

SPECIMEN COLLECTION FORM for Visit 1b (L02)

CKiD Chronic Kidney Disease in Children Cohort Study

SECTION A: GENERAL INFORMATION

A1. PARTICIPANT ID: AFFIX ID LABEL OR ENTER NUMBER IF ID LABEL IS NOT AVAILABLE

|_| - |_|_| - |_|_|_|

A2. CKiD VISIT #: 0 1 b

A3. FORM VERSION: 0 1 / 0 1 / 0 5

A4. SPECIMEN COLLECTION DATE: _____ / _____ / _____
M M D D Y Y Y Y

A5. FORM COMPLETED BY: _____
(INITIALS)

The following samples may be collected. (*Repository samples are optional.*)

<u>Samples:</u>	<u>Shipped to:</u>	<u>Shipped:</u>
Serum	CBL	IMMEDIATELY
<i>Whole Blood</i>	<i>Rutgers Repository</i>	<i>IMMEDIATELY</i>
<i>Serum</i>	<i>McKesson Repository</i>	<i>Batched</i>
<i>Plasma</i>	<i>McKesson Repository</i>	<i>Batched</i>
<i>Urine</i>	<i>McKesson Repository</i>	<i>Batched</i>
<i>Nail Clippings</i>	<i>McKesson Repository</i>	<i>IMMEDIATELY</i>
<i>Hair</i>	<i>McKesson Repository</i>	<i>IMMEDIATELY</i>

A6. Did the participant consent to have biological samples stored at McKesson, the Biological Repository?

Yes..... 1
No..... 2

A7. Did the participant consent to have blood stored at Rutgers, the Genetic Repository?

Yes..... 1
No..... 2

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SECTION B: Visit 1B BLOOD DRAW AND PROCESSING

Initial blood draw with **Syringe**: 16 mL if participant is < 30 kg; 20 mL if ≥ 30 kg.

OR

Initial blood draw with **Vacutainer or Butterfly Method**:

- If < 30 kg, immediately transfer or draw:
- 7.8 mL into three 2.6mL ACD tubes for Rutgers Genetic Repository (**ACD Tubes must be COMPLETELY FILLED TO THE TOP**)
 - 1.5 mL into Tiger-Top SST for CBL
 - 3 mL into SST for McKesson Biological Repository
 - 3 mL into PST for McKesson Biological Repository

- If ≥ 30 kg, immediately transfer or draw:
- 7.8 mL into three 2.6mL ACD tubes for Rutgers Genetic Repository (**ACD Tubes must be COMPLETELY FILLED TO THE TOP**)
 - 1.5 mL into Tiger-Top SST for CBL
 - 5 mL into SST for McKesson Biological Repository
 - 5 mL into PST for McKesson Biological Repository

CBL

RUTGERS

MCKESSON

Invert the Tiger Top SST 5-10 times gently to mix

Invert each of the 3 pediatric yellow-top ACD Tubes 6 times gently to mix blood with additives

Invert the SST 5-10 times gently to mix

Invert the PST 8-10 times gently to mix

Stand SST upright to allow clotting at room temperature for 30 mins

Keep tubes at room temperature.
DO NOT FREEZE.

Stand SST upright to allow clotting at room temperature for 30 mins

Centrifuge PST at 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle)

Centrifuge SST at 1100-1300g for 10 mins in swinghead **OR** 15 mins in fixed angle.
*If incomplete separation, centrifuge again 10-15 mins

Follow packaging instructions and ship immediately to Rutgers Repository with accompanying forms.
Specimen can be shipped on Friday.

Centrifuge SST at 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle)

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert.

Pipette 0.5 mL of serum into a clear-top transport tube for CBL chemistries (iPTH and wrCRP)

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial

Store sample in freezer at -70°C or lower. Batch up to 40 samples, contact McKesson for mailing shipper and follow packaging instructions.

Follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

Store sample in freezer at -70°C or lower. Batch up to 40 samples, contact McKesson for mailing shipper and follow packaging instructions.

Notify: Paula Maier: paula_maier@urmc.rochester.edu
Alicia Wentz: awentz@jhsph.edu

Notify Rutgers Repository by completing Shipping Blood log on Rutgers' website:
<http://rucdr.rutgers.edu>
Notify: Alicia Wentz via email: awentz@jhsph.edu

Notify: Heather Higgins:
niddkrepository@mckessonbio.com
Rich Frome: rich.frome@mckessonbio.com
Alicia Wentz: awentz@jhsph.edu

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B1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

Reasons Code List *	1 = Not required	3 = Participant Refused	5 = Inadvertently Destroyed	7 = Consent not obtained
	2 = Difficult Blood Draw	4 = Red Blood Cell Contamination	6 = Oversight	

Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Volume Distributed into Tubes:	(d) Centrifuged at Clinical Site:		(e) Additional Requirements:
	Yes	No			Yes	No	
B2. Serum for iPTH & wrCRP (1.5 mL in Tiger Top SST)	1 (skip to c→)	2	_____ (skip to B3)	____ . ____ mL	1	2	N/A
B3. Whole Blood for Rutgers Cell & DNA Repository (7.8 mL in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	1 (skip to c→)	2	_____ (skip to B4)	____ . ____ mL	N/A		N/A
B4. Serum for McKesson Biological Repository (*3.0 mL or *5.0 mL in Tiger Top SST)	1 (skip to c→)	2	_____ (skip to B5)	____ . ____ mL	1	2	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
B5. Plasma for McKesson Biological Repository (*3.0 mL or *5.0 mL in Green Top PST)	1 (skip to c→)	2	_____ (skip to B6)	____ . ____ mL	1	2	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y

* Collect 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children ≥ 30 kg

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SECTION C: Visit 1B URINE COLLECTION AND PROCESSING

Collect 15mL – 60mL of FRESH urine in a blue top urine collection cup.

Transfer urine into four (4) 15mL sterile centrifuge tubes. **Place no more than 15 mL in each tube.** Close top tightly to prevent leakage.

Centrifuge urine tube(s) at MAX SPEED (between 1100-1300g) for 10 mins (swinghead units) **OR** 15 mins (fixed angle units).
If incomplete separation, centrifuge again for 10- 15 minutes.

Decant (pour off) the supernate (liquid reaction) into an orange top urine collection cup with protease inhibitor (PI) tablet(s). One protease inhibitor tablet should be used for 10-15 mL of urine (**see Table C**). For example if 30 mL of urine is centrifuged, **ONLY 2 PI tablets** are needed. The sediment will remain at the bottom of the centrifuge tube and should be discarded. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL.**)

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablets are completely dissolved, pour urine into 10 mL urine transport tubes.
Pour no more than 9 mL of urine in each tube. This allows room for specimen to expand when frozen.

Check that all information is correct on the urine transport tube, promptly freeze and store sample(s) at -70°C or lower. Batch up to 36 samples, contact McKesson for mailing shipper and follow packaging instructions.

Notify: Heather Higgins: niddkrepository@mckessonbio.com, Rich Frome: rich.frome@mckessonbio.com and Alicia Wentz: awentz@ihsph.edu

Urine Volume	# of PI Tablets
10 – 15 mL	1
16 – 30 mL	2
31 – 45 mL	3
46 – 60 mL	4

Reasons Code List :	1 = Not required	3 = Participant Refused	5 = Inadvertently Destroyed	7 = Consent not obtained
	2 = Difficult Urine Collection	4 = Collection Contamination	6 = Oversight	

Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Volume Distributed into Tubes:	(d) Centrifuged at Clinical Site:		(e) Additional Requirements:
	Yes	No			Yes	No	
C1. Urine for McKesson Biological Repository (15.0 - 60.0 mL in specimen container and transferred into one to four 15mL sterile centrifuge tubes)	1	2	_____ (skip to Section D)	_____. ____ mL	1	2	i. Was supernate decanted into urine transport tube with protease inhibitor tablet? Yes.....1 No.....2 Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y

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SECTION D: NAIL CLIPPING COLLECTION

- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers for younger children and large stainless steel nail clippers for older children. The nail clippers are included in the CKiD starter package.
- Clean the blades of the nail clippers with an alcohol swab prior to use.
- Whenever possible, Study Coordinators should clip all (10) fingernails, removing approximately 1 millimeter from each nail.
- To use nail clippers, follow STEPS 1 – 5. Refer to CKiD MOP Section 12 for details.

Figure 1a

Provide 10 nail clippings that are at least 1 mm tall



Figure 1b

STEP 1



Figure 1c

STEP 2



Figure 1d

STEP 3



Figure 1e

STEP 4



Figure 1f

STEP 5

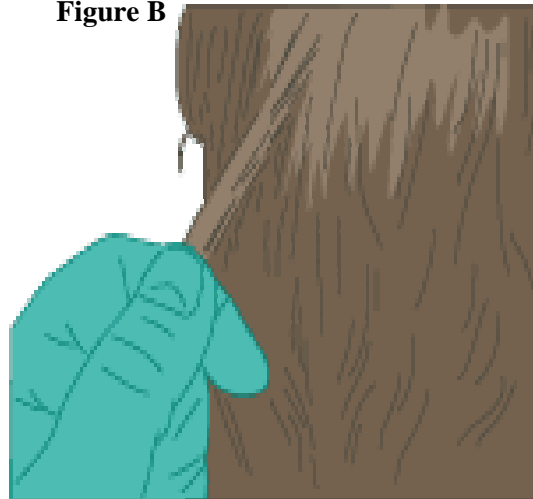


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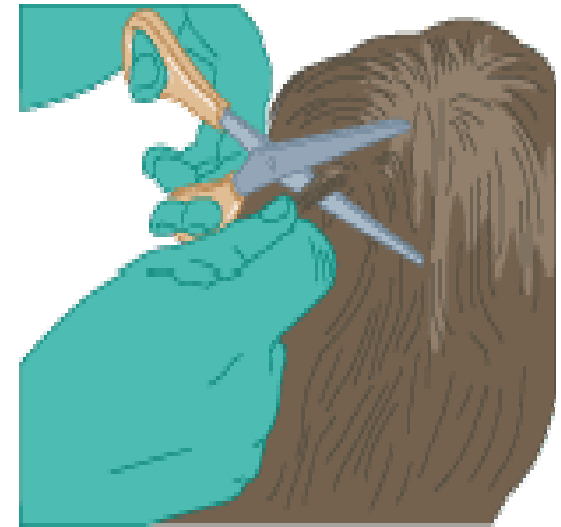
- D1. Does the participant have acrylic nails?
- Yes..... 1 **(Skip to D3)**
- No..... 2
- D2. Were 10 fingernail clippings collected?
- Yes....., 1 **(Skip to E1)**
- No..... 2
- a. How many fingernail clippings were collected?
- ___ ___
- b. Specify reason(s) fingernail clippings were not collected.
- Consent not obtained..... 1 **(Skip to E1)**
- Nails not long enough..... 2 **(Skip to D3)**
- Participant Refused..... -7 **(Skip to D3)**
- Other..... 3
- i. Specify Other Reason: _____
- D3. Were 10 toenail clippings collected?
- Yes..... 1 **(Skip to E1)**
- No..... 2
- a. How many toenail clippings were collected?
- ___ ___
- b. Specify reason(s) toenail clippings were not collected: (e.g., Nail fungus or discoloration causing pain or discomfort)
- Nail fungus or discoloration..... 1 **(Skip to E1)**
- Nails not long enough..... 2 **(Skip to E1)**
- Participant Refused..... -7 **(Skip to E1)**
- Other..... 3
- i. Specify Other Reason: _____

SPECIMEN COLLECTION FORM for Visit 1b (L02)**SECTION E: HAIR SAMPLE COLLECTION**

- STAINLESS STEEL SCISSORS MUST BE USED TO COLLECT HAIR SAMPLE. The scissors are included in the CKiD starter package.
- Clean blades of stainless steel scissors with an alcohol swab prior to use.
- Use powder-free gloves.
- Follow STEPS 1 – 6. Refer to CKiD MOP Section 12 for details.
 - STEP 1: Lift up the top layer of hair from the **occipital** region of the scalp (see Figure A). Isolate a small thatch of hair (at least 20 fibers) from this region (see Figure B).
 - STEP 2: Place the label with the participant's KID ID # tightly around all 20 strands of hair located at the **distal** end (Furthest from the scalp).
 - STEP 3: Cut the hair sample off the participant's head **as close to the scalp as possible** (see Figure C).
 - STEP 4: Place cut thatch of hair inside aluminum foil (4 X 4) and fold the top of the foil to completely enclose the hair sample.
 - STEP 5: Place the aluminum foil inside a Ziplock bag (4 X 4) with the gel desiccant pellets in it and seal.
 - STEP 6: Store sample at room temperature in a dark place prior to shipment.

Figure A**Occipital Region of Scalp****Figure B**

Use index finger and thumb to isolate a small thatch of hair (at least 20 fibers of hair) from the occipital region of the scalp.

Figure C

Cut the hair sample off the participant's head as close to the scalp as possible.

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KID#: ____ - ____ - ____

E1. Does the participant have permed, dyed, colored, straightened or chemically altered hair?

Yes..... 1 (END)

No..... 2

E2. Was the Study Coordinator able to cut at least 20 fibers of hair from the **occipital** region?

Yes..... 1 (END)

No..... 2

a. Specify reason(s) hair fibers were not collected:

Consent not obtained..... 1 (END)

Hair not long enough..... 2 (END)

Participant Refused..... -7 (END)

Other..... 3

i. Specify Other Reason:_____