

Specimen Collection – Vaginal

SAMPLING PROCEDURE FOR VAGINAL INTROITUS, POSTERIOR FORNIX AND MID-VAGINA AREAS

Aseptic technique will be used for collection of all specimens (See appendix1).

1. Spread labia to visualize vaginal introitus immediately posterior to hymenal ring/tissue.
2. Repeat vaginal pH determination of vaginal introitus immediately prior to sampling (each and every time sampling is performed) – see appendix2.
3. Proceed with obtaining vaginal introitus specimen: place one Sterile Catch-AllTM Sample Collection Swab (Epicentre Biotechnologies, Madison WI) at the vaginal introitus posterior to the hymenal ring/tissue and rotate swab along the lumen with a circular motion five times. Immediately after swabbing, the swab is swirled in 750 µL of MoBio buffer in the labeled specimen collection tube. The swab should be pressed against the tube wall multiple times for 20 seconds to ensure transfer of bacteria from swab to solution.
4. Insert pre-warmed speculum. It is preferable that the speculum be used without lubricant or water. If, in the opinion of the clinician, it is not feasible to insert the dry speculum without causing extreme discomfort to the subject, the exterior of the tip of the speculum may be moistened with tap water, taking care to use as little water as possible to avoid diluting the vaginal fluids being collected and to avoid any impact on pH measurement.
5. Visualize cervix and posterior fornix.
6. Determine pH of posterior fornix immediately prior to sampling (each and every time sampling is performed).
7. Proceed with obtaining posterior fornix specimen: place one Sterile Catch-AllTM Sample Collection Swab (Epicentre Biotechnologies, Madison WI) in the posterior fornix and rotate the swab along the lumen with a circular motion five times. Immediately after swabbing, the swab is swirled in 750 µL of MoBio buffer in an appropriately labeled specimen collection tube. The

- swab should be pressed against the tube wall multiple times for 20 seconds to ensure transfer of bacteria from swab to solution.
8. After obtaining posterior fornix specimen, proceed with collecting vaginal midpoint specimen using one Sterile Catch-All™ Sample Collection Swab (Epicentre Biotechnologies, Madison WI) to gently rub the mid-vaginal wall. Immediately after swabbing, the swab is swirled in 750 µL of MoBio buffer in an appropriately labeled specimen collection tube. The swab should be pressed against the tube wall multiple times for 20 seconds to ensure transfer of bacteria from swab to solution.
 9. Store all the tubes on ice and deliver to the clinical laboratory within approximately two hours.
 10. Follow CMMR Shipping Guidelines.

Avoid sampling of the vaginal area where there has been contact with the speculum.

Vaginal introitus, Posterior fornix and Mid-vagina areas are sampled and stored separately and labeled with the appropriate body site-specific, pre-printed clinic label.

Appendix 1

ASEPTIC TECHNIQUE

The collection and processing of all samples will be done utilizing Aseptic Technique. All collection materials will be cleaned and sterile per SOP or confirmed sterile upon purchase and use.

The following are recommendations for Aseptic Technique. All site SOPs for Aseptic Technique will be applied where applicable.

Collection of Subject Specimens:

1. Follow all safety guidelines of your local safety committee and/or institutional policies for handling biological specimens. Gloves, safety glasses or face shield, and a lab coat must be worn at all times when aliquoting sera. Observe Universal Precautions guidelines when collecting any biological specimens to include at the least wearing of gloves.
2. When handling the specimen collection tubes during sampling, care should be taken to maintain a cleanly gloved hand, so as to not contaminate the outer or inner tube areas.
3. Clean disposable gloves are recommended for all specimen collections.
 - a. When collecting specimens from the skin sites and the nasal cavity, the four skin sites should be sampled before the nares. The investigator collecting the samples may wear a single pair of gloves to sample all of the sites, provided that the hand used to stretch the skin around the sampling areas does not contact the actual sampling areas. If contact occurs, the gloves may be contaminated and should be changed before sampling the next site.

- b. Study personnel may sample the various sites within a subject's oral cavity without changing gloves between collections. Similarly, when collecting the three vaginal specimens from a subject, it is not necessary to change gloves between collections.

Appendix 2

DETERMINE VAGINAL pH

VAGINAL INTROITUS:

1. Spread labia to visualize vaginal introitus immediately posterior to hymenal ring/tissue.
2. Gently apply the microelectrode pH meter (Oakton, model pH Spear) to the vaginal mucosa at the center most point of the vaginal introitus.
3. Take at least two separate recordings (digital recordings of pH), and derive a mean pH. Record the pH readings. T

POSTERIOR FORNIX

1. Insert prewarmed speculum (either Medium Pederson or Large Pederson). It is preferable that the speculum be used without lubricant or water. If, in the opinion of the clinician, it is not feasible to insert the dry speculum without causing extreme discomfort to the subject, the exterior of the tip of the speculum may be moistened with tap water, taking care to use as little water as possible to avoid any impact on pH measurement.
2. Visualize cervix and posterior fornix.
3. With complete visualization, gently apply the microelectrode pH meter to the vaginal mucosa at the highest point of the posterior fornix.
4. Take at least two separate recordings (digital recordings of pH), and determine a mean pH.

