

Saliva Collection and Storage Procedures

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8.1 Overview

Saliva specimens in the Kenya Breast Health Study are collected from all participants. The Interviewer should instruct and demonstrate to the participant how to collect approximately 2 mL of saliva in the collection tube. Additionally, the Interviewer should complete the blue Saliva Collection Form, recording responses from the participant. The saliva specimens are stored upright and at room temperature in 7x7 cardboard containers.

8.2 Saliva Collection Kits and Labels

The biospecimen Master Kit contains a Saliva Collection Kit (labeled with a blue circle) and a light blue Saliva Collection Form. To facilitate saliva collection, the Oragene- OG-600® Saliva Collection Kit (Exhibit 2- 1) has been pre-labeled with the Master Kit Sample ID. The Saliva Collection Kit contains:

- Manufacturer’s saliva collection instructions;
- Pre-labeled saliva collection tube; and
- Collection tube cap.

NOTE: It is recommended that study staff wear gloves when handling an open collection kit to maintain universal precautions and to prevent contamination of the sample.

Study Staff should double-check that all of the sample IDs on the collection kit items match. Verify that the root Sample ID on the Saliva Collection Kit bag (AKU#####-SV01) and on the Saliva Collection Tube (AKU#####-1101) match the Sample ID on the Master Kit bag. If there are mismatched Sample IDs within the Master Kit, the entire Master Kit and forms within it should be discarded and a new Master Kit and Sample ID should be assigned to the participant.

Exhibit 2-1. Saliva Collection Kit

Oragene•DNA OG-600



8.3 Completing the Saliva Collection Form

The Participant ID (PID) label should already have been placed on the blue Saliva Collection Form (Appendix 8-1) in preparation for collecting biospecimens. If the PID label is missing, place it on the form in the upper left hand corner. Verify that the root Sample ID (AKU#####) on the Saliva Collection Form (AKU#####-SV01) matches the Sample ID on the Saliva Collection Tube (AKU#####-1101).

Confirm that the participant has provided her consent to participate in the study and is willing to provide a saliva sample. If the participant did not initial on the Informed Consent that she agreed to provide a saliva sample, then do not collect the sample. Regardless of whether or not a saliva sample was collected, the Interviewer should complete Items A and B in the shaded Collection Summary box of the Saliva Collection Form. Instructions for completed the saliva forms are in Appendix 8-2.

If the participant has provided consent, the Interviewer should ask questions 1 and 2 in Section 1 of the Saliva Collection Form before the saliva is collected to determine when the specimen should be collected. Participants who have had anything to eat or drink (including water or chewing gum) or have smoked in the last 30 minutes will have to wait until 20 minutes have passed before providing a saliva specimen.

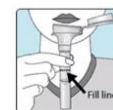
8.4 Procedures for Saliva Sample Collection

The Interviewer and participant will use the following procedures to obtain saliva specimens for the study. A short video of these procedures can be viewed by going to the following website:

<http://www.youtube.com/watch?v=jwXKwPuLx9Q>.

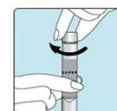
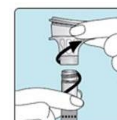
Always use universal precautions including wearing gloves when handling biospecimens.

1. Use the Demonstration Tube to review the saliva collection method with the participant.
 - Tell the participant to spit or drool into the funnel until the amount of liquid saliva reaches above the fill line.



TIP: To increase saliva production, suggest the participant imagine a favorite food or rub outside of cheeks and allow saliva to pool in the mouth.

2. Once the tube is adequately filled, gently tap the upright tube against a hard, flat surface to eliminate any bubbles.
3. Once the amount of liquid saliva (not bubbles) has reached the fill line, take the tube from the participant and hold the tube upright with one hand. Close the funnel lid with the other hand (as shown to the right) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the saliva.
4. Make sure that the lid is closed tightly. Hold the tube upright. Unscrew the funnel from the tube.
5. Use the small cap provided in the Oragene® Kit to close the tube tightly.
6. Shake the capped tube for five seconds. Discard the funnel.



8.5 Storage Procedures

Send the tube to the lab to be stored upright at room temperature in a 7x7 (49 position) cardboard box provided by until it is ready to be shipped to the NCI Biorepository .

8.6 Form Review

Regardless of whether or not a saliva sample was collected, the appropriate questions contained in the shaded Collection Summary Box should be completed.

- Check the form for completeness and legibility.
- Complete any items accidentally left blank.
- If any problems are encountered with the saliva collection or with completing the Saliva Collection Form, bring them to the study manager's attention as soon as possible.