

MICROBIOME STOOL COLLECTION

1. Background

Visit 4 will involve the collection of one stool sample using the Omnigene Gut collection kit. This project is designed to collect stool samples and preserve them at the MrOS Administrative Center, thus providing a stool biolibrary for future microbiome studies. DNA and RNA from the microbiome will be stored and collected. We will also be collecting dietary data in conjunction with this project.

2. Equipment and Supplies

All kits will be shipped to MrOS clinical sites from DNA Genotek. There is a 6-month shelf life for each kit. Sites should estimate how many kits they will need over a 6-month period and inform Cathie Pedersen at OHSU when supplies are low to re-order.

Each site will be supplied with sheets of ID barcode labels. There are two stickers for each participant. One is for the TELEform and one is for the collection tube.

The following supplies will be shipped from OHSU:

- Alcohol wipes
- Exam gloves
- Postage-paid padded envelope with ‘EXEMPT HUMAN SPECIMEN’ sticker on the outside.
 - Each envelope will have an OHSU address on it.
- Inside the padded envelopes is a biohazard bag with cotton balls placed in it
- ‘Hats’ for bulk stool collection

3. Administration

If the participant agrees to provide a stool sample, complete Question 1 on the Microbiome Specimen Collection TELEform. Ask the participant: “Have you been on a special diet during the past year?” If yes, indicate which special diets the participant has been on during the past year and during the past two weeks. Complete Question 3. Ask the participant if he has taken any antibiotics within the two weeks prior to the clinic visit. If yes, make sure that these antibiotics are listed on the Medication Inventory Form.

Preparing the kit and forms for the participant

- Open the stool kit and place the label that says “Kit” on the collection tube.
- Place the other label that says “Form” on the Microbiome Specimen Collection TELEform.
- Hand write the MrOS ID# on the participant’s instructions sheet.

Reviewing instructions and materials with the participant

- Explain the stool collection procedures

- Read through the instructions sheet with the participant.
- Explain how the ‘hat’ is placed on the toilet.
- Remove the tube from the package and unscrew the cap, then show him where the stool sample should go and let him know that only a small amount of stool is needed.
- Tell the participant that he should dispose of the hat in his garbage.
- Please make sure the participant knows that only the purple cap should be removed. Ask him to not unscrew the yellow cap. It may be necessary to add a small label to be placed around the yellow cap that states ‘Do Not Remove’.
- Show the participant the additional instruction sheet with the time and date of collection. This sheet should have the MrOS ID# hand written on the top.
- Tell the participant that he must write down the date and time he collected his stool, and that he must put that completed sheet into the envelope with the stool sample.
- Remind the participant that he must be eating his normal diet a week prior and up to collecting his stool. If the participant has eaten something that he normally does not eat (e.g., sushi), then he must wait 7 days to collect his stool and eat his normal diet for those 7 days.
- Put all supplies into a bag for the participant to take with him at the end of the visit

Appendix A shows the participant instruction sheet with the time and date of collection.

Appendix B shows the stool collection instructions sheet with figures.

4. Procedures: After Visit 4 clinic visit

Please send a list of participants (ID#s) that have agreed to collect a stool sample to Melanie Abrahamson at OHSU every Friday. Melanie will email sites when a sample has arrived and let each site know the date and time the stool was collected, so the rest of the Microbiome Specimen Collection TELEform can be completed. If OHSU has not received the sample a week after a participant’s clinic visit, please call him and remind him to collect the sample. If the participant has changed his mind and does not want to collect the sample, please notify OHSU and complete the Microbiome Specimen Collection TELEform. If the participant is still willing to collect a stool sample, ask the participant if he has any questions you can answer and ask him to collect and send sample as soon as possible.

5. Contact Information

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Appendix A: Participant Instructions Sheet

ID # _____

**MrOS Visit 4
STOOL COLLECTION**

Time you collected the stool sample: ____ : ____ AM/PM

For example 8 : 30 **AM**/PM

Date you collected the stool sample ____ / ____ / 2015

For example **5 / 23 / 2015**

Date you mailed the sample: ____ / ____ / 2015

**PLEASE SEND THIS FORM BACK WITH THE STOOL
SAMPLE IN THE BROWN PADDED ENVELOPE**

ID # _____

MrOS Visit 4
STOOL COLLECTION INSTRUCTIONS

Please collect your stool sample within 24-48 hours after your MrOS clinic visit.



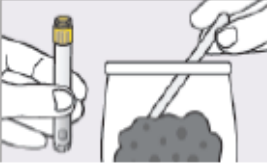


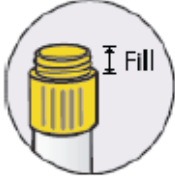

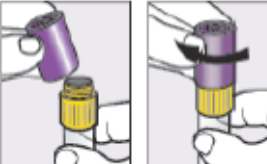



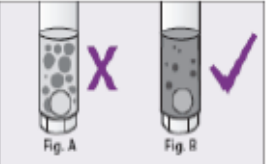
You must have eaten your usual diet. If you had any very unusual meals that you don't normally eat, please wait 7 days before you collect your stool sample.

Collecting the sample

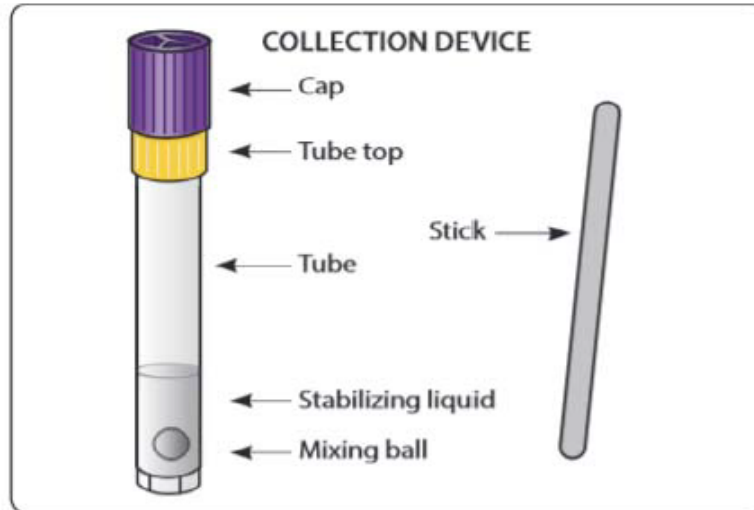
- Bring all materials for your collection into the area near your toilet. If you need to urinate, empty your bladder before beginning your stool collection.
- Place the plastic "Hat" onto the toilet. Collect stool sample in hat. **Do not allow water or urine to mix with sample.**
- We can't accept your stool sample if you have diarrhea or other liquid/urine in the sample. If this occurs, collect a sample from the next bowel movement.
- For placing the stool sample into the collection tube, follow the instructions that are included with the sample tube. Gloves are included. There is an alcohol swab to wipe down the outside of the tube, if needed.
- Once the sample is added to the tube and the tube is clean and shaken, place the tube into the ziplock bag with the cotton balls and seal the bag.
- Please write the time and date you collected your sample on the sheet provided, and put the form in the postage-paid brown padded mailing envelope.
- Place the sealed ziplock bag in the postage-paid brown, padded mailing envelope.
- Seal the envelope by removing the adhesive stripe and sealing securely.
- Mail the envelope via the US Postal Service within 24 hours of sample collection.
- If you have any questions, please contact us at XXXXXX.

Appendix B: Microbiome Stool Collection Instructions

MICROBIOME COLLECTION

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- 1**  Unscrew the purple cap from the collection device and set it aside for later use.
IMPORTANT:
Do NOT remove the yellow tube top.
Do NOT spill the stabilizing liquid in the tube. 
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- 2**  Use the stick to collect a small amount of fecal sample. 
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- 3**  Transfer the fecal sample into the yellow tube top
Repeat until the sample reaches the top and fills it completely.
IMPORTANT: Do NOT push sample into the tube. 
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- 4**  Scrape horizontally across the tube top to level the sample and remove any excess. Discard the stick. Wipe exterior of tube and top with toilet paper or tissue as needed.
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- 5**  Screw the purple cap back onto the yellow tube-top until tightly closed. 
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- 6**  Shake the sealed tube as hard and fast as possible in a back and forth motion for a minimum of 30 seconds. 
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- 7**  The fecal sample will be mixed with the stabilizing liquid in the tube; not all particles will dissolve.
IMPORTANT: Continue shaking if large particles remain as shown in Figure A.
Send the sample for processing following the delivery instructions supplied by the kit provider.
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MICROBIOME COLLECTION



Preparation:

- **Empty your bladder before beginning the collection.**
- **Collect fecal sample free of urine or toilet water.**
- **Toilet paper or tissues may be required.**