Saliva – Self Collection
Maternal, Paternal, Adolescent, and Middle Childhood (able to self-collect)

Collection, Processing and Storage Protocol
Home or Site Collection

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# Table of Contents

A. Overview .................................................................................................................................................... 3
B. Guidelines .................................................................................................................................................. 3
C. Collection Kit, Supplies and Kit Assembly ............................................................................................. 3
   1. Saliva Self Collection Kit (Fisher BioServices) .................................................................................... 3
   2. Supplies (Site) ........................................................................................................................................ 4
   3. Kit Assembly ........................................................................................................................................... 4
   4. Home Collection: Kit Distribution and Specimen Receipt ...................................................................... 5
D. Site Collection ............................................................................................................................................ 5
   1. Site Pre-Collection Instructions for the Staff ........................................................................................... 5
   2. Site Collection Instructions for the Participant ....................................................................................... 6
   3. Site Post-Collection Instructions for the Staff .......................................................................................... 6
E. Processing .................................................................................................................................................. 6
   1. Site Collection ......................................................................................................................................... 6
   2. Home Collection ................................................................................................................................... 6
F. Storage ....................................................................................................................................................... 6
G. Shipping to Biorepository ........................................................................................................................... 7
H. Supporting Documents ............................................................................................................................... 7
A. Overview

- The Saliva collection procedures apply to mothers, fathers, and children who are able to provide saliva in a tube without assistance. It is recommended that children older than five years use the self-collect method.
- Saliva collection is performed for genetic testing only. It is an acceptable alternate to blood collection.
- Saliva self-collection can occur at home or on site during the participant’s visit.
- If a participant/caregiver chooses to collect the specimen at home, study staff can mail the saliva collection kit, provide it during a site visit, or take it to the participant’s home.
- Once collected, the participant/caregiver can mail the saliva and completed Specimen Information Form (SIF) to the site, bring to the next site visit, or study staff can pick it up from their home.

B. Guidelines

- Saliva specimen is provided in a collector (tube) in this collection method.
- Most participants take between 2 and 5 minutes to deliver a saliva specimen.
- Wait at least 30 minutes after eating, drinking, smoking, or chewing gum before beginning collection of the specimen.
- Do not remove the plastic film from the funnel lid.
- The goal is to collect up to 2.0 mL saliva in the collector provided in the kit. If a cohort plans to collect saliva for their cohort-specific aims, a minimum of 1.0 mL is collected directly into the collector for ECHO-wide Cohort Data Collection Protocol.
- A standard video collection instructions for the OGR-600 can be found at the following link: https://www.youtube.com/watch?v=N5K6LXmasK8#action=share

C. Collection Kit, Supplies and Kit Assembly

1. Saliva Self Collection Kit (Fisher BioServices)
   - Oragene OGR-600 package includes:
     a. Instructions
     b. Collector
     c. Tube cap
   - One (1) biohazard bag
   - One (1) triplet specimen ID labels
2. Supplies (Site)
   - Storage Container/Large envelope
     a. Suggested Container: 5.71 x 5.71 x 4.80 in. box; 4 x 4 grid (holds 16 tubes)
   - Saliva – Self Collection – Collection Instruction Sheet (CIS)
     Note: A user instruction sheet is already in the kit but the CIS includes additional guidelines and mailing instructions for home collections. This user instruction sheet can be discarded, if desired.
   - Saliva – Self Collection – Specimen Information Form (SIF)
   - Saliva – 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.
   - Confirm that the collection kit includes a biohazard bag, triplet specimen ID labels, and the Oragene 600 package including a collector and tube cap.
• Print CIS, SIF and STF.
• Fill out the headers on the SIF and STF.
• Remove the collector from the plastic case.
• There will be three identical labels for each specimen ID. Affix the first label to the collector. Apply the second matching label to the field labeled SPECIMEN LABEL on the STF. Apply 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 participant to prevent misplacement or confusion about the forms/tubes.
• Place the collector back in the package containing the tube cap, and close it.
• Place the SIF and CIS in the biohazard bag.
• Fill out 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 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. In the upper left corner, place a site address label
  c. In the center, place a caregiver address label
• Place the biohazard bag and package prepared in the previous step in the padded envelope.
• Prepare another prepaid return mailer (padded envelope) for the participant/caregiver to send the specimen to the site.
  a. Add appropriate postage
  b. In the upper left corner, place a caregiver address label
  c. In the center, place a site address label
  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 Staff
• Put on a pair of gloves.
• Remove kit contents from the biohazard bag and package.
• Review the contents and CIS with the participant/caregiver to ensure that he/she understands the procedure.
• Provide SIF to the participant/caregiver to complete.
• Show the collection instruction video, if possible: https://www.youtube.com/watch?v=N5K6LXmasK8#action=share

2. Site Collection Instructions for the Participant
   • Follow steps on the Saliva (Self Collection) Collection Instruction Sheet (CIS).
   • Complete the SIF.

3. Site Post-Collection Instructions for the Staff
   • Place the tube in the biohazard bag and seal it.
   • Discard any used supplies.
   • Collect SIF from the participant/caregiver and retain at site.

E. Processing
1. Site Collection
   • Complete STEP 1: COLLECTION section of the STF and mark STEP 2: RECEIPT as not applicable.

2. Home Collection
   • Upon receipt of the collection at the site, complete STEP 1: COLLECTION and STEP 2: RECEIPT sections of the STF.

F. Storage
   • Store saliva placed in the biohazard bag in a labeled storage container.
   • Storage must be in a dry place away from direct sunlight. Temperature should be ambient.
   • The storage container can be placed on a shelf, such as a filing cabinet, until shipped to the Biorepository.
   • Complete the 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.
G. Shipping to Biorepository

This information is available in the Laboratory Manual of the ECHO-wide Cohort Data Collection Protocol.

H. Supporting Documents

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