

Biomarker Urine Collection **Instructions for Research Coordinator**

1. Check kit contents thoroughly, using the kit label as a reference.
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit number
Discovery Site	RC ID
Clinical Center	
3. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
4. Using the patient instructions provided in the kit, instruct the patient to perform Clean-Catch Mid-Stream urine collection using BZK antiseptic wipes and the 90mL urine cup provided.
5. The patient should fill the 90mL cup completely if possible.
6. Verify collection by marking “yes” and record the volume collected, collection date, and collection time (24 hour clock) on the Biomarker Urine Specimen Tracking Form.
7. Invert the urine cup 3 times and using the transfer pipette provided, transfer 10mL of urine into the provided urinalysis tube.
8. Follow the manufacturer instructions and perform a dipstick urinalysis on the specimen using the Siemens Multistix[®] 10 SG urinalysis strips provided by the TATC and record the results on the Biomarker Urine Specimen Tracking Form. **Do not place the dipstick directly in the urine cup!**
9. Cap and discard the urinalysis urine and tube according to your institutional guidelines.
10. Pour the remainder of the sample into the two kit barcode labeled 50mL conical tubes provided. Equally divide the sample between the two tubes and do not fill either tube above 45mL.
11. Retain ~5mL of urine in the urine collection cup so that a urine culture (to be performed at every visit) and pregnancy test (if needed) can be performed according to your institutional guidelines.
12. Any specimen observations or discrepancies should be written in the comment section (*i.e.* low volume, blood in urine, patient collection issues, time at -20°C before moved to -80°C *etc.*). If the comment space is not large enough use the back of the tracking form. If there are no specimen comments, check the “None” box.
13. Do not put any participant PHI on the 50mL tubes or the tracking form.
14. Immediately store the 50mL tubes upright in the -80°C freezer until shipment. Record the time the tubes were placed in the freezer (24 hour clock) on the Biomarker Urine Tracking Form.
 - *If a -80 °C freezer is not immediately available, the specimens may be placed on dry ice until they can be placed into a -80 °C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80 °C (the time frozen).*

RC Biomarker Urine Specimen Instructions

15. Keep a copy of the tracking form for your records.
16. Ship the specimens to the TATC once per month (or when samples from 8 patients are collected) following the urine shipment instructions and record shipment date on the Biomarker Urine Specimen Tracking Form.

Female Microbiome Urine Collection

Instructions for Research Coordinator

1. Check kit contents thoroughly, using the kit label as a reference.
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit Number
Discovery Site	RC ID
Clinical Center	

3. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
4. Using the patient instructions provided in the kit, instruct the patient to perform Clean-Catch First-Void (VB1 yellow sticker) and Mid-Stream (VB2 green sticker) urine collection using saline wipes and the 60mL urine cups provided.
5. Note that the VB1 (yellow sticker) container is for the First-Void urine and is a ~20mL collection, and the VB2 (green sticker) container is for the Mid-Stream urine and is a ~40mL collection.
6. Check the “Yes” box to confirm that a specimen was collected on the tracking form and record the collection date and collection time (24 hour clock) on the Female Microbiome Tracking Form.
7. Record the total volume collected for each collection type.
8. Urinalysis is to be performed at week 0 from the VB2 microbiome urine specimen, or at any visit where no Biomarker urine sample is collected.
 - *If urinalysis is to be performed on this specimen (if there was no biomarker urine collected at this visit), invert the VB2 urine cup 3 times and using a transfer pipette, transfer 10mL of VB2 urine into a urinalysis tube.*
 - *Follow the manufacturer instructions and perform a dipstick urinalysis on the specimen in the urinalysis tube using the Siemens Multistix[®] 10 SG urinalysis strips provided by the TATC and record the results on the Female Microbiome Urine Specimen Tracking Form. **Do not place the dipstick directly in the urine cup!***
 - *Cap and discard the urinalysis urine and tube according to your institutional guidelines.*
9. Invert the urine cups 3 times and transfer each of the urine specimens to the respective 50mL orange top conical tube provided (VB1 urine cup contents into VB1 orange top conical tube and VB2 urine cup contents into VB2 orange top conical tube).
10. Urine culture and pregnancy test (if needed) are to be performed at week 0 from the VB2 microbiome urine specimen, or at any visit where no Biomarker urine sample is collected
 - *Retain ~5mL of VB2 urine in the urine collection cup so that a urine culture and pregnancy test (if needed) can be performed according to your institutional guidelines.*
11. Any specimen observations or discrepancies should be written in the comment section (*i.e.* low volume, blood in urine, patient collection issues, time at -20°C before moved to -80°C *etc.*). If the

RC Female Microbiome Urine Specimen Instructions

comment space is not large enough use the back of the tracking form. If there are no specimen comments, check the “None” box.

12. Do not put any of the participant’s PHI on the 50mL tubes or on the tracking form.
13. Immediately store the orange top 50mL tubes upright in the -80°C freezer until shipment. Record the time the tubes were placed in the freezer (24 hour clock) on the Female Microbiome Tracking Form.
 - *If a -80 °C freezer is not immediately available, the specimens may be placed on dry ice until they can be placed into a -80 °C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80 °C (the time frozen).*
14. Keep a copy of the tracking form for your records.
15. Once a month ship the specimens to the TATC following the urine shipment instructions and record shipment date on the Female Microbiome Tracking Form.

Male Microbiome Urine Collection

Instructions for Research Coordinator

1. Check kit contents thoroughly, using the kit label as a reference.
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit Number
Discovery Site	RC ID
Clinical Center	

3. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
4. Using the patient instructions provided in the kit, instruct the patient to perform Clean-Catch First-Void (VB1 yellow sticker) and Mid-Stream (VB2 green sticker) urine collection using saline wipes and the 60mL urine cups provided.
5. Note that the VB1 (yellow sticker) container is for the First-Void urine and is a ~20mL collection, and the VB2 (green sticker) container is for the Mid-Stream urine and is a ~40mL collection.
6. Check the “Yes” box to confirm that a specimen was collected on the tracking form and record the collection date and collection time (24 hour clock) on the Male Microbiome Tracking Form.
7. Record the total volume collected for each collection type.
8. Urinalysis is to be performed at week 0 from the VB2 microbiome urine specimen, or at any visit where no Biomarker urine sample is collected.
 - *If urinalysis is to be performed on this specimen (if there was no biomarker urine collected at this visit), invert the VB2 urine cup 3 times and using a transfer pipette, transfer 10mL of VB2 urine into a urinalysis tube.*
 - *Follow the manufacturer instructions and perform a dipstick urinalysis on the specimen in the urinalysis tube using the Siemens Multistix[®] 10 SG urinalysis strips provided by the TATC and record the results on the Male Microbiome Urine Specimen Tracking Form. **Do not place the dipstick directly in the urine cup!***
 - *Cap and discard the urinalysis urine and tube according to your institutional guidelines.*
9. Invert the urine cups 3 times and transfer each of the urine specimens to the respective 50mL orange top conical tube provided (VB1 urine cup contents into VB1 orange top conical tube and VB2 urine cup contents into VB2 orange top conical tube).
10. Urine culture is to be performed at week 0 from the VB2 microbiome urine specimen,, or at any visit where no Biomarker urine sample is collected.
 - *Retain ~5mL of VB2 urine in the urine collection cup so that a urine culture can be performed according to your institutional guidelines.*

RC Male Microbiome Urine Specimen Instructions

11. Immediately store the orange top 50mL tubes upright in the -80°C freezer until shipment. Record the time the tubes were placed in the freezer (24 hour clock) on the Male Microbiome Tracking Form.
 - *If a -80 °C freezer is not immediately available, the specimens may be placed on dry ice until they can be placed into a -80 °C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80 °C (the time frozen).*
12. If the patient consents to the VB3 collection, the physician will perform a prostate massage.
13. Using the patient instructions provided in the kit, instruct the patient to perform Clean-Catch First-Void (VB3 blue sticker) urine collection using saline wipes and the 60mL urine cup immediately after the prostate massage.
14. Note that the VB3 (blue sticker) container is for the First-Void urine and is a ~30mL collection.
15. Record the collection time (24 hour clock) on the Male Microbiome Tracking Form.
16. Record the total collection volume for the VB3 collection type.
17. Invert the urine cup 3 times and transfer urine specimen to the respective 50mL orange top conical tube provided (VB3 urine cup contents into VB3 orange top conical tube).
18. Any specimen observations or discrepancies should be written in the comment section (*i.e.* low volume, blood in urine, patient collection issues, time at -20°C before moved to -80°C etc). If the comment space is not large enough use the back of the tracking form. If there are no specimen comments, check the “None” box.
19. Do not put any of the participant’s PHI on the 50mL tubes or on the tracking form.
20. Immediately store the orange top 50mL tube upright in the -80°C freezer until shipment. Record the time the tube was placed in the freezer (24 hour clock) on the Male Microbiome Tracking Form.
 - *If a -80 °C freezer is not immediately available, the specimen may be placed on dry ice until it can be placed into a -80 °C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80 °C (the time frozen).*
21. Keep a copy of the tracking form for your records.
22. Once a month ship the specimens to the TATC following the urine shipment instructions and record shipment date on the Male Microbiome Tracking Form.

Universal Microbiome Urine Collection

Instructions for Research Coordinator

1. Check kit contents thoroughly, using the kit label as a reference.
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit Number
Discovery Site	RC ID
Clinical Center	

3. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
4. Using the patient instructions provided in the kit, instruct the patient to perform Clean-Catch Mid-Stream (VB2 green sticker) urine collection using saline wipes and the 60mL urine cup provided.
5. Note that the VB2 (green sticker) container is for the Mid-Stream urine and is a ~40mL collection.
6. Check the “Yes” box to confirm that a specimen was collected on the tracking form and record the collection date and collection time (24 hour clock) on the Universal Microbiome Tracking Form.
7. Record the total volume collected.
8. Urinalysis is to be performed from the VB2 microbiome urine specimen at any visit where no Biomarker urine sample is collected.
 - *If urinalysis is to be performed on this specimen (if there was no biomarker urine collected at this visit), invert the VB2 urine cup 3 times and using a transfer pipette, transfer 10mL of VB2 urine into a urinalysis tube.*
 - *Follow the manufacturer instructions and perform a dipstick urinalysis on the specimen in the urinalysis tube using the Siemens Multistix[®] 10 SG urinalysis strips provided by the TATC and record the results on the Universal Microbiome Urine Specimen Tracking Form. **Do not place the dipstick directly in the urine cup!***
 - *Cap and discard the urinalysis urine and tube according to your institutional guidelines.*
9. Invert the urine cup 3 times and transfer the urine specimen to the respective 50mL orange top conical tube provided.
10. Urine culture and pregnancy test (if needed) are to be performed from the VB2 microbiome urine specimen at any visit where no Biomarker urine sample is collected
 - *Retain ~5mL of VB2 urine in the urine collection cup so that a urine culture and pregnancy test (if needed) can be performed according to your institutional guidelines.*
11. Any specimen observations or discrepancies should be written in the comment section (*i.e.* low volume, blood in urine, patient collection issues, time at -20°C before moved to -80°C *etc.*). If the comment space is not large enough use the back of the tracking form. If there are no specimen comments, check the “None” box.
12. Do not put any of the participant’s PHI on the 50mL tube or on the tracking form.

RC Universal Microbiome Urine Specimen Instructions

13. Immediately store the orange top 50mL tube upright in the -80°C freezer until shipment. Record the time the tube was placed in the freezer (24 hour clock) on the Universal Microbiome Tracking Form.
 - *If a -80 °C freezer is not immediately available, the specimen may be placed on dry ice until it can be placed into a -80 °C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80 °C (the time frozen).*
14. Keep a copy of the tracking form for your records.
15. Once a month ship the specimens to the TATC following the urine shipment instructions and record shipment date on the Universal Microbiome Tracking Form.

Rectal Swab Collection

Instructions for Research Coordinator

1. Check the kit contents thoroughly, using the kit label as a reference.
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit number
Discovery Site	RC ID
Clinical Center	
3. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
4. Follow all appropriate institutional safety guidelines and wear gloves throughout the entire rectal swab collection procedure to avoid contamination.
5. Pull open the swab packages from one end.
6. Remove one of the swabs from its package.
7. Insert the swab into the rectum 1 cm past the anal sphincter while gently rotating the swab against the rectal wall.
8. Once the specimen is collected, remove the cap from the barcoded tube containing buffer provided in the kit.
9. Transfer the swab containing the sample all the way to the bottom of the barcoded tube containing buffer provided in the kit.
10. Break the swab at the molded breakpoint
11. Repeat steps 6-11 for the remaining 2 swabs.
12. Screw the cap tightly to prevent leakage.
13. Mix briefly and visually confirm that the samples on the swab tips are in direct contact with the buffer in the tube.
14. Stand the tube upright for 5 minutes before freezing to ensure the swabs absorb the buffer.
15. Verify collection by marking “yes”, record the date and time of collection, and the time placed at -80°C on the Rectal Swab tracking form.
 - *If a -80°C freezer is not immediately available, the specimens may be placed on dry ice until they can be placed into a -80°C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80°C (the time frozen).*
16. Any specimen observations or discrepancies should be written in the comment section (*i.e.* patient collection issues, storage temperature issues *etc.*). If the comment space is not large enough use the back of the tracking form. If there are no specimen comments, check the “None” box.

RC Rectal Swab Specimen Instructions

17. Place the tube containing all 3 swabs in buffer upright in the vaginal/rectal swab storage and shipment box provided by the TATC in a -80⁰C freezer immediately after collection.
18. Do not put any participant PHI on the tubes or the tracking form.
19. Store the samples at -80⁰C until shipment.
20. Keep a copy of the tracking form for your records.
21. Ship the specimen in batches on dry ice to the TATC once per month according to the swab shipment instructions and record shipment date on the Rectal Swab Tracking Form.

Vaginal Swab Collection **Instructions for Research Coordinator**

1. Check the kit contents thoroughly, using the kit label as a reference
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit number
Discovery Site	RC ID
Clinical Center	
3. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
4. Follow all appropriate institutional safety guidelines and wear gloves throughout the entire vaginal swab collection procedure to avoid contamination.
5. Pull open the swab packages from one end.
6. Remove one of the swabs from its package.
7. Separate the labia with one hand and without touching the labia, insert the swab about 5 cm (2 inches) into the vaginal opening while gently rotating the swab against the vaginal wall.
8. Once the specimen is collected, remove the cap from the barcoded tube containing buffer provided in the kit.
9. Transfer the swab containing the sample all the way to the bottom of the barcoded tube containing buffer provided in the kit.
10. Break the swab at the molded breakpoint
11. Repeat steps 6-11 for the remaining 2 swabs.
12. Screw the cap tightly to prevent leakage.
13. Mix briefly and visually confirm that the samples on the swab tips are in direct contact with the buffer in the tube.
14. Stand the tube upright for 5 minutes before freezing to ensure the swabs absorb the buffer.
15. Verify collection by marking “yes”, record the date and time of collection, and the time placed at -80°C on the Vaginal Swab tracking form.
 - *If a -80°C freezer is not immediately available, the specimens may be placed on dry ice until they can be placed into a -80°C freezer. Please use the “Comments” section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the “Time placed in freezer” is the time the specimen is placed on dry ice or at -80°C (the time frozen).*
16. Any specimen observations or discrepancies should be written in the comment section (*i.e.* patient collection issues, storage temperature issues *etc.*). If the comment space is not large

RC Vaginal Swab Specimen Instructions

enough use the back of the tracking form. If there are no specimen comments, check the “None” box

17. Place the tube containing all 3 swabs in buffer upright in the vaginal/rectal swab storage and shipment box provided by the TATC in a -80°C freezer immediately after collection.
18. Do not put any participant PHI on the tubes or the tracking form.
19. Store the samples at -80°C until shipment.
20. Keep a copy of the tracking form for your records.
21. Ship the specimen in batches on dry ice to the TATC once per month according to the swab shipment instructions and record shipment date on the Vaginal Swab Tracking Form.

STIM Tube Collection

Instructions for Research Coordinator

1. Check kit contents thoroughly, using the kit label as a reference.
2. Bring TruCulture™ tubes to room temperature prior to venipuncture according to the manufacturers recommendation found in the “Instructions for using TruCulture™ tubes” document provided in the kit.
3. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit number
Discovery Site	RC ID
Clinical Center	
4. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
5. Indicate the tube thaw method and the time placed at room temperature (room T) on the STIM Tube Acquisition Tracking Form.
6. If you will be collecting both plasma and STIM tubes using the same venipuncture, use the following procedure to switch from the multifly needle adaptor to the vacutainer hub (also demonstrated in the MAPP STIM/Plasma tube blood draw video):
 - a. Prepare a vacutainer hub by inserting a butterfly needle set, then remove and discard the tubing and needle portion of a butterfly set into a sharps container according to your institutional guidelines.
 - b. **Always collect the TruCulture™ tubes before the plasma blood collection or any other blood collection.** Aseptically perform the venipuncture according to the “Instructions for using TruCulture™ tubes” document provided in the kit using the multifly needle.
 - c. Collect TruCulture™ tubes in the following order:
 1. LPS-1
 2. FLS-1
 3. NULL
 - d. After all 3 TruCulture™ tubes have been collected use a hemostat to gently clamp the multifly tubing to stop the flow of blood.
 - e. Remove the multifly adaptor, and replace it with the vacutainer hub prepared in step 6a.
 - f. Attach the ACD solution A vacutainer tube and collect the plasma tube according to the plasma specimen collection instructions.
7. Verify collection by marking “yes” and record the date and time of collection and the TruCulture™ LOT # for each tube type on the STIM tube acquisition tracking form.
8. Any specimen observations or discrepancies should be written in the comment section (*i.e.* low volume, collection/incubation issues, *etc.*). If there are no specimen comments, check the “None” box.
9. Do not put any participant PHI on the tubes or on the tracking form.

RC STIM Specimen Instructions

10. Barcode each TruCulture™ tube with the barcodes included in the kit placing the LPS-1 label on the LPS-1 tube, the FLS-1 label on the FLS-1 tube, and the NULL label on the NULL tube.
11. Incubate specimen with the cap up in a heating block at 37⁰C and record time placed in the block.
12. After 24 hour incubation, remove the TruCulture™ tubes from the heating block
13. Process the TruCulture™ tubes according to steps 12-14 of the manufacturer's "Instructions for using TruCulture™ tubes" document provided in the kit.
14. Cap the tubes securely.
15. Record the Processing date and the time removed from 37⁰C block on the STIM Tube Processing Tracking Form.
16. Any specimen observations or discrepancies should be written in the comment section (*i.e.* processing or incubation issues, *etc.*). If there are no specimen comments, check the "None" box.
17. Sign in the "Processing Coordinator's Signature" box.
18. Immediately store the specimens upright at -80⁰C and record the time placed at -80⁰C.
 - *If a -80⁰C freezer is not immediately available, the specimens may be placed on dry ice until they can be placed into a -80⁰C freezer. Please use the "Comments" section to indicate any storage/temperature variations of this type. Be sure to include the time and temperature in the comment. Note that the "Time placed in freezer" is the time the specimen is placed on dry ice or at -80⁰C (the time frozen).*
19. Do not put any participant PHI on the tubes or the tracking form.
20. Store at -80⁰C until shipment to the TATC.
21. Keep a copy of the tracking form for your records.
22. Once a month ship the specimens to the TATC on dry ice according to the STIM Tube shipment instructions and record shipment date on the STIM Tube Tracking Form.

Plasma Collection – Monday through Thursday

Instructions for Research Coordinator

1. Check the kit contents thoroughly, including the expiration date of the yellow top ACD solution A vacutainer, and the barcode labels. Get a new kit for the plasma collection if the vacutainer is expired. **Be sure that there are two ice packs refrigerated for shipping this specimen.** Keep two cold packs refrigerated at all times.
2. On the tracking form, record the following data in the appropriate space:

Participant ID	CRF Date
PIN #	Visit number
Discovery Site	RC ID
Clinical Center	
3. When collecting STIM tubes using the same venipuncture, refer to the STIM Tube Collection Instructions for Research Coordinator. **Always collect the STIM Tubes before the plasma blood collection or any other blood collection.**
4. Perform venipuncture using the barcoded vacutainer provided in the kit, invert vacutainer 8 times.
5. Verify collection by marking “yes” and record the date and time of collection.
6. Sign the patient consent certification on the tracking form (yellow block in the middle of the page).
7. Immediately after collection, place the yellow top vacutainer into the barcode labeled blue top transport tube provided in the kit. Make sure that the lid of the transport tube is closed properly. Place tube into the provided biohazard bag
8. Any specimen observations or discrepancies should be written in the comment section (*i.e.* incomplete draw, collection issues *etc.*).
9. Do not put any participant PHI on the tubes or on the tracking form.
10. Immediately refrigerate the specimen at 4°C and record the time the sample was refrigerated.
11. Keep the sample refrigerated until the time of shipping.
**ALL PLASMA SAMPLES MUST BE SHIPPED ON THE DAY OF COLLECTION!!
DO NOT COLLECT OR SHIP SAMPLES ON SATURDAY OR SUNDAY.**
12. Samples collected on Friday must be shipped following the “Plasma Collection – Friday Collections, Instructions for Research Coordinator” protocol.
13. Record the shipping date on the tracking form.
14. Keep a copy of the tracking form for your records, enclose the original in the outer pouch of the biohazard bag.
15. Place one chilled cold pack on the bottom of the styrofoam shipping box.

16. Place the biohazard bag with the specimen and tracking form on top of the chilled cold pack.
17. Place the second chilled cold pack on top of the specimen.
18. Please note that if more than one specimen is collected in a day, you may batch ship two specimens in one shipping container.
19. Place the Styrofoam lid, close the outer cardboard flaps of the box and seal the shipping container closed with packing tape.
20. Register the shipment in the DMS shipping Module.
21. Drop off the pre-addressed container at the nearest FedEx package drop-off site on the same day of collection Monday - Thursday.

Plasma Collection – Friday
Instructions for Research Coordinator

1. Sites must notify TATC as early in the week as possible that a plasma sample will be collected and shipped on Friday.
2. Friday Collection/Saturday Delivery Labels must be requested by email from Andrea Osypuk (Andrea.Osypuk@UCDenver.edu) and will be emailed to the requesting research coordinator.
3. Collect blood and fill out the tracking form according to the Plasma Collection – Monday through Thursday Instructions for Research Coordinator document.
4. Package the blood sample in the Plasma shipment box and tape the box closed according to the Plasma Collection – Monday through Thursday Instructions for Research Coordinator document.
5. Use a black marker to black out the FedEx label currently attached to the box.
6. Print out and place the Friday shipment/Saturday delivery label over the blacked out label using packing tape or a FedEx label pouch.
7. Register the plasma shipment via the DMS website, and notify Andrea of the shipment via email (Andrea.Osypuk@UCDenver.edu). Include the FedEx tracking number in your email.
8. Drop off the pre-addressed container at the nearest FedEx package drop-off site on the Friday that the sample was collected.

Friday Shipment/Saturday delivery label:

5/30/2014		FedEx Ship Manager - Print Your Label(s)	
From: (319) 384-9265 Mary Eno University of Iowa 200 Hawkins Dr. 3120 RCP IOWA CITY, IA 52242	Origin ID: IOWA		Ship Date: 30MAY14 ActWgt: 2.0 LB CAD: 101310627/NET3490
			Dim: 8 X 8 X 9 IN
SHIP TO: (303)724-3069		BILL SENDER	Delivery Address Bar Code 
Andrea Osypuk UCD Biorepository 2100 31st St. Denver, CO 80216			Ref # 63004599 Invoice # PO # Dept #
			SATURDAY 12:00P PRIORITY OVERNIGHT
		TRK# 7701 4430 7342 0201	80216 CO-US DEN
		X0 BKFA	
			<small>S22G162D3F220</small>

Please Note that the "SHIP TO" name may change weekly

3 Day Salivette Home Collection

Instructions for Research Coordinator

1. Check the kit contents thoroughly, using the kit label as a reference.
2. Record the Patient ID and the Discovery site on the upper left corner of the tracking form, and on the kit label.
3. Record the scheduled collection dates for the participant on the tracking form.
4. Make a copy of the tracking form for your site records.
5. Write your research coordinator contact information on the bottom of the instruction portion of the tracking form. Include your name, your institution, your address, your phone number and your email address. Encourage the participant to contact you if they have any questions or concerns.
6. Instruct the patient on the salivette collection and shipping procedure using the instructions on the back of the tracking form.
7. Send the Salivette collection kit home with the participant and instruct the participant to begin collections the following morning.

Sample Type	Collection Container	Wipe	Final Specimen Container(s)	Special Instructions	Catch Type(s)	Freeze/ Refrigerate	Shipping Frequency	Shipping Requirements
Biomarker Urine Specimen (Male and Female)	90mL urine cup (1)	BZK antiseptic	50mL Conicals (2)	Perform and record urinalysis using a dipstick	Mid-Stream	Freeze immediately at -80°C	Monthly	Dry Ice
Female Microbiome Urine Specimen	60mL urine cup (2, Labeled VB1 yellow dot, VB2 green dot)	Saline Wipes	50mL Conical (2 Labeled VB1 yellow dot, & VB2 green dot)	Perform and record urinalysis on VB2 specimen using a dipstick if no Biomarker specimen is collected	(VB1) First Void & (VB2) Mid-Stream	Freeze immediately at -80°C	Monthly	Dry Ice
Male Microbiome Urine Specimen	60mL urine cup (3, Labeled VB1 yellow dot, VB2 green dot, & VB3 blue dot)	Saline Wipes	50mL Conical (3 Labeled VB1 yellow dot, VB2 green dot, & VB3 blue dot)	Perform and record urinalysis on VB2 specimen using a dipstick if no Biomarker specimen is collected	(VB1) First Void , (VB2) Mid-Stream & (VB3) First Void post prostate massage	Freeze immediately at -80°C	Monthly	Dry Ice
Universal Microbiome Urine Specimen (Male and Female)	60mL urine cup (1)	Saline Wipes	50mL Conical (1)	Perform and record urinalysis on VB2 specimen using a dipstick if no Biomarker specimen is collected	Mid-Stream	Freeze immediately at -80°C	Monthly	Dry Ice
STIM Tube	TruCulture STIM tubes LPS-1, FLS-1, NULL		TruCulture STIM tubes LPS-1, FLS-1, NULL	Aseptically perform venipuncture according to TruCulture instructions and your institutional guidelines		Incubate at 37°C overnight, use valve separator, freeze at -80°C	Monthly	Dry Ice
Plasma	10mL vacutainer yellow top, ACD solution A		10mL vacutainer yellow top, ACD solution A inside the 50ml transport tube	Aseptically perform venipuncture according to your institutional guidelines		Refrigerate at 4°C & ship on the day of collection	Monthly	Cold packs
Vaginal and Rectal Swab	3 swabs and 1 tube provided in kit		Tube provided in kit	Let swabs stand upright in tube for 5 minutes prior to freezing to allow for absorption of buffer		Freeze immediately at -80°C	Monthly	Dry Ice
Salivette Home Collection	6 salivette tubes (3 Day)		6 salivette tubes (3 Day)			Refrigerate at 4°C	After the last collection	Room Temperature

Urine Shipment Instructions for Research Coordinator

1. All urine specimens should be stored at -80°C at the site.
2. All urine specimens should be shipped in batches and on dry ice once per month.
3. Ship no more than 25 urine tubes per shipment.
4. Follow all institutional guidelines for shipping biological materials on dry ice.
5. **DO NOT SHIP SAMPLES ON THURSDAY, FRIDAY, SATURDAY, SUNDAY OR ON OR BEFORE MAJOR HOLIDAYS.** Please contact Andrea Osypuk (Andrea.Osypuk@UCDenver.edu 303-724-3069) if you have any questions regarding shipping dates.
6. To ship the specimens, place all of the specimens in the biohazard bags with desiccant paper provided in the urine kits. Seal the bags.
7. Add a layer of dry ice to the bottom of the provided insulated shipping box.
8. Set the specimens in their biohazard bags on top of the dry ice.
9. Completely cover the specimens with dry ice and fill the rest of the box with dry ice.
10. Place the styrofoam lid.
11. Enter the date of shipment on all tracking forms for all specimens included in the shipment (keep copies of all tracking forms for site records).
12. Place the completed tracking forms for all of the samples included in the shipment on top of the styrofoam lid in the plastic bag provided in the shipping kit.
13. Close the outer cardboard flaps of the box and seal the shipping container closed with packing tape.
14. Completely remove or use a black marker to black out any old/invalid FedEx labels or stickers.
15. Adhere the UN3373 sticker, the pre-filled dry ice sticker, the address label, and the preprinted FedEx label included in the shipping kit to the outside of the box.
16. Register all shipments to the TATC in the MAPP DMS shipping module.
17. Drop off the container at the nearest FedEx package drop-off site Monday - Wednesday.

Swab and STIM Tube Shipment Instructions for Research Coordinator

1. All rectal and vaginal swab and STIM tube specimens should be stored upright at -80°C at the site.
2. All rectal and vaginal swab and STIM tube specimens should be shipped in batches on dry ice once per month.
3. Ship no more than 2 boxes of specimens per shipment (either 2 boxes of swabs, 2 boxes of STIM tubes, or 1 box of swabs and 1 box of STIM tubes).
4. Follow all institutional guidelines for shipping biological materials on dry ice.
5. **DO NOT SHIP SAMPLES ON THURSDAY, FRIDAY, SATURDAY, SUNDAY OR ON OR BEFORE MAJOR HOLIDAYS.** Please contact Andrea Osypuk (Andrea.Osypuk@UCDenver.edu 303-724-3069) if you have any questions regarding shipping dates.
6. To ship the specimens, place each box of specimens in a zipper bag with desiccant paper provided in the swab and STIM tube shipping kit. Seal the bags.
7. Add a layer of dry ice to the bottom of the provided insulated shipping box.
8. Set the boxes in their zipper bags on top of the dry ice.
9. Completely cover the specimens with dry ice and fill the rest of the box with dry ice.
10. Place the styrofoam lid.
11. Enter the date of shipment on all tracking forms for all specimens included in the shipment (keep copies of all tracking forms for site records).
12. Place the completed tracking forms for all of the samples included in the shipment on top of the styrofoam lid in the plastic bag provided in the shipping kit.
13. Close the outer cardboard flaps of the box and seal the shipping container closed with packing tape.
14. Completely remove or use a black marker to black out any old/invalid FedEx labels or stickers.
15. Adhere the UN3373 sticker, the pre-filled dry ice sticker, the address label, and the preprinted FedEx label included in the shipping kit to the outside of the box.
16. Register all shipments to the TATC in the MAPP DMS shipping module.
17. Drop off the container at the nearest FedEx package drop-off site Monday - Wednesday.