

<b>PROCEDURE</b>	<b>Rectal Swab Collection</b>	
<b>PREPARED BY</b>	GAPPS Staff	
<b>DATE ADOPTED</b>		
<b>REVIEWED BY</b>	<b>SIGNATURE</b>	<b>REVIEWED DATE</b>

<b>SUMMARY OF CHANGES TO THIS SOP</b>
<b>Version 1.0</b>
1. Initial protocol implementation

**PURPOSE**

This Standard Operating Procedure (**SOP**) describes a procedure for collection, processing and storage of 2 rectal swab specimens.

**SCOPE**

This procedure covers the collection, and storage of cervical-vaginal and rectal specimens placed immediately in cryo-vials and the collection, immediate processing with stabilizing buffers. It does not cover shipping, testing, Gram staining or any other analysis of the specimens collected.

**Authority and Responsibility for SOP's**

1. The GAPPS Medical 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.
3. 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.

### Limitations of the Procedure

1. Rectal specimen collection and processing must be completed in less than 4 hours.
2. Vaginal swabs may be collected concurrently with the Rectal swab collection using the Vaginal kit and protocol. Cervical swabs may be collected concurrently with the Initial Cervical swab or Cervical swab protocols, depending on visit and participant collection status (i.e., prior Initial Cervical swab collection).
3. After transfer of the collected material on the swabs to the storage cryo-vials (see Specimen Processing) the vials should be frozen at -20°C or -80°C as soon as possible. If not immediately frozen they should be held at 4- 8°C and then transferred to -20°C or -80°C in less than 2 hours.

### Supplies

On Site:  
n/a

Supplied in Kit:

1. 1 double-tipped BBL™ CultureSwab™ EZ Swab
2. 2 GAPPS labeled, yellow capped, 2ml Cryo-vials

### 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.

### Rectal Swab Collection

1. Insert a double-tipped, sterile BBL™ CultureSwab™ EZ swab approximately 1 inch into anal canal and rotate slowly for 10 seconds.
2. Place the swab back in the CultureSwab™ EZ swab tube.
3. Swabs must be frozen within 4 hours after collection.

## **Specimen Processing**

1. Specimens are to be processed as close to collection as possible and no more than 4hrs post collection. The Research Coordinator (RC) should arrange the Rectal kit tubes in a micro-centrifuge rack since the tubes are pre-loaded with stabilizing solutions and must be kept up-right when un-capped.
2. Uncap the **yellow** capped 2mL tubes labeled "Rectal DNA" and "Rectal Bact". Remove the swabs from the double-tipped EZ swab collection tube used for the rectal collection and place one swab in the tube labeled "Rectal DNA" and the other in the tube labeled "Rectal Bact".
3. 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.
4. Place the tubes on dry ice or the -80°C freezer within 5 minutes of completing the transfers. If not immediately frozen they should be held at 4- 8°C and then transferred to -20°C or -80°C in less than 2 hours.
5. Record information on the lab requisition form.

## **Specimen Storage**

1. Freeze as soon as possible at -80°C until shipped to the core repository.
2. Consult "Shipping SOP" when specimens are ready to be shipped.