# 8. LABORATORY SPECIMENS AND THE CENTRAL BIOCHEMISTRY LABORATORY

## 8.1 INTRODUCTION

The primary function of the Central Biochemistry Laboratory (CBL) within the GoKinD study is to perform testing for basic biochemistries and renal evaluations and to collect and process blood for genetic analysis on the participants. The CBL will interact with the personnel at the Coordinating Center (COC) and the clinical sites in collecting data to produce precise and accurate assay results. The CBL will also provide temporary storage space for aliquots of study specimens at conditions to preserve the integrity of the blood and urine components prior to shipping samples to the Centers for Disease Control and Prevention (CDC) for permanent storage. This chapter primarily addresses technical issues and the quality of the specimens for the study.

## 8.2 PREPARATION

### 8.2.1 Participant Contact

When the proband/parent arrives for their clinic visit explain the GoKinD study to them. Carefully review the consent form and all procedures related to the collection of the blood and urine specimens. Allow the proband/parent to ask questions about the study and answer all of them before the proband/parent signs consent form.

Since the study also depends on the voluntary participation of probands/parents, every effort must be made to make the entire procedure as convenient as possible for them. The best way to achieve this is for the staff to be thoroughly knowledgeable about all aspects of the procedures.

The GoKinD study involves the collection of approximately 35 mL of blood and a completely voided random sample of urine from each participant. A total of four tubes of blood is collected. Any participant who is concerned about the volume of blood should be reassured that the total amount of blood drawn is just over two tablespoons, although it may look like more. The technician may also assure participants that thirteen times as much blood (450 mL) is collected when they donate a pint of blood.

### 8.2.2 Supplies Provided by the CBL

The CBL will provide all blood collection tubes to the GoKinD clinics. These include the 8 mL draw black and blue top Vacutainer (CPT$^{TM}$) tubes, the 10 mL lavender top EDTA Vacutainer tubes, and the 10 mL red and gray top Vacutainer tubes.

The CBL will also provide the GoKinD clinics all supplies necessary for the transfer of whole blood, plasma, serum, and urine to the CBL. These supplies include the polypropylene sample aliquot tubes, the transfer pipettes necessary for the aliquotting of samples, and the transport boxes needed for proper temperature storage of the specimens en route to the CBL.

If you are running short of any supplies, please fax the CBL Supply Reorder Form (Form 205GK) to the CBL.

Prenumbered labels for collection, aliquot, and storage tubes will be available to all clinics from the CDC and ATSDR Specimen and Data Bank (CASPIR) facility (see Figure 8.4).

### 8.2.3 Blood Collection Tray and Tubes

Prior to venipuncture, prepare a tray for each participant. The tray holds the tubes used in the blood collection and the various plastic vials, which will contain the final serum, plasma, and urine aliquots. These final vials are to be frozen and sent to the CBL for analysis and storage.

#### 8.2.3.1 Blood Collection Tray

First, the staff organizes and prepares the blood collection tray. The tray itself should be made of hard plastic, which is unbreakable and can be easily cleaned. The tray should have individual compartments which are filled with the supplies listed below.

- A test tube rack to hold the four blood collection tubes which are drawn from each participant. These tubes are described in detail in the next section.
- Sterile, disposable 21-gauge butterfly needles.
- A plastic tube guide.
- Luer adapters.
- Sterile alcohol swabs.
- Gauze sponges.
- A tourniquet.
- Bandages ("Band Aids").
- Smelling salts, ice packs, and wash cloths should be readily available in the specimen collection area for probands/parents who become faint during the blood draw.

#### 8.2.3.2 Blood Collection Tubes

About 35 mL of blood is drawn from each participant using four blood collection tubes. Samples from these four tubes will be used for genetic and biochemical assays and long-term storage specimens. The collection tubes are provided to the sites by the CBL.

### 8.2.4 Venipuncture

Before applying the tourniquet, screw the Luer adapter into the plastic tube guide. Insert the butterfly tubing onto the adapter. It is also acceptable for the venipuncture to be performed using a standard 21-gauge Vacutainer needle screwed directly into the plastic tube guide.

With jacket or sweater removed, have the participant sit upright with the sleeves rolled up to expose the antecubital fossa (elbow). The preferred arm to draw from is the left arm. The right arm should be used only if blood collection is not possible from the left arm. This does not mean you must stick the left arm, only do so if an adequate vein is apparent.

PRECAUTIONS WHEN USING A TOURNIQUET: The tourniquet should be on the arm for the shortest time possible. Never leave the tourniquet on for longer than two (2) minutes. To do so may result in hemoconcentration or a variation in blood test values. If a tourniquet must be applied for preliminary vein selection, and it remains on the arm for longer than two minutes, it should be released and reapplied after a wait of two minutes. Instruct the participant that he/she should not clench his/her fist prior to the venipuncture. Doing so could cause fluctuations in the results of several of the possible analytes to be measured. If the participant has a skin problem, put the tourniquet over the participant's shirt or use a piece of gauze or paper tissue so as not to pinch the skin. Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.

Once the vein is identified:

1. Remove alcohol prep from its sterile package.

2. Cleanse the vein site with the alcohol prep using a circular motion from the center to the periphery.

3. Allow the area to dry to prevent possible hemolysis of the specimen and a burning sensation to the proband/parent when the venipuncture is performed.

4. If venipuncture becomes difficult, the vein may need to be touched again with your hand. If this happens, cleanse the site again with alcohol.

Perform venipuncture:

1. Place tube #1 into the tube holder.

2. Grasp the participant's arm firmly. Use your thumb to draw the skin taut and anchor the vein. The thumb should be 1 or 2 inches (2.5 or 5.0 cm) below the venipuncture site.

3. With the needle bevel upward, enter the vein in a smooth continuous motion.

4. Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. It may be helpful to have the participant make a fist with the opposite hand and place it under the elbow for support. **DO NOT HAVE THE PARTICIPANT MAKE A FIST IN THE HAND OF THE ARM FROM WHICH BLOOD IS TO BE DRAWN**.

5. Grasp the flange of the needle holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle. The tube should begin filling with blood.

6. Remove the tourniquet after tube #1 fills. Once the draw has started, do not change the position of a tube until it is withdrawn from the needle. A tourniquet may be

reapplied during tubes 2-5 to spare the participant a restick, but the tourniquet must not be on for more than 2 minutes.

7. Keep a constant, slight forward pressure (in the direction of the adapter) on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow.

8. Fill each blood tube as completely as possible (i.e., until the vacuum is exhausted and blood flow ceases). If a tube fills only partially, remove the tube and attach another without removing the needle from the vein.

9. When the blood flow into the collection tube ceases, remove the tube from the holder. The shutoff valve covers the point, stopping blood flow until the next tube is inserted (if necessary). Tubes #1, #2 and #3 should be gently inverted eight times immediately following removal of the tube from the adapter then placed into the room temperature rack. Tube #4 is not inverted, but allowed to sit at room temperature for 30 minutes. Tube #4 is then centrifuged and the serum is removed, frozen, and stored for shipment to the CBL.

At the conclusion of the blood draw:

1. To remove the needle, lightly place clean gauze over venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a gauze pad. Discard needle and its cap into needle box. DO NOT ATTEMPT TO RECAP NEEDLES! Have the participant hold the gauze pad firmly for one to two minutes to prevent a hematoma.

2. If blood flow stops before collecting the final tube, restick the participant, collecting only the unfilled tubes from the previous attempt. A tourniquet may be applied in this case but should be released if possible as soon as blood flows into the first recollected tube. As always, the tourniquet must never be on for longer than two minutes.

Bandaging the arm:

1. Slip the gauze pad down over the site, continuing to apply mild pressure.

2. Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.

## 8.3 COLLECTION OF GENETIC SPECIMENS – TUBES 1, 2, AND 3

### 8.3.1 Scheduling

All diabetic probands and their parents will have blood drawn for genetic analysis. These samples may arrive at the CBL Tuesday through Saturday. Blood must not be sent to arrive at the CBL on Sundays or holidays. Monday arrival is satisfactory if Sunday collection and shipping can be arranged.

All patients with End Stage Renal Disease (ESRD) must have ESRD noted in the comment section of the Mailing Lists accompanying the samples to the CBL.

### 8.3.2 Collecting, Labeling, and Storing

A fasting specimen is not required (though fasting specimens are acceptable).

Bloods must be kept at room temperature and not refrigerated at any time. Accession numbers have been provided for genetic specimens. Vacutainer tubes for the collection will be supplied by the CBL. All extra labels will be sent with the samples to the CBL for use during laboratory processing.

1. Prior to the blood collection, label all tubes with the prenumbered adhesive labels provided by CASPIR.

2. Collect three tubes of blood. Fill the tubes to capacity. Mix blood and preservative thoroughly (invert 8 times each).

   a. Tubes #1 and #2: Two (2) sterile 15 mL (8 mL draw) black and blue top Vacutainers (CPT™) for lymphocyte cell preservation. Use the labels in the Clinic Assignment label section with the Specimen Code 'LYM-1' and 'LYM-2'

   b. Tube #3: One (1) sterile 10 mL lavender top Vacutainer (EDTA) for DNA isolation. Use the labels in the Clinic Assignment label section with the Specimen Code marked 'DNA'.

3. Store at room temperature. Do not refrigerate tube 1 and tube 2.

4. Complete the Genetic Specimen Mailing List (Form 222GK).

5. The Vacutainer tubes used to collect these specimens will be sent directly to the CBL. No local processing or aliquotting will be required for tube 1 and 2. The tubes must be sent to the CBL for arrival within 24 hours of sample collection. Tube 3 will require further aliquotting as described below.

## 8.4 HEMOGLOBIN A1C, SAVED PLASMA, AND PACKED RED CELLS

### 8.4.1 Hemoglobin A1c Labeling, Processing, and Storing

Tube #3 is the lavender-topped 10 mL tube containing the liquid anticoagulant EDTA collected for DNA isolation as described above. A 0.5 mL aliquot of whole blood will be removed and transferred to a 2 mL microvial for the hemoglobin A1c assay.

1. Invert tube #3 four times. Remove the lavender stopper. Using a graduated plastic transfer pipette, aliquot a maximum of 0.5 mL whole blood into one HA1c labeled microvial. Use the label in the Clinic Assignment label section with the Specimen Code marked 'HA1c'. Fasten white screw cap on tube. Refrigerate the whole blood hemoglobin A1c (glycosylated hemoglobin) tube at $4^{o}$ C. (In the event of a delay between blood collection and transfer of the 0.5 mL aliquot of whole blood for the Hemoglobin A1c specimen from the lavender-topped 10 mL EDTA to the microvial, invert the capped lavender-topped blood tube 10 times for adequate mixing. Then proceed with the transfer. This will ensure a quality blood sample and an accurate hemoglobin A1c result.)

2. Complete the Hemoglobin A1c Specimen Mailing List (Form 223GK).

3. One tube for each proband/patient will be shipped refrigerated using frozen gel packs to the CBL within five days of collection.

### 8.4.2 Saved Plasma Labeling, Processing, and Storing

Saved plasma specimens are to be obtained from all probands/parents when a blood specimen is drawn for the DNA isolation. The purpose of this collection is to have a central storage of extra plasma so that assays, currently unspecified, may be performed in the future. Tube #3 is the lavender-topped 10 mL tube containing the liquid anticoagulant EDTA collected for DNA isolation as described above. Once the 0.5 mL whole blood aliquot for HA1c is removed, centrifuge the remaining blood in the 10 mL tube 3 as described below.

1. Place the lavender stopper onto tube #3. Centrifuge tube #3 at 3000 rpm for ten minutes at room temperature. (Tube #3 may be centrifuged with tube #4.)

2. Remove the lavender top tube (tube #3) from the centrifuge and place it in the sample test tube rack.

3. Remove the stopper from tube #3. Using a plastic transfer pipette, and being careful not to disturb the cell layer, remove the clear plasma supernatant. The pipette tip should not get any closer than one-half inch from the cells. Using the 1 mL marking on the transfer pipette (just below the bulb), aliquot 1.0 mL plasma into each of three microvials labeled Psav. Use the labels in the Clinic Assignment label section with the Specimen Code marked ‘Psav’.

4. Fasten lavender screw caps on each of these vials and place in freezer until shipment to the CBL.

5. Restopper the sample collection tube #3.

6. Complete the Saved Specimen Mailing List (Form 230GK). This form will also include the Ssav and the Usav tube collection.

### 8.4.3 Packed Cells Labeling, Processing, and Storing

Tube #3 is the lavender-topped 10 mL tube containing the liquid anticoagulant EDTA collected for DNA isolation as described above. Once the 0.5 mL whole blood aliquot for HA1c is removed and the plasma is removed for Saved Plasma, process the tube as described below.

1. Restopper the lavender top tube (tube #3) labeled DNA.

2. Place the tube in the room temperature rack with the CPT tubes until shipped later that day to the CBL for DNA isolation.

## 8.5 COLLECTION OF LIPIDS (CHOLESTEROL AND HDL CHOLESTEROL), CREATININE, CYSTATIN C, AND SAVED SERUM – TUBE 4

There are no requirements for the probands/parents to fast prior to the collection of cholesterol and HDLC. Serum creatinine and serum cystatin C will also be assayed from this blood collection for measures of renal function.

Saved specimens are to be obtained from all probands/parents when a blood specimen is drawn for the assay of lipids. The purpose of this collection is to have a central storage of extra serum so that assays, currently unspecified, may be performed in the future.

Tube #4 is a 10-mL red and gray-topped tube. Label the collection tube using the labels in the Clinic Assignment label section with the Specimen Code marked 'LIP'. This tube does not contain anticoagulant, so it does not need to be mixed following collection. After drawing, allow the blood to clot at room temperature for 30 minutes. As soon as possible after the 30 minutes and not longer than 45 minutes after blood collection, spin tube #4 at 3000 rpm for 10 minutes at room temperature. (Tube #3 and tube #4 may be centrifuged together.)

1. Remove the red and gray top tube (tube #4) from the centrifuge and place it in the sample test tube rack.

2. Remove the stopper from tube #4. Using the 0.75 mL marking on a graduated plastic transfer pipette (the second marking below the bulb), aliquot 0.75 mL serum into one microvial labeled 'LIPm', one microvial labeled 'CrCy', and into three microvials labeled 'Ssav'. All of these labels are located in the Clinic Label Assignment section.

3. Fasten red screw caps on each of these vials and place in freezer until shipment to the CBL within one week of collection.

4. Complete the Lipid, Serum Creatinine and Cystatin C Mailing List (Form 224GK).

## 8.6 RANDOM URINE COLLECTION AND PROCESSING

### 8.6.1 Urine Specimen Collection for Albumin/Creatinine Ratio (ACR)

As part of the GoKinD study, a random urine specimen is obtained at the site during the proband's/parent's visit. Collect the specimen in a container labeled with the participant's GoKinD Laboratory accession number. Use the label in the Clinic Assignment label section with the Specimen Code marked 'UcrA.' Collection time of the random specimen must be recorded on the Urine Specimen Mailing List (Form 225GK).

Urine collections should not be done if the proband/parent has an active UTI, illness, or menses.

### 8.6.2 Urine Aliquotting

All rules regarding safe blood specimen handling must be observed when processing urines.

1. Mix the urine specimen by tipping the container four times.

2. Transfer 4.5 mL of well-mixed urine into one appropriately labeled urine 4.5 mL Nunc tube. Use the labels in the Clinic Assignment label section with the Specimen Code marked 'UScr1, UScr2, or UScr3' describing the sequence of the participant's urine collection. Transfer an additional 4.5 ml urine aliquots into each of three tubes labeled 'Usav.' Use the labels in the Clinic Assignment label section with the Specimen Code 'Usav.' The 'Usav' aliquots are to be sent only once and may be collected at the UScr2 or UScr3 collection.

3. A random void collection must have a minimum volume of 13.5 mL. Transfer 4.5 mL of well-mixed urine to at least three labeled urine tubes. The first tube must contain 4.5 mL and appropriately labeled with 'UScr1, UScr2, or UScr3.' The other two tubes are labeled 'Usav.'

4. Cap tubes with clear or yellow screw caps or inserts.

5. Freeze all specimens after transfer to labeled tubes.

   a) One UScr1, UScr2, or UScr3 tube will be sent to the CBL in the weekly shipment.

   b) All USav tubes will be sent to the CBL in the weekly shipment and forwarded to the CDC for permanent storage in liquid nitrogen freezers.

6. Complete the Urine Specimen Mailing List (Form 225GK).

### 8.6.3 Screening Cases and Controls

In order for cases and controls to qualify for the study, it may be necessary for three separate urines (one month apart) to be sent to the CBL. See Chapter 2 for the requirements for eligibility.

After the initial urine specimen is analyzed by the CBL, the results will be sent to the COC. The COC will forward the results to the clinic who will alert the proband to send in another urine sample using the urine container(s), mailer, and labels that have been given to the proband. These urine kits are ordered by the clinical centers from the CBL and contain a random urine collection container, a plastic disposable pipette, a blue-capped plastic specimen tube, a small Styrofoam holder and cardboard sleeving, one small and one large plastic bag, an absorbent pad and patient instructions. The proband returns the kit containing the urine samples to the clinical center via the US mail. The clinic then sends the urine sample on to the CBL in their frozen weekly shipment.

A historical urine sample, from a screening urine or from a GoKinD site's database, may be used for the first urine screen, if the sample has been collected in the past 12 months. In general, the ACR at examination will represent a second ACR. An additional sample may also be required if the ACR measurement does not provide a second elevated value. As currently envisioned, the second urine will typically be the one stored for future analyses.

However, we will carefully monitor such cases to determine whether this policy should be revised.

## 8.7 PACKAGING, SHIPPING AND STORAGE OF SPECIMENS

The two CPT tubes and the one lavender top packed cells tube remain at room temperature before being shipped to the CBL on the day of collection. The one 0.5 mL whole blood microvial for hemoglobin A1c is placed into the refrigerator until shipment to the CBL within 5 days of collection. The one cryovial for lipids, the one cryovial for creatinine and cystatin C, the three serum aliquot tubes, the three plasma aliquot tubes, the one 4.5 mL aliquot tube for urine albumin and creatinine and the three 4.5 mL saved urine aliquot tubes are stored in the freezer before the weekly dry ice shipment to the CBL.

### 8.7.1 Packaging of Genetic Tubes (Tubes #1, #2, and #3)

Shipping must occur on the day of specimen collection. Specimen collection should be scheduled for Monday through Thursday (if possible), as tubes #1, #2, and #3 must be shipped the same day for receipt at the CBL the following day (Tuesday through Friday, if possible).

Tubes #1, #2, and #3 (after processing) remain in a rack at room temperature until shipment. Keep tubes #1 and #2 sealed to preserve sterility. Do not centrifuge tubes #1and #2. Tube #3 is processed as described in Section 8.4.2 and the original lavender top tube with only the packed cells remaining is sent with tubes #1 and #2. The tubes are shipped in a foam tube holder assembly placed inside a shipping box, both provided by the CBL. To package tubes for shipment:

1. Place tubes #1, #2, and #3 into the foam tube holder. Close the box containing the holder, and place it into an 8" x 10" ziplock bag. Seal the bag. If specimens are collected from more than one participant, additional foam tube holders can be used. Multiple tube holder assemblies can be included in the same shipping box as described below.

2. Place a <u>room temperature</u> gel pack on the bottom of the shipping box. Do not refrigerate or freeze the gel pack. Put the foam tube holder assembly or multiply assemblies on top of the refrigerant pack.

3. Place packing material (crumpled paper, etc.) on top of the assemblies to occupy any remaining space in the box.

4. Place the Genetic Specimen Mailing List (Form 222GK) for each participant specimen set included in the shipment on top of the packing material. Replace lid on styrofoam box.

5. Seal the outer shipping box with strapping tape. Affix biohazard label to outside of box.

6. Address the shipping box using the preaddressed Federal Express airbill provided by the CBL. Place air bill into an air bill pouch affixed to outside of shipping box.

7. Contact Federal Express (800-GO-FEDEX) for pickup.

### 8.7.2 Packaging of Refrigerated Hemoglobin A1c Specimens

The samples remain in the refrigerator until they are shipped. This must be accomplished within five days of collection.

The bags of refrigerated whole blood samples are packed and shipped with frozen refrigerant packs in styrofoam boxes provided by the CBL. Packaging instructions are:

1. Place all 0.5 mL whole blood sample vials into a styrofoam 5-tube mailer (each slot can hold two vials) to protect from freezing. Place mailer into its cardboard sleeve.

2. Place the mailer into one 8” x 10” plastic storage bag.

3. Place a frozen refrigerant pack on the bottom of the styrofoam box.

4. Put the bag with mailer of sample tubes into the styrofoam box on top of the pack.

5. Place a second frozen refrigerant pack on top of the samples.

6. Place the Hemoglobin A1c Mailing List (Form 223GK) on top of the packing material.

7. Place the lid on the styrofoam box. Seal the outer box tightly with strapping tape. Affix biohazard label to outside of box.

8. Address box. Use the preaddressed Federal Express air bill provided by the CBL.

9. Contact Federal Express (800-GO-FEDEX) for pickup.

### 8.7.3 Packaging of Frozen Specimens

Frozen specimens should be sent Monday through Thursday each week (being careful to avoid any weeks in which a holiday may occur). Shipping on Monday or Tuesday avoids problems in transporting the specimens over weekends. Any shipment deviations or questions should be discussed directly with the CBL.

Each clinical center should utilize the following protocol:

1. Place the frozen sample vials into plastic storage bags grouped by proband/parent ID number and accession number assigned.

2. Using the insulated shipping containers provided by the CBL for frozen specimens, pack the specimens with at least two and a half to three pounds of dry ice. This amount should be increased during the warmer months.

3. Place a layer of dry ice on the bottom of the styrofoam transport box.

4. Place some storage bags containing microvials on top of the dry ice.

5. Layer more dry ice and place remaining storage bags containing microvials on top of the dry ice. Place dry ice on top.

6. Enclose the completed Lipid, Serum Creatinine, & Cystatin C Specimen Mailing List (Form 224GK), Urine Specimen Mailing List (Form 225GK), and Saved Specimen Mailing List (230GK) on top of the insulated shipping container prior to sealing the cardboard box. Affix biohazard label and dry ice label to outside of box.

7. Address box. Use the preaddressed Federal Express air bill provided by the CBL.

8. Contact Federal Express (800-GO-FEDEX) for pickup.

## 8.8 GOKIND CLINIC REMOTE SITE COLLECTIONS

In some circumstances, the GoKinD proband/parent may be unwilling or unable to travel to a GoKinD clinic for the GoKinD study. In these situations, it will be necessary for the GoKinD center to collaborate with local laboratories and/or health care providers for the collection, processing and shipment of blood and urine samples for the GoKinD study. Additionally, assistance may be needed to obtain specified vital statistics (i.e. height, weight, sitting blood pressure) or other physical measurements. Logistic arrangements and reimbursement issues (if necessary) should be handled on a case-by-case basis.

### 8.8.1 GoKinD Clinic Responsibilities

A GoKinD recruiter (MMG or the clinic coordinator) will identify potential patients. The clinic coordinator will contact the proband/parent via telephone to obtain the informed consent, complete a study related questionnaire, and discuss local options for laboratory specimen collections.

1. The GoKinD center will contact the identified health care provider and/or facility to discuss the GoKinD study and specimen collection requests. If feasible, an appointment will be made for the proband/parent. Otherwise, the proband/parent will be instructed to schedule the appointment with the identified provider or laboratory.

2. The local provider and/or lab should be given the telephone and fax numbers for the GoKinD center to facilitate communication as needed prior to, during, or following the proband's/parent's visit.

3. A mailing will be sent to the proband/parent containing: all self-administered questionnaires with instructions for completion. A self-addressed envelope should be provided.

4. Depending on the circumstances, a remote site collection and transport box will be sent to the proband/parent or to the local provider or lab after completing the following tasks:

a.) Assign a barcode to the GoKinD participant from the spool of labels provided. Each proband/relative will have a set of 40 clinic labels and 35 CBL labels. The top labels are the clinic labels followed by a blank row that directs the clinic to "cut below and send to CBL." This blank row is then followed by the CBL's labels. Include this set of 35 CBL labels in the remote transport box to be sent to the proband/parent and then on to the CBL.

b.) Include two 15 mL (8 mL draw) black and blue top Vacutainers (CPT™) labeled LYM-1 and LYM-2 from the Clinic Assignment label section.

c.) Include one 10 mL lavender top Vacutainer (EDTA) labeled DNA and one white top microvial labeled HA1c from the Clinic Assignment label section.

d.) Include one 10 mL red and gray top Vacutainer labeled LIP from the Clinic Assignment label section and two red top microvials labeled LIPm and one labeled CrCy from the Clinic Assignment label section.

e.) Include a urine container labeled UCrA and a 5 mL yellow cap tube labeled UScr1, Uscr2, or Uscr3 from the Clinic Assignment label section.

f.) Include three disposable transfer pipettes, specimen collection and processing instruction, a return self addressed envelope, one preprinted FedEx airbill, and one biohazard label.

g.) Write the assigned GoKinD accession number on the appropriate 3-ply mailing lists and include in the remote transport box.

5. The GoKinD center should follow-up with the local provider or lab to assure successful completion of sample collections and shipment of samples to the CBL.

6. A letter and/or telephone call should be made to the local provider or lab upon the completion of the requested collections. Follow-up regarding reimbursement for services (if any) should be handled as needed on an individual basis.

7. A letter and/or telephone call should be made to the proband/parent once all procedures have been completed and forms returned to the GoKinD center.

### 8.8.2 Proband/Parent Responsibilities

1. Complete all self-administered questionnaires and return to the GoKinD center.

2. Schedule the appointment with the local provider and/or lab if not previously done by the GoKinD center.

3. Review personal preparation instructions for blood/urine collections prior to the scheduled appointment date and contact the GoKinD center if any questions.

### 8.8.3 Local Provider and/or Laboratory Responsibilities

The detailed instructions outlined are to be followed by the local provider and/or laboratory when providing the GoKinD clinical center with specimen acquisition, processing and shipping of samples from GoKinD participants.

NOTE: Upon receipt of this mailer, remove the refrigerated Styrofoam container from its sleeving, press the gel pack into the bottom of the Styrofoam box and place in freezer until ready for specimen packing.

#### 8.8.3.1 Blood/Urine Collection and Processing

1. Tubes #1 and #2: Two (2) sterile 15 mL (8 mL draw) black and blue top Vacutainers (CPT™) to be filled to capacity. Invert tubes eight (8) times and store at room temperature. These tubes do not need to be processed or refrigerated.
   *Note: If there is poor venous access, fill just one blue and black top tube followed by one lavender topped tube and then the red and black topped tube.*

2. Tube #3: One (1) sterile 10 mL lavender top Vacutainer (EDTA) to be filled to capacity. Invert tubes eight (8) times and store at room temperature. A 0.5 mL aliquot of whole blood will be removed and transferred to a 2 mL microvial for the hemoglobin A1c assay. Invert tube #3 four times. Remove the lavender stopper. Using a graduated plastic transfer pipette, aliquot a maximum of 0.5 mL whole blood into one HA1c labeled microvial. Use the tube labeled 'HA1c'. Fasten white screw cap on tube. Refrigerate the whole blood hemoglobin A1c (glycosylated hemoglobin) tube at $4^{o}$ C. (In the event of a delay between blood collection and transfer of the 0.5 mL aliquot of whole blood for the Hemoglobin A1c specimen from the lavender-topped 10 mL EDTA to the microvial, invert the capped lavender-topped blood tube 10 times for adequate mixing. Then proceed with the transfer. This will ensure a quality blood sample and an accurate hemoglobin A1c result.)

3. Tube #4: One (1) 10 mL red and gray topped tube labeled LIP to be filled to capacity. After drawing, allow blood to clot at room temperature for a minimum of 30 minutes. As soon as possible after 30 minutes but not longer than 45 minutes, spin tube at 3000 rpm for 10 minutes at room temperature. After centrifuging, using a transfer pipette, aliquot serum equally into one microvial labeled 'LIPm' and one microvial labeled 'CrCy'. Do not overfill. Place in refrigerator until shipment later that day.

5. Random Urine Specimen collection: Collect random urine sample in a urine container labeled UCrA, mix by inverting container 4 times. With a transfer pipette, aliquot 4.5 mL mixed urine into a 5 mL yellow cap Nunc tube labeled UScr1, Uscr2, or Uscr3. Store in refrigerator until shipping later that day.

6. Complete the Genetic Mailing List (Form 222GK), the Hemoglobin A1c Mailing List (Form 223GK), the Lipid, Serum Creatinine and Cystatin C Mailing List (Form 224GK) and the Urine Mailing List (Form 225GK).

### 8.8.3.2 Specimen Packing and Shipping

The remote site collection samples are shipped to the CBL in the dual temperature combined specimen shipping boxes provided by the CBL. Samples may be collected any day of the week, but Saturday and Sunday collections should be discouraged. Specimens must be shipped on the day of collection. Therefore, using the Federal Express airbill provided, mark *Priority Overnight* for shipments Saturday through Thursday and *Saturday Delivery* for shipments sent on Friday.

1. Place two black and blue topped tubes and one lavender topped tube into the 5-slotted Styrofoam container that also contains an absorbent strip. Replace the container in the cardboard sleeve and carefully insert this box into the ziplock bag. Place into one half of the transport box including two room temperature gel packs on either side.

2. Wrap the one white top microvial labeled HA1c, the two serum vials and the urine tube in the two sheets of paper toweling provided for protection, including the absorbency strip. Place wrapped specimens into ziplock bag and then into the Styrofoam container with the frozen gel pack. Put into cardboard sleeve and place into other half of transport box.

3. Include the original copy of the 3-ply completed mailing lists in the transport box. Seal the box with strapping tape.

4. Include the other two copies of the mailing lists in the stamped self-addressed envelope provided and mail to the referring GoKinD clinic.

5. Affix biohazard label to box. Use the air bill provided and contact FedEx for pickup. (1-800-GO-FEDEX)

## 8.9 CTI REMOTE SITE COLLECTIONS

CTI Network, Inc. has been contracted by George Washington University Biostatistics Center to centrally coordinate homecare services including vital signs and blood and urine collection in the homes of probands' parents who do not reside near one of the GoKinD clinical centers on an as-needed basis. Probands are strongly encouraged to utilize the GoKinD clinical center for their screening baseline visit, but under extreme conditions, may use the CTI homecare services.

A GoKinD recruiter (MMG or the clinic coordinator) will identify potential patients. The clinic coordinator will contact the proband/parent via telephone to obtain the informed consent and then notify CTI of the patients requiring homecare study services. The local homecare nurse will then contact the parent to complete a study-related questionnaire and schedule the home visit.

### 8.9.1 CTI Responsibilities

CTI will be provided collection kits for all of the samples by the CBL. These kits will include collection tubes, plastic bags, and packaging and shipping materials. Shipping materials will include a transport box containing two cardboard covered Styrofoam containers

for ambient and refrigerated samples and a biohazard label. CTI will label all tubes in the kits, include the 35 CBL labels, mailing lists, collection and processing instructions, a laboratory flow chart, a self-addressed stamped envelope, and preprinted Federal Express airbill. CTI will then forward the kits to the appropriate homecare agencies

Once the following tasks have been completed, CTI will then forward the kits to the appropriate homecare agencies.

1. Assign a barcode to the GoKinD participant from the spool of labels provided. Include the 35 CBL labels in the remote box.

2. Include two 15 mL (8 mL draw) black and blue top Vacutainers (CPT™) labeled LYM-1 and LYM-2 from the Clinic Assignment label section.

3. Include one 10 mL lavender top Vacutainer (EDTA) labeled DNA from the Clinic Assignment label section and one white top microvial labeled HA1c from the Clinic Assignment label section.

4. Include a urine container labeled UCrA and a 5 mL yellow cap tube labeled UScr1, UScr2, or UScr3 from the Clinic Assignment label section.

5. Include two disposable transfer pipettes, specimen collection and processing instructions, a return self addressed envelope, one preprinted FedEx airbill, and one biohazard label.

#### 8.9.1.1 Screening for Cases and Controls

In rare circumstances when a proband is seen by the CTI homecare team, it may be necessary for the proband to send three separate urine collections (one month apart) to the CBL to prove eligibility as a case or control. The referring GoKinD clinic will notify the patient when this is necessary.

A historical urine sample, from a screening urine or from a GoKinD site's database, may be used for the first urine screen if the sample has been collected in the past 12 months. In general, the ACR at examination will represent a second ACR. An additional sample may also be required if the ACR measurement does not provide a second elevated value.

After the initial urine specimen is analyzed by the CBL, the results will be sent to the COC. The COC will forward the results to the referring clinic who will alert the proband to send in another urine sample using the urine container(s), mailer, and labels that have been sent to the proband by CTI.

These urine kits are ordered by CTI from the CBL and contain a random urine collection container, a plastic disposable pipette, a blue-capped plastic specimen tube, one small Styrofoam holder and cardboard sleeving, one small and one large plastic bag, an absorbent pad and patient instructions. The tubes and a section of the mailing list will be labeled by CTI. CTI will then send two urine kits to the homecare agency to deliver to the proband during the home visit.

The proband collects the urine according to the instructions included in the kit, completes the mailing list and returns the kit containing the urine samples to the CBL via the US mail. The proband will include the original mailing list in the urine kit, mail the yellow copy in the stamped self addressed envelope enclosed to the Coordinating Center and retain the pink copy for his/her own files.

### 8.9.2 CTI Homecare Responsibilities

Once the remote site kits have been received from CTI, the homecare agency should complete the following tasks:

1. Call Federal Express at 1-800-463-3339 to obtain specific courier information for the shipment of the completed collection kits to the CBL.

2. Remove the refrigerated Styrofoam container from its sleeving, press the gel pack into the bottom of the Styrofoam box and place in freezer until ready for specimen packing.

3. Check the expiration date on the kit. Since the expiration date of the kit corresponds to the shortest expiration date of the tube(s) within the kit, **do not collect samples with expired containers.**

4. Provide all other ancillary supplies necessary for the patient's home visit

#### 8.9.2.1 Blood/Urine Collection and Processing

1. Tubes #1 and #2: Verify that tubes are labeled with the pre-numbered labels provided in the blood collection kit. Collect **8 mL** of blood in each of the two **black and blue top** Vacutainer tubes labeled LYM-1 and LYM-2 (Note: 15 mL tubes, 8 mL draw). Mix immediately by inverting the tube gently 8 times to mix the anticoagulant and cell-separating agent. Store at room temperature. **DO NOT REFRIGERATE.**

2. Tube #3: Verify that tube is labeled with the pre-numbered label provided in the blood collection kit. Fill 10 mL **lavender-topped** Vacutainer tube labeled DNA (completely fill the tube provided). Mix immediately by inverting the tube gently 8 times to mix the anticoagulant. Remove the lavender stopper. Using a graduated plastic transfer pipette, aliquot a maximum of 0.5 mL whole blood into one HA1c labeled microvial. Fasten white screw cap on tube. Refrigerate the whole blood hemoglobin A1c (glycosylated hemoglobin) tube at $4^{o}$ C. (In the event of a delay between blood collection and transfer of the 0.5 mL aliquot of whole blood for the Hemoglobin A1c specimen from the lavender-topped 10 mL EDTA to the microvial, invert the capped lavender-topped blood tube 10 times for adequate mixing. Then proceed with the transfer. This will ensure a quality blood sample and an accurate hemoglobin A1c result.) Tube #3 can then be kept with tubes #1 and #2 at room temperature.

3. Random Urine Specimen collection: Verify that the collection container is labeled with the participant's GoKinD laboratory accession number. Collect random urine sample, mix by inverting container 4 times. With a transfer pipette, aliquot 4.5 mL mixed urine into a 5 mL yellow cap Nunc tube labeled Uscr1. Record the collection time on the Urine Specimen Mailing List (Form 225GK). Do not collect sample if participant has an active urinary tract infection, illness or menses.

4. Complete the 3-ply Genetic Mailing List (Form 222GK), the Hemoglobin A1c Mailing List (Form 223GK), and the Urine Specimen Mailing List (Form 225GK) provided by CTI with the date specimen drawn, date and time of urine collection and the ship date. Include the original mailing lists in the remote site transport box. Retain one copy for the homecare clinic files and mail the other copy in the stamped self addressed envelope enclosed to CTI. CTI will retain one copy for its files and forward a xerox copy to the COC.

### 8.9.2.2 Specimen Packing and Shipping

1. Place two black and blue topped tubes and one lavender topped tube into the 5 slotted Styrofoam container that also contains an absorbent strip. Replace the container in the cardboard sleeve and carefully insert this box into the ziplock bag. Place into one half of the transport box including two room temperature gel packs on either side.

2. Wrap the one white top microvial labeled HA1c and the urine tube in the two sheets of paper toweling provided for protection, including the absorbency strip. Place wrapped specimens into ziplock bag and then into the Styrofoam container with the frozen gel pack. Put into cardboard sleeve and place into other half of transport box.

3. Affix biohazard label to box. Use the air bill provided and contact FedEx for pickup. (1-800-GO-FEDEX)

## 8.10 PRIORITY COLLECTIONS FOR ALL SITES

If a situation occurs where it is uncertain that the entire specimen set can be collected (e.g., poor venous access or limited lab processing facilities), the following priority collection sequence should be followed:

1. Two (2) sterile 15 mL (8 mL draw) black and blue top Vacutainers (CPT™) for lymphocyte cell preservation. One CPT tube is acceptable.

2. One (1) sterile (10 mL draw) lavender top tube for hemoglobin A1c, DNA isolation, and saved plasma. One full tube is needed. The saved plasma is not collected at remote or CTI sites.

3. One 10 mL red and gray top tube for lipids, creatinine, cystatin C, and saved serum. The saved serum may be omitted if this tube is not fully collected and is not collected at remote or CTI sites.

4. One random urine collection for creatinine and albumin and saved urine samples. The saved urine is not collected at remote or CTI sites.

## 8.11 QUALITY CONTROL

In large multicenter clinical trials, external quality control surveillance programs are established to monitor the performance of the entire specimen acquisition, processing, shipping, analysis and result reporting. A 10% masked submission of duplicate specimens will be sent from the clinics to the CBL for analysis. There will be a separate memo from the COC outlining the specific procedures for quality control.

## 8.12 MAILING INSTRUCTIONS TO THE CBL

All shipping containers are sent to the CBL by overnight Federal Express to ensure receipt within 24 hours. Shipping containers and other supplies will be returned to each of the clinical centers by UPS or the U. S. Postal Service. Shipping containers to the CBL are addressed as follows:

GoKinD Central Biochemistry Laboratory
Fairview-University Medical Center
Room L275 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455
Telephone: (612) 273-3391 (office)
Telephone: (612) 273-3645 (lab)
**FedEx Number: 2334-5204-1**

## 8.13 STORAGE OF SPECIMENS

The CBL will ship the following samples obtained from participants in the GoKinD study to the CDC and ATSDR Specimen and Data Bank (CASPIR) facility:

- 3X 0.75 mL aliquots of saved serum
- 3X 1.0 mL aliquots of saved plasma
- 3X 4.5 mL aliquots of saved urine
- 0-4X 1mL aliquots of cryopreserved lymphocytes
- 4X 1mL aliquots of transformed lymphocytes
- 1X stabilized cell lysate from 8.5 mL whole blood to be used for DNA isolation

CDC's CASPIR facility will ship the stabilized cell lysate from 8.5 mL whole blood tube to the CDC National Diabetes Laboratory's Diabetes and Molecular Risk Assessment Laboratory (DMRAL) at the Chamblee, Georgia facility. The DMRAL laboratory will complete the Gentra Puragene DNA isolation assay to obtain DNA to be used in molecular genotyping analysis. The DMRAL laboratory will also aliquot this DNA into 31 aliquots per participant (1 25-ug aliquot, 5 10-ug aliquots, 25 1-ug aliquots), which will then be shipped back to CASPIR for storage and distribution. CASPIR will provide a secure environment for the storage, management and distribution of all samples received from the GoKinD study. These samples will be stored in liquid nitrogen freezers that are located in a state-of-the-art refurbished facility at the CDC

Lawrenceville, Georgia facility. The building is guarded 24 hours a day, 365 days a year and is contractor-operated by the American Type Culture Collection (ATCC).

## 8.14 SPECIMEN IDENTIFICATION

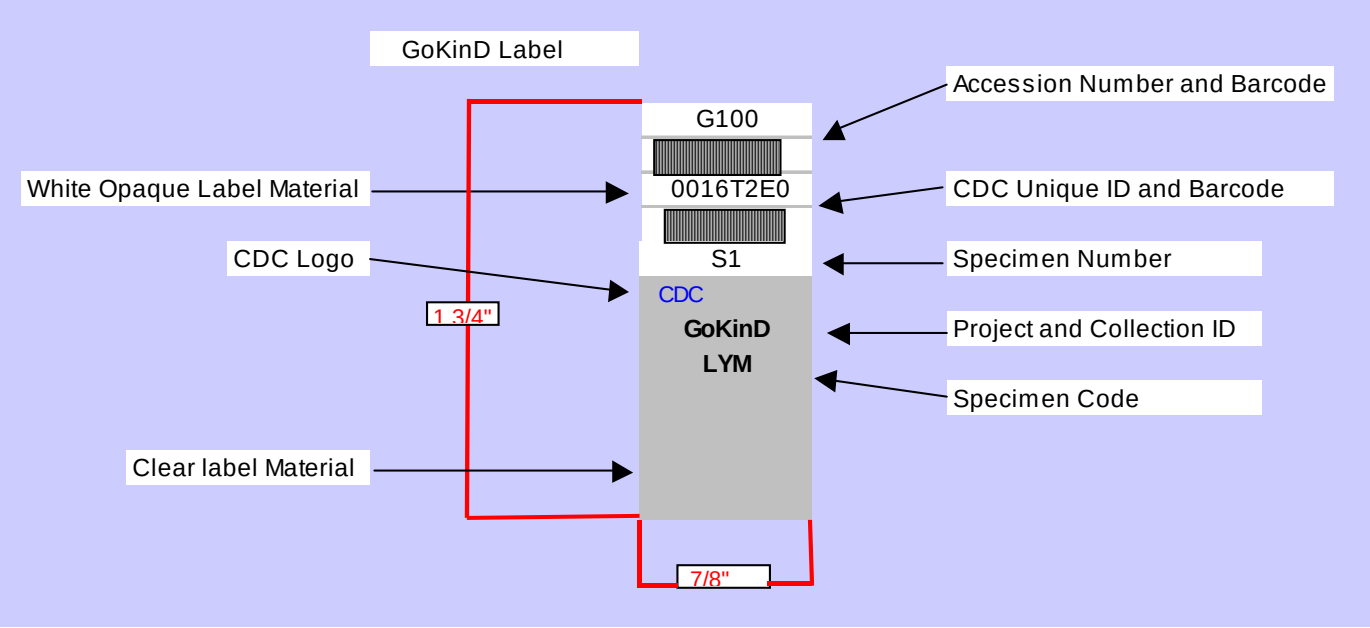
Specimens are identified by barcodes generated by CDC's CASPIR facility and provided to each of the participating clinics. (See Figure 8.1 for an example of the GoKinD labels, Figure 8.2 for the instructions for labeling the sample tube, and Figure 8.3 for an explanation of the GoKinD labels.) The barcodes are not patient specific; however, once a barcode has been designated for a patient, all of that patient's CBL assessments will be labeled with the same barcode series for that visit, including repeat collections. Labels have been provided for each specimen code preceded by an 'r' and are retained in the participant file for future use if necessary.

The barcodes are provided in spools of labels. The width (row) of the spool contains five labels. Each proband/relative will have a set of 40 clinic labels and 35 CBL labels. The top labels are the clinic labels followed by a blank row that directs the clinic to "cut below and send to CBL." This blank row is then followed by the CBL's labels. Additionally, there is a blank row of labels between each accession number.

The label contains the following information: GoKinD accession number (clinic use on all GoKinD mailing lists) and barcode, CDC unique ID and barcode (CASPIR use only), specimen number (CASPIR use only), and specimen code (clinic use).

## FIGURE 8.1

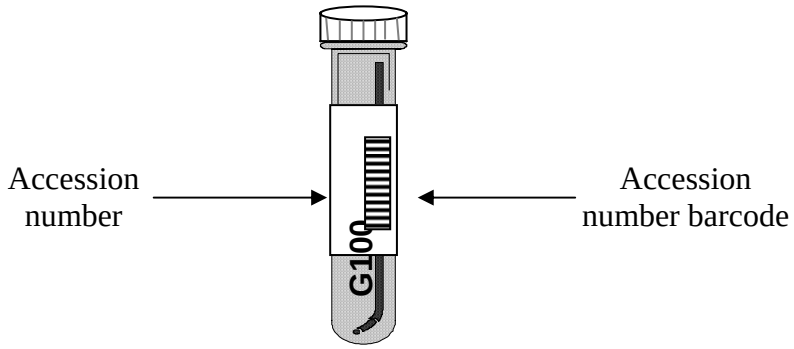
## GOKIND LABEL




** note: These barcodes are high density barcodes and can only be read by high-density barcode readers. The label program (Label View), which creates these barcodes, uses 128A barcode symbology.

## FIGURE 8.2

## APPLYING THE GOKIND LABEL TO THE SAMPLE TUBE




**Note: When applying the GoKinD label to the sample tube, apply the white portion of the label containing the accession number first – make sure that the G of the accession number is nearest to the bottom of the tube. Then wrap the rest of the label around the tube. The clear portion of the label will overlap a portion of the white part of the label without covering any identifying information. The barcode must be straight up and down from the cap to the foot of the tube in order to be able to read with a standard barcode reader.

## FIGURE 8.3

## EXPLANATION OF GOKIND LABELS

This spreadsheet contains the following information:

- CDC ID — a unique identifier that will be put on all tubes (CASPIR use only)
- Accession number — the GoKinD assigned number (Clinic use)
- Specimen number — a number to identify each independent collection from a patient (e.g., one specimen number for CPT tube1, one specimen number for CPT tube 2, one specimen number for the EDTA tube etc.) These will begin with the specimen number S1. (CASPIR use only)
- Aliquot — number of aliquots
- Specimen Code — describes the sample in abbreviated form assigned by GOKIND
- Specimen type — defines the type of sample

The clinic staff will assign the GOKIND accession number to the proband/relative and write that accession number on the 3-ply Mailing Lists. The original Mailing List must be enclosed with the specimens when shipped. Always retain a copy of the Mailing List in the clinic's files and send a copy of the Mailing List to the DCC in the monthly mailing.

| CDC ID | Accession Number | Specimen Number | Aliquot | Label Assignment | Specimen Code | Specimen Type |
|---|---|---|---|---|---|---|
| 016T2EA | G110 | S1 | | clinic | LYM-1 | CPT - lym source |
| 0016T2EB | G110 | S2 | | clinic | LYM-2 | CPT - lym source |
| 0016T2EC | G110 | S3 | | clinic | DNA | EDTA - DNA source |
| 0016T2ED | G110 | S3 | | clinic | HAIc | hemoglobin A1c |
| 0016T2EE | G110 | S3 | 1 | clinic | Psav | stored plasma |
| 0016T2EF | G110 | S3 | 2 | clinic | Psav | stored plasma |
| 0016T2EG | G110 | S3 | 3 | clinic | Psav | stored plasma |
| 0016T2EH | G110 | S4 | | clinic | LIP | red/gray serum source |
| 0016T2EI | G110 | S4 | | clinic | LIPm | Lipid measures |
| 0016T2EJ | G110 | S4 | | clinic | CrCy | creatinine and cystatin C |
| 0016T2EK | G110 | S4 | 1 | clinic | Ssav | stored serum |
| 0016T2EL | G110 | S4 | 2 | clinic | Ssav | stored serum |
| 0016T2EM | G110 | S4 | 3 | clinic | Ssav | stored serum |
| 0016T2EN | G110 | S5 | | clinic | UScr1 | 1st urine screen |
| 0016T2EO | G110 | S6 | | clinic | UScr2 | 2nd urine screen |
| 0016T2EP | G110 | S7 | | clinic | UScr3 | 3rd urine screen |
| 0016T2EQ | G110 | S8 | | clinic | UCrA | urine collection source |
| 0016T2ER | G110 | S8 | | clinic | UCrA | urine collection source |
| 0016T2ES | G110 | S8 | 1 | clinic | Usav | stored urine |
| 0016T2ET | G110 | S8 | 2 | clinic | Usav | stored urine |
| 0016T2EV | G110 | S8 | 3 | clinic | Usav | stored urine |
| 0016T2EW | G110 | S9 | | clinic | rLYM-3 | repeat CPT - lym source |
| 0016T2EX | G110 | S10 | | clinic | rLYM-4 | repeat CPT - lym source |
| 0016T2EY | G110 | S11 | | clinic | rDNA | repeat EDTA - DNA source |
| 0016T2EZ | G110 | S11 | | clinic | rHA1c | Repeat hemoglobin A1c |

| | | | | | | |
|---|---|---|---|---|---|---|
| 0016T2F0 | G110 | S12 | | clinic | rLIP | repeat red/gray tube |
| 0016T2F1 | G110 | S12 | | clinic | rLIPm | repeat LIP measures |
| 0016T2F2 | G110 | S12 | | clinic | rCrCy | repeat creatinine/cystatin |
| 0016T2F3 | G110 | S13 | | clinic | rUCrA | urine collection source |
| 0016T2F4 | G110 | S13 | | clinic | rUCrA | urine collection source |
| 0016T2F5 | G110 | S13 | 1 | clinic | rUSav | repeat stored urine |
| 0016T2F6 | G110 | S13 | 2 | clinic | rUSav | repeat stored urine |
| 0016T2F7 | G110 | S13 | 3 | clinic | rUSav | repeat stored urine |
| 0016T2F8 | G110 | | | clinic | | Extra label for clinic |
| 0016T2F9 | G110 | | | clinic | | Extra label for clinic |
| 0016T2FA | G110 | | | clinic | | Extra label for clinic |
| 0016T2FB | G110 | | | clinic | | Extra label for clinic |
| 0016T2FC | G110 | | | clinic | | Extra label for clinic |
| 0016T2FD | G110 | | | clinic | | Extra label for clinic |
| 0016T2FO | G110 | | | clinic | | Extra label for clinic |
| | | | | | Cut and | |
| | | | | | send | |
| | | | | | labels | |
| | | | | | below | |
| 0016T2FT | | | | | to CBL | |
| 0016T2FU | G110 | S1 | 1 | CBL | LYM-1 | cryopreserved Lym |
| 0016T2FV | G110 | S1 | 2 | CBL | LYM-1 | cryopreserved Lym |
| 0016T2FW | G110 | S1 | 3 | CBL | LYM-1 | cryopreserved Lym |
| 0016T2FX | G110 | S1 | 4 | CBL | LYM-1 | cryopreserved Lym |
| 0016T2FY | G110 | S2 | 1 | CBL | LYM-2 | transformed Lym |
| 0016T2FZ | G110 | S2 | 2 | CBL | LYM-2 | transformed Lym |
| 0016T2G0 | G110 | S2 | 3 | CBL | LYM-2 | transformed Lym |
| 0016T2G1 | G110 | S2 | 4 | CBL | LYM-2 | transformed Lym |
| 0016T2G2 | G110 | S3 | | CBL | DNA | processed lysate |
| 0016T2G3 | G110 | S9 | 1 | CBL | rLYM-3 | repeat cryopreserved Lym |
| 0016T2G4 | G110 | S9 | 2 | CBL | rLYM-3 | repeat cryopreserved Lym |
| 0016T2G5 | G110 | S9 | 3 | CBL | rLYM-3 | repeat cryopreserved Lym |
| 0016T2G6 | G110 | S9 | 4 | CBL | rLYM-3 | repeat cryopreserved Lym |
| 0016T2G7 | G110 | S10 | 1 | CBL | rLym-4 | repeat transformed Lym |
| 0016T2G8 | G110 | S10 | 2 | CBL | rLym-4 | repeat transformed Lym |
| 0016T2G9 | G110 | S10 | 3 | CBL | rLym-4 | repeat transformed Lym |
| 0016T2GA | G110 | S10 | 4 | CBL | rLym-4 | repeat transformed Lym |
| 0016T2GB | G110 | S11 | | CBL | rDNA | repeat processed lysate |
| 0016T2GC | G110 | | | CBL | | extra label for CBL |
| 0016T2GD | G110 | | | CBL | | extra label for CBL |
| 0016T2GE | G110 | | | CBL | | extra label for CBL |
| 0016T2GF | G110 | | | CBL | | extra label for CBL |
| 0016T2GG | G110 | | | CBL | | extra label for CBL |
| 0016T2GH | G110 | | | CBL | | extra label for CBL |
| 0016T2GI | G110 | | | CBL | | extra label for CBL |
| 0016T2GJ | G110 | | | CBL | | extra label for CBL |
| 0016T2GK | G110 | | | CBL | | extra label for CBL |
| 0016T2GL | G110 | | | CBL | | extra label for CBL |

| | | | | | | |
|---|---|---|---|---|---|---|
| 0016T2GM | G110 | | | CBL | | extra label for CBL |
| 0016T2GN | G110 | | | CBL | | extra label for CBL |
| 0016T2GO | G110 | | | CBL | | extra label for CBL |
| 0016T2GP | G110 | | | CBL | | extra label for CBL |
| 0016T2GQ | G110 | | | CBL | | extra label for CBL |
| 0016T2GR | G110 | | | CBL | | extra label for CBL |
| 0016T2FT | G110 | | | CBL | | extra label for CBL |

Figure 8.4

GoKinD Labels

Figure 8.4 cont.

GoKinD Labels

Figure 8.4 cont.

GoKinD Labels