

PROCEDURE	Cervical-Vaginal Swab Collection	
PREPARED BY	GAPPS Staff	
DATE ADOPTED		
REVIEWED BY	SIGNATURE	REVIEWED DATE

SUMMARY OF CHANGES TO THIS SOP
Version 3.0
1. Specimens must be collected, processed and frozen in less than 2 hours.
2. Protease Inhibitor and RNAlater discontinued.
3. Window to freeze samples extended to less than 4 hour, rather than 2.
Version 3.5
1. Safety section added.

PURPOSE

This Standard Operating Procedure (**SOP**) describes a procedure for collection and storage of cervical-vaginal swab specimens.

SCOPE

This procedure covers the collection, and storage of cervical-vaginal specimens placed immediately in cryo-vial with protease inhibitors. It does not cover shipping, testing or analysis of these specimens.

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. Cervical-vaginal swabs are collections that will only occur when a healthcare provider is performing a genital exam with a speculum for other clinical purposes. Participants are not asked to partake in this specimen collection as an additional procedure.
2. Specimen collection and processing must be completed in less than 4 hours.
3. If possible, Vaginal swabs and Rectal swabs should be collected concurrently using the Vaginal swab kit and Rectal swab kit.

Supplies

On Site:

n/a

Supplied in Kit:

1. 3 Polyester Swabs
2. 3 Cryo-vials

Safety

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

Cervical-Vaginal Swab Collection

1. These specimens are taken at the discretion of the health care provider.
2. Cervical-vaginal specimens are to be collected with the use of a speculum and before vaginal specimens.
3. Before collection of cervical-vaginal specimens, make sure all the listed supplies are opened and within easy reach.
4. While the speculum is still inserted and after clinical procedures have been completed; 3 swabs should be held together in one hand and swabbed simultaneously at the posterior fornix (area where the vagina and cervix meet). Do not collect swabs one after the other as this may cause a collection bias from one swab to the next.
5. The head of all three swabs are immediately placed in the separate GAPPS provided and labeled cryo-vials and the heads are then snapped off to fit in the vials and capped tightly to freeze.
6. **Do Not** use scissors or other devices to remove the head of the swab. Snap the head of the swab off to prevent cross contamination.
7. Swabs must be frozen within 4 hours after collection.
8. The specimen collection data is immediately recorded on lab requisition form.

NOTE: These are cervical-vaginal fluid collections only; do not swab the genital or anal areas with these swabs.

Specimen Storage

1. The 3 specimens are to be frozen at a minimum of -20°C for short-term storage (< 30 days), and preferably at -80°C until shipped to the core repository.
2. Consult "Shipping SOP" when specimens are ready to be shipped.