

Sample Collection Protocol

This section will be updated as soon as a replacement genetics lab is identified.

Rutgers Cell and DNA Repository (RUCDR) Dana Witt Witt@Biology.Rutgers.Edu 732-445-1498	Materials provided: NaEDTA tubes Kit to package and ship sample, including shipping box and preprinted FedEx label labels for tubes not provided
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Genetic sample:

1. Collect blood specimen in the 2 NaEDTA tubes provided in kit.
2. Invert each tube gently 8-10 times to mix blood with additives and keep them at room temperature.
3. Using labels provided by your center, record the NIDDK site number, Patient ID, and sample collection date on the labels and affix labels to tubes.
4. Complete the NIDDK Phlebotomy Collection Form. Double check NIDDK site number and Patient ID to verify that information on tubes match information on form.
5. Date and sign the NIDDK Phlebotomy Collection Form in the TO BE COMPLETED BY PHLEBOTOMIST area.
6. Place tubes with labels facing down in Styrofoam container. Package the blood tubes in the safety mailer following the enclosed instructions. Be sure to seal the Styrofoam container with the red water resistant tape.
7. Place the collection form (NIDDK Phlebotomy Collection Form) in the mailer box outside of the plastic bag. Tape cardboard box closed when assembly is complete.
8. Use the enclosed Fed Ex shipping label to ship the sample to the Rutgers University Cell Repository. Be sure shipping label is marked for priority overnight delivery.
9. For routine shipments be sure the outside of the box is labeled "Diagnostic Specimen Packed in Compliance with IATA Packing Instruction 650."
10. Call Federal Express, 1-800-GO-FEDEX (1-800-463-3339), and a courier will be dispatched to pick up the samples. Be sure to give Fed Ex the Zip Code of the PICKUP address, not that of the destination. DO NOT, UNDER ANY CIRCUMSTANCE, PUT MAILER INTO A FED-EX DROP BOX.
11. Notify the Rutgers University Cell and DNA Repository that blood is being shipped and provide the Federal Express tracking number(s) and SYNCH Patient ID(s). This can be done through the Web Portal at <http://rucdr.rutgers.edu/shippingblood>, by fax (1-732-445-1149) or phone (1-732-445-1498).

Fisher BioServices

<p>Fisher BioServices Sandra Ke sandra.ke@thermofisher.com 240-686-4702</p> <p>Heather Higgins heather.higgins@thermofisher.com 240-686-4703</p>	<p>Materials provided:</p> <p>cryovials for plasma labels for cryovials and slides slide storage boxes freezer storage boxes shipping boxes and preprinted FedEx label</p>
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Plasma (5mL or 3mL):

1. Collect blood into EDTA (purple top) tubes. Collect sufficient whole blood to yield 5mL (baseline visit only) or 3mL of plasma.
2. Gently invert the tubes 8-10 times.
3. Blood samples should be centrifuged immediately for best results. If there is a delay, samples should be cooled on wet ice or refrigerated; however, it is best not to keep the samples on ice for more than one hour. Centrifuge the blood sample at 4°C in a horizontal rotor (swing-out head) for a minimum of 10 minutes at 1,100 RCF (Relative Centrifugal Force) or per your institution's guidelines. (The refrigerated centrifuge should be turned on at least 30 minutes prior to use to allow it to cool down.)
4. Draw off supernatant and pipette 1mL aliquots into the cryovials provided. Fill as many vials as possible.
5. Record the Patient ID, sample collection date, and type of sample (P for plasma) on the cryovial labels and affix the labels to the cryovials.
6. Freeze all aliquots at -80°C until ready for batch shipment to Fisher BioServices.

Serum (10mL or 5mL):

1. Collect blood into the SST Vacutainers. Collected sufficient whole blood to yield 10mL (baseline visit only) or 5 mL of serum.
2. Invert the vacutainers 8-10 times to mix and activate the serum separator.
3. Allow blood to stand upright at room temperature for 30-45 minutes.
4. Within 1 hour of collection, centrifuge the sample for 15 minutes at room temperature at approximately 2400 RPMs (1000g).
5. Draw off supernatant and pipette 1mL aliquots into the cryovials provided. Fill as many vials as possible.
6. Record the Patient ID, sample collection date, and type of sample (S for serum) on the cryovial labels and affix the labels to the cryovials.
7. Freeze all aliquots at -80° C at your center until ready for batch shipment to a specified repository or testing laboratory.

Sample Collection Protocol

PK Samples:

Plasma:

1. Place K2 EDTA Vacutainer collection tube in an ice bath (if available) to allow it to cool for at least 10 minutes before the scheduled blood draw time.
2. Collect 3 mL whole blood into K2 EDTA Vacutainer
3. Gently invert the tubes 8-10 times.
4. Blood samples should be centrifuged immediately for best results. If there is a delay, samples must be stored on wet ice or refrigerated and plasma separated within 1 hour of collection.
5. Centrifuge the blood sample at 2400 rpm at 4°C for 10 minutes. (The refrigerated centrifuge should be turned on at least 30 minutes prior to use to allow it to cool down.)
6. Remove stopper from collection tube carefully without shaking or quick movement. Using a fresh pipette, draw off supernatant and aliquot plasma into the 1mL cryovials provided. Use at least two cryovials and distribute plasma evenly into cryovials.
7. Record the Patient ID, sample collection date and time on the cryovial labels and affix the labels to the cryovials.
8. Freeze all aliquots at -80°C until ready for batch shipment to UNC laboratory.

Urine (20mL or 10mL):

1. Collect a 20mL sample of urine (subjects participating in the PK study, schedule 1 or 2) or a 10mL sample of urine (subjects not participating in the PK study) using a clean catch in sterile collection cup or bag. This sample can be collected at anytime during the PK study visit.
2. Aliquot 5mL of urine into each storage containers.
3. Record the Patient ID, date of sample, collection time and affix labels to storage container.
4. Freeze all aliquots at -70° C or cooler until ready for batch shipment to UNC laboratory.

Ship PK samples to: Roy L. Hawke
c/o UNC coordinator
University of North Carolina, Chapel Hill
Division of Pharmacotherapy
School of Pharmacy
CB#7360 Kerr Annex, Rm 3311
Chapel Hill, NC 27599-7360

Notify UNC coordinator prior to shipping.