Toenail – Assisted Collection
Infancy, Early Childhood, Middle Childhood

Collection, Processing and Storage Protocol
Home or Site Collection

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A. Overview

- A primary caregiver will collect toenails from a child that falls under infancy, early childhood, and middle childhood life stage using child collection kit (Assisted Collection). The caregiver will also complete a Specimen Information Form (SIF) on child’s behalf.
- In cases where a child in middle childhood is able to self-collect, follow the Toenail (Self Collection) Collection, Processing and Storage Protocol.
- Toenail collection can occur at home or on site during the participant’s visit.
- Study staff will distribute the toenail collection kit to the caregiver. The study staff can mail the kit, provide it during a site visit, or take it to the caregiver’s home.
- Once collected, the caregiver can mail the toenails and completed toenail SIF to the site, bring it to the next site visit, or study staff can pick it up from caregiver’s home.

B. Guidelines

- Do not collect fingernails.
- Allow toenails to grow for at least 2 weeks before collection.
- Collect toenails after bathing and/or while child is asleep to ensure that toenails are clean and easier to clip.
- Do not attempt collection if physical limitation or other medical condition prevents toenail collection.
- If an accidental nick or cut causes bleeding, apply pressure, antibiotic ointment, and bandage, if necessary.
- Two persons should perform the child toenail collection. One person acts as the collector and the other as the helper who holds the child still.
- It may be necessary to do the collection in more than one session if the child is fussy or unable to keep still.

C. Collection Kit, Supplies and Kit Assembly

1. Toenail Collection Kit (Child) (Fisher BioServices)
   - One (1) stainless steel toenail clipper (infant size)
   - One (1) collection envelope
   - One (1) biohazard bag (4 x 6 in)
2. Supplies (Site)
   - One (1) alcohol wipe
   - Two (2) paper towels
   - Two (2) nail polish remover pads (acetone-free; methyl acetate), as needed
   - One (1) storage container/large envelope (able to fit 4 x 6 in biohazard bag)
     a. Recommendation: 5.71 x 5.71 x 4.80 in. box (30 biohazard bags per box)
   - Toenail – Assisted Collection – Collection Instruction Sheet (CIS)
   - Toenail – Specimen Information Form (SIF)
   - Toenail – Specimen Tracking Form (STF)
   - Transport materials from home collection:
     a. Collection kit distribution by mail:
        i. Padded envelope
        ii. Appropriate postage
     b. Specimen receipt at the site by mail:
        i. Padded envelope
        ii. Appropriate postage

3. Kit Assembly
   Follow the below steps to assemble the collection kit and prepare for the collection prior to meeting with the participant/caregiver.
• Confirm that the collection kit includes a biohazard bag, a collection envelope, triplet specimen ID labels, and a toenail clipper.
• Print SIF and STF and fill out the headers.
• There will be three identical labels for each specimen ID. Affix the first label to the collection envelope, place the second matching label to the field labeled **SPECIMEN LABEL** on the STF and the third matching label to the field labeled **SPECIMEN LABEL** on the SIF. Note: Study staff must complete the above steps before providing the materials to the caregiver to prevent misplacement or confusion about the forms/envelopes.
• Place the toenail clipper, collection envelope, and SIF in the same biohazard bag.
• Include two paper towels and one alcohol wipe in the biohazard bag.
• Retain the STF at the site.
• Fill out the **KIT DISTRIBUTION** section of the STF.

4. Home Collection: Kit Distribution and Specimen Receipt

Use the following steps to prepare for distribution of the collection kit and receipt of specimen by mail:
• Add the following items on the front of the padded envelope:
  a. Appropriate postage
  b. Place a site address label in the upper left corner
  c. Place a caregiver address label in the center
• Place the biohazard bag prepared in the previous step in the padded envelope.
• **Include the CIS.**
• Prepare another prepaid return mailer (padded envelope) for the participant/caregiver to send specimen to the site.
  a. Add appropriate postage
  b. Place a caregiver address label in the upper left corner
  c. Place a site address label in the center
  d. Fold the return mailer and place in the padded envelope
• Mail the padded envelope to the participant/caregiver.
• Complete the **KIT DISTRIBUTION** section of the STF.

D. Site Collection

1. Site Pre-Collection Instructions for the Study Staff
• Remove contents from the bag.
• Review the contents and collection instructions with the caregiver to ensure that he/she understands the procedure.
Two persons should perform the child toenail collection. One person acts as the collector and the other as the helper who holds the child still. Ask the caregiver which role he/she would like to play.

2. Site Collection Instructions for the Collector and Helper
- Wash hands with soap and water.
- Lay the child face up on a well-lit, safe level surface such as a changing table.
- The helper must assure throughout the entire procedure that the child does not roll off the table.
- If necessary, remove all nail polish using nail polish remover pads before collecting toenails.
- Wipe the toenail clipper with the alcohol pad and allow to air dry.
- Unfold the paper towels and place one under each foot to catch the toenail clippings.
- The helper holds the child leg still by pressing downward on the thigh above the knee so the collector can trim the toenails.
- The collector holds the child’s foot in his/her hand, and presses gently down on the pad of one toe with thumb to separate the toenail from the skin.
- The collector aligns the edge of the toenail with the clipper jaws. Make sure there is no skin in the path of the clipper jaws before clipping. Do not cut toenails too short (close to the nail bed) and clip each toenail straight across.
- There are no minimal collection requirements. The collector clips all the toenails from both feet. Try to catch all the clippings on the paper towels.
- The collector folds or rolls up the sides of one paper towel with the clippings on it and tips them into the open collection envelope. Do the same with the other paper towel.
- Once clippings are placed in the envelope, the paper towel can be discarded.
- The study staff takes the collection envelope containing the nail clippings.
- Provide the SIF to the caregiver to complete on behalf of the child.

3. Site Post-Collection Instructions for the Study Staff
- Seal the collection envelope.
- Discard any used supplies. The caregiver may keep the nail clippers if desired.
- Collect SIF from the caregiver and retain at the site.

E. Home Collection
1. Home Collection Instructions for the Caregiver
   - Refer to the Toenail (Assisted Collection) Collection Instruction Sheet (CIS).
F. Processing

1. Site Collection
   - Complete **STEP 1: COLLECTION** section of the STF. Mark **STEP 2: RECEIPT** as not applicable.

2. Home Collection
   - Upon receipt of the collection at the site, check the collection envelope against the SIF to ensure that the information is accurate and consistent.
   - Complete **STEP 1: COLLECTION** and **STEP 2: RECEIPT** sections of the STF.

G. Storage

- Store toenail collection envelope as received in the biohazard bag in a labeled storage container.
- Temperature should be ambient. Storage must be in a dry place away from direct sunlight.
- The storage container can be placed on a shelf, such as a filing cabinet, until shipped to the Biorepository.
- Complete **STEP 3: STORAGE** section on 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 ECHO-wide Cohort Data Collection Protocol.

I. Supporting Documents

1. Toenail – Assisted Collection – Collection Instruction Sheet (CIS)
2. Toenail – Specimen Information Form (SIF)
3. Toenail – Specimen Tracking Form (STF)
4. Toenail – Specimen Tracking Form (STF) Completion Instructions