after freezing.
5. If the site has a  $-70^{\circ}\text{C}$  freezer or greater, batch ship frozen specimens monthly to Massachusetts General Hospital/ Attn: Lakshimi Mysore. **If the site only has a  $-20^{\circ}\text{C}$  freezer**, ship frozen specimens weekly.
6. Include the completed DNA Blood Sample Requisition in the shipment.

Hint: Place in separate plastic bag to avoid ink running.

## Section 7. Packaging Instructions

### **Packaging ambient & frozen safety and CoQ specimens in a combo shipping container for URM Labs**

#### **Frozen specimens**

1. Remove aliquots from freezer. Place the aliquot tubes in the 95 kPa bag with the absorbent pad and seal per instructions on bag.
2. Place the bagged sample and the pink copy of the requisition inside the cooler. Fill cooler **completely** with 5 pounds of dry ice.
3. Place cover on the cooler. (Do Not Tape Cooler Closed!)
4. Place cooler in the fiberboard container.
5. Place foam insert on top of cooler.
6. Place ambient temperature cool pack on top of cooler.

#### **Ambient specimens**

1. Place the tubes in the 95 kPa bag with the absorbent pad and seal per instructions on bag.
2. Place the bagged sample and the white copy of the requisition form on the top of the ambient cool pack and close box.

#### **Packaging**

1. Seal the cardboard outer box.
2. Attach completed FedEx air way bill to the bag.
3. Complete the UN1845 dry ice label on the provided cooler per the instructions on page 16. Attach the airway bill pouch to the cooler and insert the completed FedEx air way bill.

## Section 7. Packaging Instructions (continued)

### Packaging Frozen CAG (DNA) Blood Specimens for MacDonald Laboratory at Massachusetts General Hospital

1. Remove aliquots from freezer. Place the aliquot tubes in the 95 kPa bag with the absorbent pad and seal per instructions on bag.
2. Place the bagged samples in the cooler. Fill cooler **completely** with 5 pounds of dry ice.
3. The corresponding DNA Blood Sample Requisition form for each subject's samples must accompany the shipment. (Hint: To avoid running of ink, place the paperwork in a separate plastic bag).
4. Place lid on the cooler. (Do Not Tape Cooler Closed!)
5. Place cooler in the fiberboard container.
6. Seal the cardboard outer box.
7. Complete the UN1845 dry ice label on the provided cooler per the instructions on page 16. Attach the airway bill pouch to the cooler and insert the completed FedEx air way bill.

\*NOTE: Personnel at MacDonald's Lab at Massachusetts General Hospital have been instructed not to respond to any site questions for confidentiality purposes. Contact the CTCC Project Manager with any concerns.

## Section 8. Shipping Instructions

***Packages shipped to URMC on a Friday must be marked for Saturday Delivery.***

**Notification of Shipment:** Complete the **2Care Specimen Shipment Notification Form** (*available for download from the eRT system*) and email a copy to URMC Labs Study Support at [LabSRSS@urmc.rochester.edu](mailto:LabSRSS@urmc.rochester.edu).

**Call Fed Ex at 1-800-463-3339 to schedule a pick up.**

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### **Frozen Samples**

**NOTE:** Prior to beginning the study establish a source for dry ice at your facility. A supplier may be found by accessing [www.dryiceinfo.com](http://www.dryiceinfo.com). Ship via FedEx priority overnight with 5 pounds or more of dry ice to:

a. **CAG Genotyping (DNA) Samples**

**NOTE:** Ship only on Monday or Tuesday

Lakshmi S. Mysore  
Center for Human Genetic Research  
Richard B. Simches Research Center  
Massachusetts General Hospital  
185 Cambridge Street  
5th Floor, CPZN, 5300-D2  
Boston, MA 02114

Phone: (617) 726-5726

b. **CoQ Plasma Samples:**

**NOTE:** To avoid delays in delivery, please do NOT ship to URMC Labs the day before a holiday.

URMC Labs  
77 Ridgeland Road  
Rochester, NY 14623

## 8. Shipping Instructions (continued)

### Frozen Shipments

<b>US Airbill</b> FedEx Tracking Number: 8693 6842 7670		Form ID No. 0215 Sender's Copy	
<b>1 From</b> Please print and press hard. Date: <u>1</u> Sender's Name: <u>A. COORDINATOR</u> Phone: <u>(555) 555-1100</u> Company: <u>THE RESEARCH CENTER</u> Address: <u>123 MAIN STREET</u> City: <u>ANYTOWN</u> State: <u>CA</u> ZIP: <u>55331</u>		<b>4a Express Package Service</b> <input checked="" type="checkbox"/> FedEx Priority Overnight <input type="checkbox"/> FedEx Standard Overnight <input type="checkbox"/> FedEx 2Day <input type="checkbox"/> FedEx Express Saver	
<b>2 Your Internal Billing Reference</b> SURE-PD		<b>4b Express Freight Service</b> <input type="checkbox"/> FedEx 1Day Freight <input type="checkbox"/> FedEx 2Day Freight	
<b>3 To</b> Recipient's Name: <u>URMC CENTRAL LAB</u> Phone: <u>(585) 350-2670</u> Company: <u>PATHOLOGY &amp; LAB MED/TRLs ECFW</u> Recipient's Address: <u>77 RIDGELAND RD</u> City: <u>ROCHESTER</u> State: <u>NY</u> ZIP: <u>14623-3111</u>		<b>5 Packaging</b> <input type="checkbox"/> FedEx Envelope* <input type="checkbox"/> FedEx Pak* <input type="checkbox"/> FedEx Box <input type="checkbox"/> FedEx Tube <input checked="" type="checkbox"/> Other	
0401613043		<b>6 Special Handling</b> <input checked="" type="checkbox"/> SATURDAY Delivery <input type="checkbox"/> Dry Ice <input type="checkbox"/> Cargo Aircraft Only	
		<b>7 Payment</b> Bill to: <input type="checkbox"/> Sender <input checked="" type="checkbox"/> Recipient <input type="checkbox"/> Third Party <input type="checkbox"/> Credit Card <input type="checkbox"/> Cash/Check	
FedEx Acct. No. <u>3887-0676-7</u> Exp. Date:		<b>8 Residential Delivery Signature Options</b> <input type="checkbox"/> No Signature Required <input type="checkbox"/> Direct Signature <input type="checkbox"/> Indirect Signature	
Total Packages: <u>3</u> Total Weight: Total Declared Value: \$ <u>.00</u>		519	

- Using the air bills (i.e. URM Labs or Massachusetts General Hospital) supplied, enter the shipment date and Sender Info in Section 1.
- Under Section 6:
  - a. Check the 'Yes, Shipper's Declaration not required' box, **Does this shipment contain dangerous goods?**
  - b. Check the box for "dry ice", record the # of packages and record the number of Kg of dry ice (2 lb = 1 kg)
- Enter the **Total Weight** of the package in pounds
- For **Friday** shipments to **URMC**, **Check Box for Saturday Delivery!**

**Remember, DNA blood sample shipments to Massachusetts General Hospital must be shipped only on Monday or Tuesday, as this lab cannot receive shipments on Thursday or Friday.**

## Section 8. Shipping Instructions (continued)

### Completing the Dry Ice UN 1845 Shipping label

Shipper's Declaration not Required.  
Dry Ice amount must be in kilograms.  
Note: 2 lbs. = 1 kg.

Airwaybills / airbills must have the following:  
1. Dry Ice; 9; UN 1845  
2. \_\_\_\_\_ x \_\_\_\_\_ Kg  
(Number pgs) (wt)

**Dry Ice**  
\_\_\_\_\_ kg.

**UN 1845**

Shipper's Name and Address  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Consignee Name and Address  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

106426 1/01 MWI

1. Enter number and weight of the entire box in Kg (2 lb = 1 kg)
2. Enter the weight of the dry ice in kg
3. Enter Shipper's Name and Address
4. Enter Consignee's Name and Address:

Jayalakshmi S. Mysore  
Center for Human Genetic Research  
Richard B. Simches Research Center  
Massachusetts General Hospital  
185 Cambridge Street  
5<sup>th</sup> Floor, CPZN, 5300-D2  
Boston, MA 02114

Or

URMC Labs  
77 Ridgeland Road  
Rochester, NY 14623

## **Section 9. Laboratory Result Reports**

Lab Results reports will be faxed to your office to the attention of the Investigator. A sample report is included in the appendices of this manual.

### Report Turn Around Times

Testing will be completed and results reported within 24 hours of specimen receipt at URM Labs.

### Result Flags

Results above the normal range for an assay will be flagged “H”.  
Results below the normal range for an assay will be flagged “L”.

Results that are out of normal range may require additional follow up. The subject should be referred to his/her treating physician as necessary.

### Lab Exclusion Criteria at Screening Visit

- Creatinine > 2.0 mg/dL
- ALT > 3x Upper Limit of Normal
- Total Bilirubin > 3x Upper Limit of Normal
- Absolute Neutrophil Count  $\leq 10^3/uL$
- Platelet Count <  $10^3/uL$
- Hematocrit
  - Female < 33%
  - Male < 35%
- Coagulation Tests:
  - PT > 1.5x Upper Limit of Normal
  - PTT > 1.5x Upper Limit of Normal

### Result Blinding

No Central Lab testing is blinded

## Section 10. Data Queries

Data queries may be opened at sample accessioning in the laboratory for several reasons:

- Missing specimens
- Incorrect specimens
- Damaged or incorrectly prepared samples
- Extra or unnecessary specimens
- Unlabeled, specimens labeled with incomplete information, or mislabeled specimens
- Incomplete or indecipherable information recorded on the test requisition
- Discrepant demographic information provided
  - Test requisition compared to specimen tube labels
- Duplicate subject identifiers

These queries will be faxed to your site daily to the attention of the Coordinator and must be completed and returned within 2 business days. Some queries may delay reporting of laboratory results.

### Data Inconsistencies Identified After Report Issuance

When the subject's visit report is received, it is important to review the subject demographic and visit information for accuracy. Some errors are not identifiable at the time of accessioning at the lab. For example, a unique subject identifier with the correct numbering scheme may have been recorded on the test requisition. It would have passed the edit checks at URM Labs, but upon investigation turns out that it was the wrong identifier for the subject.

Should you discover an error when reviewing the report, you may either fax a request to make a correction and re-issue the report, or send an e-mail to the study support team. A correction request form has been provided in the appendices of this manual for your use. If you e-mail the request, be sure to include the kit number of the order to be changed, the item to be changed, the item's current value, and the value that you would like to have the item corrected to.

Most changes are completed within one business day and a corrected report will be issued to your site after the correction is complete.

### Data Queries Issued by the Coordinating Center

At data lock or periodically throughout the study the Coordinating Center will run edit programs to check for discrepancies between the lab data and the data recorded on the case report form. The CTCC may query the data and provide instruction directly to the laboratory to modify demographic and visit data. Based upon the sponsor's direction, corrected lab reports may be issued to your site.



## Section 11. Frequently Asked Questions

This section is provided to address many common questions that arise to URMC Labs in conducting a study. However, this manual contains a significant amount of additional information regarding the lab services designed specifically for your study. It is recommended that you read the entire manual to obtain the most complete information.

### ***How can I order additional lab supplies?***

**A:** Additional supplies may be requested by faxing a completed URMC Labs Supply Order Form to 585-419-6115. Supplies will arrive at your site within 5 to 7 business days. If you need supplies sooner than this, please call 800-405-1889 or 585-350-2670 to place your order.

### ***I don't have a -70°C to -80°C freezer available to store frozen specimens. What should I do?***

**A:** If a freezer meeting this specification is not available, place tubes on dry ice and ship to appropriate lab(s) on day of collection. Use the Metal Freezing Block to freeze specimens per the instructions on Page 14 in Section 6 of this manual. Refer to Sections 7 and 8 of this manual for packing and shipping instructions.

CAG Genotyping (DNA) samples that cannot be frozen at **-70°C to -80°C or even -20°C** must be shipped at room temperature (no freezing or batch shipping) on the **FIRST MONDAY FOLLOWING COLLECTION**. Do NOT freeze or refrigerate prior to shipment. The samples will still be stable.

### ***My centrifuge is not refrigerated. What should I do?***

**A.** If a refrigerated centrifuge is not available at your site, may place the tubes in an ice/water mix at 0°C for 10 minutes prior to centrifugation. Do not leave the tube in the ice/water mix for longer than 40 minutes.

### ***My centrifuge is not able to meet the speed/force indicated. What should I do?***

**A.** Centrifuge at the highest speed available for up to 35 minutes to achieve full separation of cells from plasma/serum. Document the centrifuge rate used and duration of spin on the Test Requisition Form.

## Section 11. Frequently Asked Questions (continued)

***My copy of your lab licensure and accreditation is expiring. When will you send me an updated copy?***

**A:** We will send an updated copy to you as soon as it is available to us. Historically, we do not receive an updated copy of our NYS license until 4 to 8 weeks after our inspection occurred. These inspections may not be conducted on an exact schedule and the current accreditation is considered valid until the inspection results are provided to us. The most current versions of our licensure and accreditation are also available in PDF format at the following web address:  
[www.urmc.rochester.edu/Path/clinlabs.html](http://www.urmc.rochester.edu/Path/clinlabs.html)

***The patient was a difficult draw and I wasn't able to obtain the entire required specimen. What should I do?***

**A:** Document the situation on the comments section of the test requisition and send everything that you could obtain. We will attempt to perform as much testing as possible from the available sample and notify you if any testing needs to be canceled.

***How do I order a test that isn't part of the study schedule?***

**A:** Tests that are not part of the study must be done outside of the protocol through your own site's clinical lab. No additional testing may be requested through the 2CARE study.

***I haven't received a report for a lab visit that I collected. Where is it?***

**A:** The report may not be available yet due to:

- Outstanding test results – Refer to the Reporting section for information about test turn around.
- The need to re-run and verify results
- An open data query

***The investigator needs one of the test results right away. What should I do?***

**A:** Contact study support at (800) 405-1889 or (585) 350-2670 to notify them of the situation. They will work with you to determine the soonest a result can be available and the best way to get the result to the investigator when it is.

***I have a patient with a scheduled lab visit that falls on a holiday. What should I do?***

**A:** Contact the Project Manager at the CTCC to determine when you should collect the specimen. Refer to section 2 of this manual for information about holiday shipping.

## Section 11. Frequently Asked Questions (continued)

***I can't find my copy of a test requisition for a kit that I shipped to the lab. How can I get a copy?***

**A:** If you sent the yellow copy of the test requisition to the lab it will be mailed back to you, generally within a week of receipt. If it is over 2 weeks since the visit, or if you know that it was misplaced at your site, contact study support to request a copy of the requisition received by the laboratory.

***One of the tests that I sent to you was canceled due to hemolysis. How did that happen?***

**A:** Hemolysis can be caused by several factors:

- Difficulty in obtaining blood from patient (hard draw)
- Prolonged Tourniquet use
- Use of too large or too small needle gauge for the patient
- Improper venipuncture
- Insufficient clot time prior to centrifugation
- Delay in sample separation
- Inadequate drying time after use of alcohol prep at draw site
- Vigorous shaking or mixing of the sample after draw
- Exposure to excessive heat or cold
- Patient health conditions, such as hemolytic anemia

## **Section 12. Required Documentation and Licensure**

- Reference Ranges
- Medical Directors' Curriculum Vitae
- Medical Director's License
- Laboratory Licensure and Certifications

### **Section 13. Appendices**

- Sample Requisitions
- Sample Report
- Supply Order Form
- Correction Request Form
- Data Discrepancy Form
- 2CARE Specimen Shipment Notification Form
- MSDSs