# SUBJECT: Genital and Varied Specimen Collection Guide – for APTIMA and ThinPrep

1. **Scope:**

This policy applies to all personnel involved in the collection of specimens for Genital pathogen testing.

1. **Purpose:**

To outline the collection procedure and the use of supplies for urine specimens, genital swab specimens, and specimens collected in thin prep media for the purpose of genital pathogen testing.

1. **Supplies:**

 3.1 APTIMA Urine Specimen Collection Kit for Male and Female Urine Specimens

3.2 APTIMA Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens

3.3 APTIMA Multitest Swab Specimen Collection Kit

3.4 APTIMA Unisex Specimen Collection and Transport Kits

 3.5 Plastic, preservative-free, urine collection cup

3.6 Thin Prep collection devices and preservative media

1. **Procedure:**

 4.1 Specimen Collection- Urine

4.11 Instruct patient not to urinate for at least one hour prior to specimen collection.

4.12 Patient should collect the **first** 20-30 ml of urine (First part of the stream).

4.13 Pour a minimum of 2 mLs urine into an APTIMA GenProbe urine collection (yellow) transport vial. Label specimen with appropriate label. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube.

4.14 Urine specimens must be transferred into the APTIMA transport tube within 24 hrs. of collection.

4.15 Specimens are stable 30 days at 2°-30°C when preserved.

 4.2 Specimen Collection- Endocervical Swab

4.21 Remove excess mucous from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the packing with red printing). **Discard the cleaning swab**.

 **Note: DO NOT USE THE LARGE-TIPPED CLEANING SWAB FOR SPECIMEN COLLECTION.**

4.22 Insert the specimen collection swab (blue shaft swab in the package with the green printing) into the endocervical canal. Gently rotate the swab for 10 to 30 seconds to ensure adequate sampling.

4.23 Withdraw the swab carefully; avoid any contact with the vaginal mucosa.

4.24 Verify that all Swab Transport buffer is at the bottom of the tube. If necessary, tap or shake the solution down to the bottom of the tube.

4.25 Unscrew the cap of the transport tube. Place the specimen collection swab (blue shaft swab) into transport tube.

4.26 Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft.

4.27 Replace the cap securely; making sure that the swab fits into the cap. Screw on the cap until it clicks into place.

 4.28 Label transport tube with appropriate label containing name, DOB, and date/time of collection.

4.29 Specimen stable 60 days when stored at 2 to 300 C.

4.3 Specimen Collection- Male Urethral Swab

4.31 Instruct patient not to urinate for at least one hour prior to specimen collection.

**Note: Discard the cleaning swab for male collections. DO NOT USE THE LARGE-TIPPED CLEANING SWAB FOR SPECIMEN COLLECTION.**

4.32 Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra. Gently rotate for 2-3 seconds in the urethra to ensure adequate sampling.

4.33 Verify that all Swab Transport buffer is at the bottom of the tube. If necessary, tap or shake the solution down to the bottom of the tube.

4.34 Unscrew the cap of the transport tube. Place the specimen collection swab (blue shaft swab) into transport tube.

4.25 Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft.

4.36 Replace the cap securely; making sure that the swab fits into the cap. Screw on the cap until it clicks into place.

4.37 Label transport tube with appropriate label including patient name, DOB, and date/time of collection.

4.38. Specimens stable 60 days when stored at 2 to 300C.

 4.4 Specimen Collection – Vaginal / Penile Meatal / Lesion / Rectal /Throat

 4.41 Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.

4.42 Hold swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do Not hold the swab shaft below the score line.

4.43 See specific site collection instructions below

4.43.1 **Vaginal** – carefully insert the swab into the vagina 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.

4.43.2 **Penile Meatal** – roll the swab on the tip of the penis, outside the opening of the penis (hole through which urine is passed). It is not necessary to put the swab inside the opening of the penis. Make sure to roll the swab all the way around the opening of the penis to get the best sample. Ensure the swab does not touch any other area of the skin.

4.43.3 **Lesion** – Do NOT use disinfectants or cleaners on the lesion before the specimen is collected. If needed, expose the base of the lesion to access fluid. Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.

4.43.4 **Rectal** – carefully insert the swab into the rectum about 1-2 inches (3-5 cm) past the anal margin and **gently rotate the swab clockwise for 5 to 10 seconds**. Withdraw the swab without touching the skin.

4.43.5 **Throat** – carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.

 4.44 While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.

 4.45 Immediately place swab into the transport tube so that the score line is at the top of the tube.

 4.46 Carefully break the swab shaft at the score line against the side of the tube.

 4.47 Discard the top portion of the swab shaft.

 4.48 Tightly screw the cap onto the tube.

 4.49 Specimen stability varies. See testing specific formularies.

 4.5 Specimen Collection- Thin Prep specimens using PAPETTE device

4.51 Place patient in lithotomy position, expose cervix using a vaginal speculum moistened with warm water.

4.52 Contact the cervix with the PAPETTE and insert the central bristles into the cervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Do not force the shorter bristles into the cervical os to prevent unintended separation of the brush from the handle.

4.53 While maintaining gentle pressure in the direction of the cervix, rotate the brush 5 times in either direction.

4.54 Rinse the brush into the PreservCyt solution for use with the ThinPrep Pap Test by pushing the brush into the bottom of the vial 10 times, forcing the bristles apart. Swirl the brush vigorously to further release material. Discard the collection device.

4.55 Tighten the PreservCyt vial cap so that the torque line on the cap passes the torque line on the vial.

4.56 Label ThinPrep with appropriate label including patient name, DOB, date/time of collection.

4.6 Specimen Collection- Thin Prep specimens using Medscand Sample Collection Kit

4.61 Place patient in lithotomy position, expose cervix using a vaginal speculum moistened with warm water.

4.62 To collect from exocervix, select contoured end of plastic spatula and rotate it 3600 around the entire exocervix while maintaining tight contact with exocervical surface. Remove spatula.

4.63 Rinse contoured end of plastic spatula in a vial of PreservCyt Solution by swirling vigorously 10 times. Discard plastic spatula. Place cap on vial.

4.64 Insert CytobrushPlus GT device into the endocervix until only the bottom-most bristles are exposed. Slowly rotate ¼ to ½ turn in one direction. Remove device. Do NOT over-rotate. Additional rotating may cause bleeding and contaminate specimen.

4.65 Rinse the CytobrushPlus GT device in the same PreservCyt solution used with plastic spatula in step 4.53 by rotating the device in the solution 10 times while pushing it against the wall of the vial. Swirl the device vigorously to further release material. Discard device.

4.66 Tighten the PreservCyt vial cap so that the torque line on the cap passes the torque line on the vial.

4.67 Label specimen appropriately including patient name, DOB, and date/time of collection.

**5.0 Procedure Notes:**

5.2 For complete instructions and illustrations, refer to individual package inserts.

**6.0 References:**

HOLOGIC APTIMA Urine Specimen Collection Kit for Male and Female Urine Specimens package insert

HOLOGIC APTIMA Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens package insert

HOLOGIC APTIMA Multitest Swab Specimen Collection Kit package insert

HOLOGIC APTIMA Specimen Transfer Kit package insert

 Papette collection device for use with Thin Prep Pap Test package insert

 Medscand Sample Collection kit package insert.

**Policy Review**: Michele R. Homan MLT/ASCP

**Date:**  4/29/24

**Policy Approval:** Dr. Patrick Feasel M.D.

 Laboratory Medical Director

**Date:**  5/7/24