PROCEDURE	Maternal and Infant Buccal Swab Collection	
PREPARED BY	GAPPS Staff	
DATE ADOPTED		
REVIEWED BY	SIGNATURE	REVIEWED DATE

SUMMARY OF CHANGES TO THIS SOP		
Version 1.5		
Safety section added.		
Version 1.6		
Modified for microbiome collection		

PURPOSE

This Standard Operating Procedure (**SOP**) describes a procedure for collection and storage of oral Buccal swabs.

SCOPE

This procedure is intended for the general collection and storage of Buccal swabs. It does not cover shipping, DNA extraction or analysis of these specimens.

AUTHORITY AND RESPONSIBILITY

- 1. The GAPPS Director (or his/her designee) and Laboratory Manager have the authority to establish this procedure.
- 2. The GAPPS Laboratory and the QA monitors are responsible for the implementation of SOP documentation at participating sites.

- The site's Coordinator is responsible for the implementation of this procedure at their site and for ensuring that all appropriate personnel are trained and sign "Acknowledgement of Understanding" document for this SOP.
- 4. All health care providers and technicians who implement this SOP at study sites are responsible for reading and understanding this SOP prior to performing the procedures described.
- 5. All health care providers and technicians are expected to be trained and follow the procedures described in any of the GAPPS SOPs and have their signature on file at the collection site.

Supply Description

Site Supplied:

n/a

Supplied in Kit:

- 1. 2 double-tipped Polyester swabs
- 2. 4 red capped Cryovials, 2 ml, GAPPS labeled

Safety

- 1. Required Training for processing
 - a. Blood borne pathogens
 - b. Standard laboratory practices
- 2. Risks
 - a. Biofluid exposure
- 3. Required safety equipment
 - a. Lab coats/scrubs
 - b. Face shield/safety goggles
 - c. Closed toed shoes
 - d. Gloves

All health care providers and technicians are expected to be trained and follow universal precautions when handling biological or hazardous materials when performing the any procedures described in any of the GAPPS SOPs.

BUCCAL SWAB SPECIMEN COLLECTION

UTILIZE A MATERNAL BUCCAL SWAB KIT FOR MATERNAL COLLECTIONS AND AN INFANT BUCCAL SWAB KIT FOR INFANT COLLECTIONS. THE KITS CONTAIN THE SAME COMPONENTS, BUT THE CODING ON THE TUBES DIFFERS BETWEEN KITS. THE COLLECTION PROCEDURE IS THE SAME FOR BOTH COLLECTIONS.

- 1. Specimen donor should not have consumed any food or beverages 1 hour prior to providing an oral buccal swab specimen.
- 2. Swab the oral cavity of the right cheek up and down 10 times with a double-tipped, sterile BBL™ CultureSwab™ EZ swab.
- 3. Remove the swab and place it back in the tube.
- 4. Repeat with a new Sterile BBL™ CultureSwab™ EZ swab, and swab the mid-portion of the left cheek up and down 10 times.
- 5. Within 15 minutes of receiving samples, the Research Coordinator (RC) should arrange the buccal kit specimen tubes in a micro-centrifuge rack. The tubes are pre-loaded with stabilizing solutions and must be kept up-right when un-capped.

- 6. Uncap the red capped 2 mL tubes labeled "M Cheek DNA" and "M Cheek Cyto". Remove the swabs from one of the EZ swab collection tubes and place one swab in the "M Cheek DNA" tube and one swab in the "M Cheek Cyto" tube.
- 7. Spin the swabs in the tubes for 10 seconds to dislodge any material into the liquid in the tubes (both swabs can be swirled simultaneously if the tubes are left side-by-side in the rack). Remove and discard the swabs and re-cap the tubes.
- 8. Repeat for red capped tubes "M Cheek Bact" and "M Cheek Xtra" with the respective remaining pair of swabs.
- 9. Place the tubes on dry ice or the -80°C freezer within 5 minutes of completing the transfers.
- 10. Immediately record the specimen collection data on lab requisition form.

SPECIMEN STORAGE

- 1. Within 2 hours of collection, buccal swab specimens must be stored at -80° until shipped to the core repository.
- 2. Consult "Shipping SOP" when specimens are ready to be shipped.