Meconium & Stool – Diaper Collection
Perinatal, Infancy, & Early Childhood

Collection, Processing, and Storage Protocol
Site and Home Collection

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A. Overview

- The meconium & stool diaper collection procedures apply to children in perinatal, infancy, and early childhood life stages who are not potty-trained, so the specimen is collected in a diaper.
- The diaper is not provided in the kit, hence the specimen will be collected in the participant’s diaper. Once collected, the parent, caregiver, or study staff will aliquot meconium/stool into three tubes provided by Fisher BioServices for the ECHO-wide Cohort Data Collection Protocol (EWCP).
- The instructions in this protocol are for site collection during a participant’s visit and for home collection.
- For home collection, study staff may take the collection kit to the participant’s home or provide it during an on-site visit for the caregiver to take home. The caregiver transports the stool specimen in person or mails the specimen the same day of collection via overnight FedEx. The specimen is transported on three freezer gel packs to the site and should NOT be collected on Friday, Saturday, or Sunday, or on a federal holiday, to ensure that the specimen will arrive at the site during a regular work day.

B. Guidelines

- The goal is to collect one scoop of meconium or stool specimen in a Zymo DNA/RNA shield fecal collection tube and one scoop in each of the two fecal collection tubes from each participant.
- For children in infancy, repeated sampling at 1 month and 6 months of age is recommended.
- For children in early childhood, repeated sampling at 1 year and 3 years of age is recommended. If the child is potty-trained by age 1, site should use the Stool Hat Collection, Processing, and Storage (CPS) Protocol for collections.
- Collect stool specimen even if a participant does not have normal bowel movement, e.g., has diarrhea (loose bowels).
- For home collections, encourage the caregiver to mail the specimen the same day of collection. If participant/caregiver cannot mail the specimen on the day of specimen collection, they should store all three tubes in their freezer compartment (-20°C).
- All three tubes with specimen must be placed in a −80°C freezer immediately upon collection or receipt of specimen at the study site (if sent from home).
- If collected at the site, ensure that the child is wearing a diaper upon his/her arrival.

C. Collection Kit, Supplies and Kit Assembly

1. Meconium and Stool Kit (Fisher BioServices)
   - 1x Zymo DNA/RNA Shield collection tube
   - 2x Fecal tubes
1. Supplies (Site)

- Gloves
- Biohazard container
- 
  -80°C freezer
- Meconium and Stool – Diaper Collection – Collection Instruction Sheet (CIS)
- Meconium and Stool – Specimen Information Form (SIF)
- Meconium and Stool – Specimen Tracking Form (STF)
- Cryobox for tubes: (5 x 5 x 3 in.; 25 cell; 5 x 5 grid)
- Transport materials for home collection:
  - Insulated padded envelope: ULINE silver glamour bubble mailers; 7 x 6 ¾ in.; Model #: S-7786IL
b. Sealable padded mailer envelope 8 ½ x 11 in.

c. 3 gel packs: PP6
https://www.thermosafe.com/subcategory/Gel+Packs

d. 1 absorbent sheet 6 x 9 in.

e. 1 zip-lock bag with biohazard symbol
https://www.fishersci.com/shop/products/fisherbrand-biohazard-specimen-transport-bags-10/0180003#?keyword=01-800-03

3. Kit Assembly

Follow the steps below to assemble the collection kit and prepare for the collection prior to meeting with the participant and caregiver.

- Confirm that the collection kit includes one biohazard bag, three collection tubes, a pair of gloves, and three sets of triplet specimen ID labels.

**Note:** Confirm that all materials needed to collect the specimen are available.

- Print the CIS, SIF and STF.
- Fill out the headers on SIF and STF.
- There will be three identical labels for each specimen ID. Affix the first label to the Zymo DNA/RNA shield collection tube. Apply the second matching label to the field labeled **SPECIMEN LABEL** in STEP 2 on the STF. Apply the third matching label to the field labeled **SPECIMEN LABEL** on the SIF.

a. Repeat the labeling procedure for the two fecal tubes and place matching labels in STEP 2A on the STF

**Note:** Study staff must complete the above steps before providing the materials to the caregiver to prevent misplacement or confusion about the forms/tubes.

- The labeled tubes, gloves, biohazard bag, CIS, and SIF will be provided to the caregiver.
- Complete the **KIT DISTRIBUTION** section of the STF.
- Retain the STF at the site.
4. Home Collection: Kit Distribution and Specimen Receipt

Use the following steps to prepare for distribution and return of the collection kit to the site via mail or in person.

- Place the assembled kit contents in a mailing box.
- Include a prefilled and prepaid FedEx Express Overnight air bill for return of specimen to the site, three gel packs, a biohazard bag, an absorbent sheet, an insulated (silver) padded envelope, and a return padded mailer envelope.
- Ship the mailing box to the participant’s home.
- Complete the **KIT DISTRIBUTION** section of the STF.

Note: Dry ice is an alternative to gel packs if the specimen is brought to the site in-person by the study staff.

D. Site Collection

1. Site Pre-Collection Instructions for the Study Staff

- Ensure that the child is wearing a diaper.
- Have labeled collection tubes, gloves, CIS, and SIF available. Caregiver completes the SIF on behalf of the child.
- Review the contents and procedure on the CIS with the caregiver to ensure that he/she understands aliquoting instructions. Site staff can also choose to aliquot the specimen.

2. Site Collection Instructions for the Study Staff or Caregiver

- Follow instructions on the Meconium & Stool – Diaper Collection – Collection Instruction Sheet.

3. Site Post-Collection Instructions for the Study Staff

- Collect the completed SIF from the caregiver.
- Complete **STEP 1: COLLECTION INFORMATION, STEP 1A: TYPE OF SPECIMEN, and STEP 1B: COLLECTION METHOD** sections of the STF. Mark **STEP 3: TRANSPORT AND RECEIPT** as not applicable.
- Retain the SIF and STF at the site.

E. Home Collection

1. Home Pre-Collection Instructions for the Study Staff

- Inform the caregiver about the expected date of collection kit arrival at their house.
- Encourage the participant to contact the site for any questions.
• If the study staff plans to bring specimen back to the site, ensure that the transport instructions included on the CIS are followed. Dry ice is an acceptable alternative to freezer gel packs. 
  Note: The freezer gel packs must be placed in a freezer for 24 hours or longer prior to use.

2. Home Collection Instructions for the Participants
   • Refer to the Meconium & Stool (Diaper Collection) Collection Instruction Sheet.

F. Processing
• Upon specimen collection or receipt of the specimen at the site, check the collection tubes labels against the SIF to ensure that the specimen ID labels match.
• Complete STEP 1: COLLECTION INFORMATION, STEP 1A: TYPE OF SPECIMEN, STEP 1B: COLLECTION METHOD, and STEP 3: TRANSPORT AND RECEIPT sections on the STF.

G. Storage
• Place three specimen tubes in a labeled cryobox and store in a −80°C freezer immediately.
• Complete STEP 4: STORAGE section of the STF.
• Data from SIF and STF should be entered into Bio-Track immediately or within 48 hours of storing the specimen.
• Retain the SIF and STF at the site.

H. Shipping to Biorepository
This information is available in the Laboratory Manual of the EWCP.

I. Supporting Documents
1. Meconium and Stool – Diaper – Collection Instruction Sheet (CIS)
2. Meconium and Stool – Specimen Information Form (SIF)
3. Meconium and Stool – Specimen Tracking Form (STF)
4. Meconium and Stool – Specimen Tracking Form (STF) Completion Instructions