

<b>PROCEDURE</b>	<b>Vaginal 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 2.0</b> 1. Specimen collection and storage must be completed in less than 2 hours. 2. Removed one swab for freezing.
<b>Version 3.0</b> 1. Slide storage changed to frozen (from ambient).
<b>Version 3.5</b> 1. Safety section added.
<b>Version 3.6</b> 1. Clarified storage conditions.
<b>Version 3.7</b> 1. Added stabilized specimen protocol 2. Removed glass slide as a collection 3. Added self collections

**PURPOSE**

This Standard Operating Procedure (**SOP**) describes a procedure for collection, processing and storage of 10 vaginal swab specimens from pregnant women.

**SCOPE**

This procedure covers the collection, immediate processing, and storage of vaginal specimens in cryo-vials with or without buffer. It does not cover Gram staining of the slide or any analysis of 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. Vaginal collections are taken when a healthcare provider is performing a vaginal or cervical exam (with or without a speculum) or collecting other genital specimens for clinical purposes.
2. Every effort should be taken to acquire specimens without contamination with lubricant. If lubricant is present prior to sampling this should be recorded on the both the paper and e-Lab Requisition forms.
3. Vaginal swabs may also be self administered and then the kit transferred to the care provider or site coordinator for processing.
4. Swab collected in the cryo-vials for freezing should be frozen at -20°C or -80°C as soon as possible. If it is not immediately possible it should be placed immediately in a refrigerator or ice bucket at 4- 8°C and then at -20°C or -80°C in less than 4 hours.

**NOTE:** These are vaginal fluid collections only. Do not swab the genital or anal areas with these swabs.

### **Supplies**

#### On Site:

n/a

#### Supplied in Kit:

1. 5 dbl-tipped BBL™ CultureSwab™ EZ II swabs
2. 8 blue capped Cryo-vials, 2ml GAPPS labeled
3. 2 Green capped Cryo-vials, 2ml GAPPS labeled
4. Visible SOP for self administered collection

### **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.

### **Vaginal Swab Collection**

1. If cervical or cervical-vaginal specimens are to be collected from the participant those specimens should be collected before the vaginal swab specimens.
2. Before collection of vaginal swabs, make sure all the listed supplies are opened and within easy reach.
3. A speculum may or may not be used for a vaginal swab collection and is at the discretion of the healthcare provider.
4. Participants may carry out a self-administered collection using the visual SOP provided in the collection kit.
5. Insert a lubricated speculum. When sampling, avoid the vaginal area where there has been contact with the speculum.
6. If a speculum is used for cervical exams, partially withdraw the speculum then make a full circular swab of the vagina with the swabs.
7. Collect the vaginal midpoint specimen using one sterile dbl-tipped BBL™ CultureSwab™ EZ swab to sample an area on the vaginal sidewall about halfway between the introitus and the cervix. Use caution to avoid contamination by the cervical mucus.
8. Gently press the swab into the vaginal sidewall and rotate the swab four times to thoroughly coat the swab.
9. Remove the swab and place it back in the tube.
10. Repeat with a new Sterile dbl-tipped BBL™ CultureSwab™ EZ swab for each swab required.
11. Within 15 minutes of receiving samples, the Research Coordinator (RC) should arrange the vaginal kit tubes in a microcentrifuge rack. The tubes are pre-loaded with stabilizing solutions and must be kept up-right when un-capped.
12. Uncap the blue capped 2 mL tubes labeled “Vaginal DNA 1” and “Vaginal DNA 2”. Remove the swabs from one of the EZ swab collection tubes and place one swab in the tube labeled “Vaginal DNA 1” and the other in the tube labeled “Vaginal DNA 2”.
13. 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.
14. Repeat for blue capped tubes labeled “Vaginal RNA 1”, “Vaginal RNA 2”, “Vaginal Lipid”, “Vaginal Cyto”, “Vaginal Bact”, and “Vaginal Xtra” with respective pairs of swabs.
15. With the remaining GAPPS stickered double-tipped swabs, place the head of the first swab in an empty GAPPS labeled green capped 2ml cryo-vial (sample code pattern xx-xxxxxxx) and snap off the plastic shaft to make sure polyester head fits in the vial and is easily capped. Do

not use scissors to cut head off of swab. Repeat with the 2nd swab and green capped GAPPS tube.

16. Place the tubes on dry ice or the -80°C freezer within 5 minutes of completing the transfers.
17. Record information on the lab requisition form.
18. If a speculum is not used: if a healthcare provider chooses to not use a speculum, the swabs can be collected from a blind vaginal insertion following the same steps (1-11) for processing and storage.

### **Specimen Storage**

1. Freeze as soon as possible at -20°C (< 30 days), and preferably at -80°C until shipped to the core repository.
2. Consult "Shipping SOP" when specimens are ready to be shipped.