

**Specimen Collection Instructions of clinician and patient self-collected vaginal swabs, clinician collected rectal and throat swabs for *N. gonorrhoeae*, and *C. trachomatis* testing using HOLOGIC APTIMA® Multitest Swab Collection Kit**

**I. Collection kit**

- A. Collection kit for clinician & patient self-collected vaginal, clinician collected rectal and throat specimens (orange-labeled tube). This is an IATA Category B.
- B. Check the expiration date. Do not use an expired collection kit.
- C. Verify the patient's identity at the time of collection. Best practice is to ask patient to spell their first and last name.

**II. Patient preparation and sample collection:**

- A. Ask the patient to read the collection instructions.
- B. If all the instructions are understood, provide the patient with the collection kit.
- C. Do not touch the soft tip or lay the swab down at any time during the collection. If the swab tip is touched or dropped, start with a new kit.
- D. Peel open the swab package. Hold the swab between your thumb and forefinger covering the scored line in the middle of the shaft to remove the swab from the package
- E. Carefully insert the swab into the vagina about 2 inches past the introitus, and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina and absorbs the moisture.
- F. Remove the swab without touching the skin or other surfaces and place in transport tube (See V)

Refer to Hologic – Instructions for Obtaining Patient-Collected Aptima Vaginal Swab Specimens, at the end of this document.

**III. Throat Swab (female and male)**

- A. Use a tongue blade to hold down the patient's tongue. Look at the back of the throat and tonsils for inflammation or exudate.
- B. Insert the specimen collection swab (orange shaft swab) and, carefully but firmly, rub the swab over the inflamed areas. If there is no inflammation or exudate, rub the swab over the tonsils and posterior pharynx.
- C. Do not touch the cheeks, teeth or gums with the swab.
- D. Carefully remove the swab and place in transport tube (See V)
- E. Do not let the swab touch the skin or other surfaces.

**IV. Rectal Swab (male and female)**

- A. Insert the specimen collection swab (orange shaft swab) into the rectum

- B. Swab the anal crypts just inside the anal ring. Rotate the swab for 2 to 3 seconds.
- C. Carefully remove the swab and place in transport tube (See V).
- D. Do not let the swab touch the skin or other surfaces
- E. Avoid fecal contamination as much as possible during the collection. If the swab is grossly contaminated with fecal material, discard it, and start with a new kit to collect another specimen.

#### **V. Transport Tube**

- A. Remove the cap from the swab specimen transport tube. **Do not pour off the liquid preservative contents from the tube.** Immediately place the specimen collection swab into the transport tube.
- B. Carefully break the swab shaft against the side of the tube at the scored line, using care to avoid splashing of the liquid. Discard the top portion of the swab shaft, leaving the tip of the swab in the tube.
- C. Screw the cap on the transport tube as evenly and tightly as possible. Tape or Para-film® around the cap, but **DO NOT** put tape over the top of the cap.
- D.

#### **VI. Labeling**

- A. Label the transport tube with the complete patient's name and at least 1 unique identifier (For example: specimen number, date of birth, medical record number, etc.)
- B. Enter the required information on the test requisition form. The patient's name and unique identifier on the form must be entered **exactly** the same as the information on the tube.
- C. If there are multiple specimens from the same patient, please label the specimen tubes with the source also. The lab may be unable to determine the specimen source if not identified on the tube.
- D. If there are multiple specimens from the same patient, use a separate test requisition and collection kit for each specimen.

#### **VII. Packaging and Shipping:**

- A. Specimens should be sent to the lab as soon as possible after collection.
- B. Insert the specimen and absorbent pad into the small plastic bag provided. Make sure it is sealed. Place in the large plastic bag with the Biohazard symbol (Bio-Bag).
- C. Place the completed test requisition in the outside pocket of the Bio-Bag. Seal the bag.
- D. Close the box and secure with sealing tape on both sides of the flap.
- E. Attach the completed address label with the UN3733 label included in kit.
- F. Send to the Saginaw County Health Department laboratory as soon as possible (e.g. courier or United Parcel Service (UPS) etc.).
- G. The specimen will not be tested if:
  - 1. The specimen container is received leaking.
  - 2. The specimen is not properly labeled, or the test requisition not completed.
  - 3. The specimen label does not match the test requisition.
  - 4. The collection device is expired.
  - 5. The specimen was collected more than 60 days prior to receipt.
  - 6. Specimen is collected with the wrong collection device.

VIII. Packaging and shipping are the responsibility of the shipper. Please be sure it is in compliance with shipping regulations.



Chlamydia & Gonorrhea-Amplified Test-Mulittest Swab

Instructions for Obtaining Patient-Collected Aptima Vaginal Swab Specimens

**For *in vitro* diagnostic use.**

**NOTE:** *If you have any questions about this procedure, please ask your doctor, nurse or care-provider.*

Wash your hands before starting.

In the privacy of the examination room or restroom, you will need to undress from the waist down. You will need to comfortably position yourself to maintain balance during the collection procedure.

Open kit package and set the tube aside before beginning instructions.

**WARNING:** *If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internal*

1. Partially peel open the swab package as shown in Diagram 1. 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, request a n Aptima Vaginal Swab Specimen Collection Kit.*
2. Hold the swab in your hand as shown in Diagram 2, 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.*
3. Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening the vagina (as shown in Diagram 3) and gently rotate the swab for 10 to 30 second Make sure the swab touches the walls of the vagina so that moisture is absorbed b the swab and then withdraw the swab without touching the skin.
4. While holding the swab in the same hand, unscrew the cap from the tube as show Diagram 4. *Do not spill contents of the tube. Note: If the tube contents are spilled, discard and replace with a new Aptima Vaginal Swab transport tube.*
5. Immediately place the swab into the transport tube so that the score line is at the to the tube as shown in Diagram 5.
6. Carefully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.
7. Immediately discard the top portion of the swab shaft as shown in Diagram 7.
8. Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your doctor, nurse or care-provider.



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## SELF-COLLECTED VAGINAL SWAB SPECIMEN PATIENT INFORMATION SHEET

9. A self-collected vaginal swab is one way to test for Chlamydia trachomatis and Neisseria gonorrhoeae infection. Other options are available. If you have questions about the self-collected vaginal swab, other sample collection options, or about STDs, consult your doctor, nurse or care-provider.
10. Vaginal swab self-collection is an option in healthcare facilities if you agree to perform the procedure. Counseling from your doctor, nurse and care-provider is available for the self-collection procedure.
11. Carefully read the vaginal swab self-collection instructions on the reverse side. If you feel you can perform this self-collection procedure and wish to use this method of testing for STDs, inform your doctor, nurse or care-provider.

### IMPORTANT INFORMATION TO CONSIDER

12. IF YOU ARE PREGNANT, PLEASE INFORM YOUR DOCTOR, NURSE OR CARE-PROVIDER.
13. Before you collect a vaginal swab specimen, inform your doctor, nurse or care-provider if you have:
  - recent pelvic pain
  - pain with sexual intercourse
  - unusual vaginal discharge or bad odor

These symptoms can be due to pelvic inflammatory disease (PID). Prompt diagnosis and treatment of PID can help prevent infertility and ectopic pregnancy associated with PID.

14. Do not take this collection kit or your self-collected vaginal specimen home or out of the clinic.



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