

Instructions for Using the Aptima® Multitest Swab Specimen Collection Kit for Patient-Collected Specimens

PATIENT INFORMATION REGARDING SELF-COLLECTED SPECIMENS

- A self-collected swab is one way to test for sexually transmitted infections (STIs). Other options are available. If you have questions about the self-collected swab, other sample collection options, or about STIs, consult your health care provider.
- Self-collection is an option in clinical settings if you agree to perform the procedure. Counseling from your health-care provider is available for the self-collection procedure.
- Carefully read the swab self-collection instructions below. If you feel you can perform this self-collection procedure and wish to use this method of testing for STIs, inform your health-care provider.
- **Do not take the collection kit or your self-collected specimen out of the clinic.**
- Some self-collected specimen types are not available with all assays. Refer to the appropriate assay package insert for appropriate specimen types.

GENERAL INSTRUCTIONS FOR ALL COLLECTION METHODS

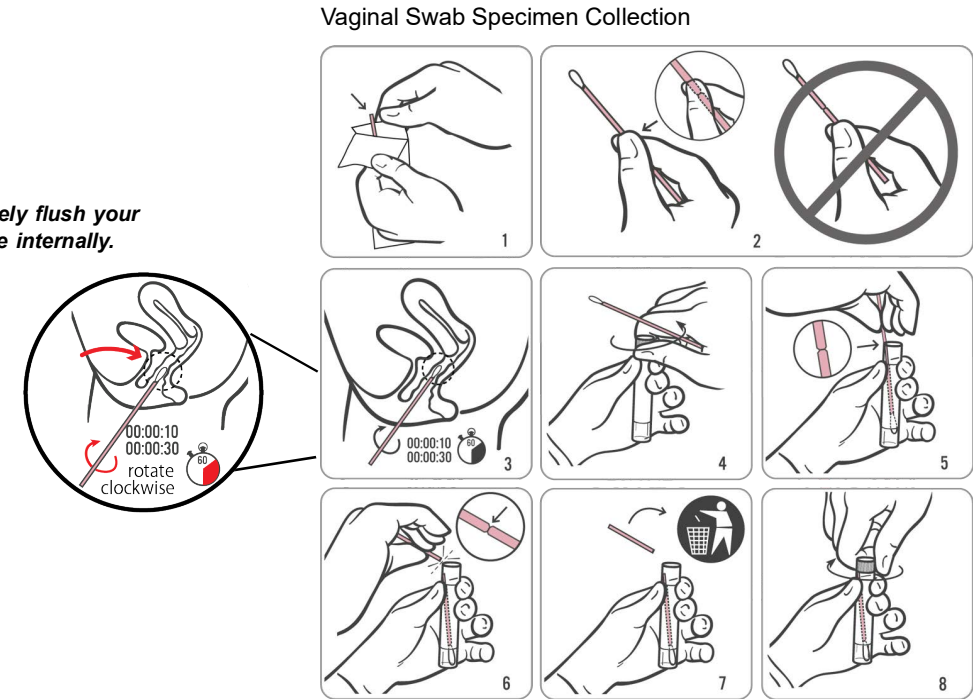
Carefully follow procedures for reliable results. If you have any questions about any procedure, ask your health-care provider.

1. Wash your hands before starting.
2. In the privacy of the examination room or restroom, you will need to undress, as necessary. You will need to comfortably position yourself to maintain balance during the collection procedure.
3. Open kit package. Remove the swab and the tube. Set the tube aside before beginning instructions below to collect the specimen or specimens requested by your health-care provider.

WARNING: If at any time 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 health-care provider if irritation develops. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit. Do not take internally.

VAGINAL SWAB SPECIMEN COLLECTION

1. **Before proceeding, read the patient information and general instructions above.**
2. 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 new Aptima Multitest Swab Specimen Collection Kit.
3. 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 (black line).
Do not hold the swab shaft below the score line (black line).
4. Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening of the vagina (as shown in Diagram 3) and **gently rotate the swab clockwise** 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.
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4.
Do not spill the contents of the tube. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.
6. Immediately place the swab into the transport tube so that the score line (black line) is at the top of the tube as shown in Diagram 5.
7. Carefully break the swab shaft at the score line (black line) against the side of the tube as shown in Diagram 6.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 7.
9. Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.

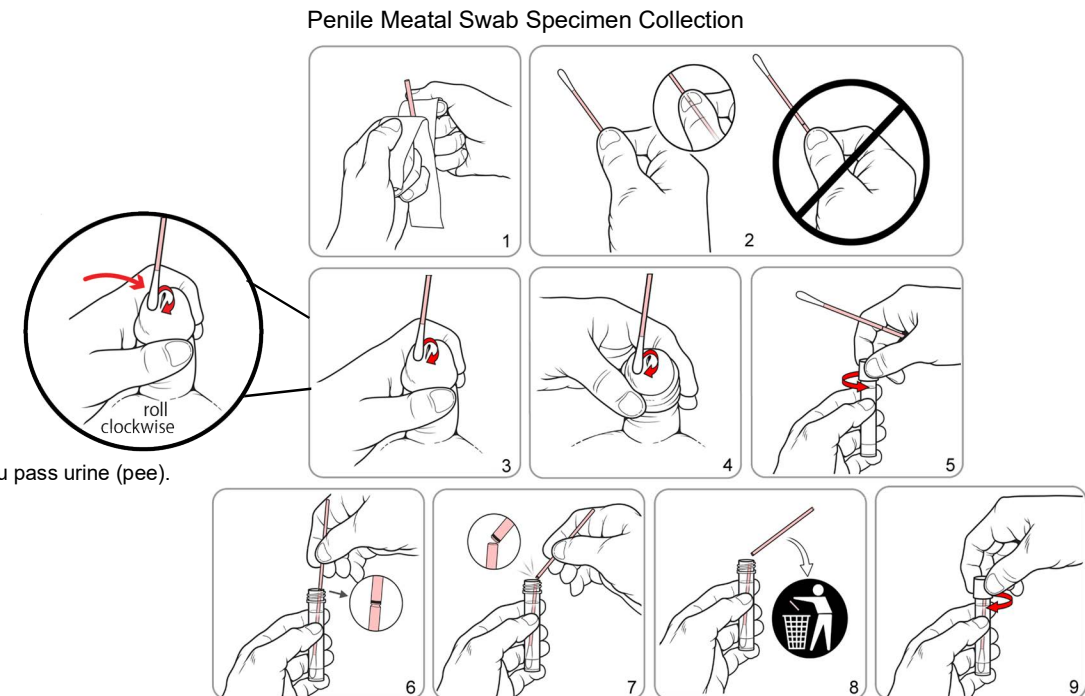


Important Information to Consider

- IF YOU ARE PREGNANT, PLEASE INFORM YOUR HEALTH-CARE PROVIDER.
 - Before you collect a vaginal swab specimen, inform your health-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.*

PENILE MEATAL SWAB SPECIMEN COLLECTION

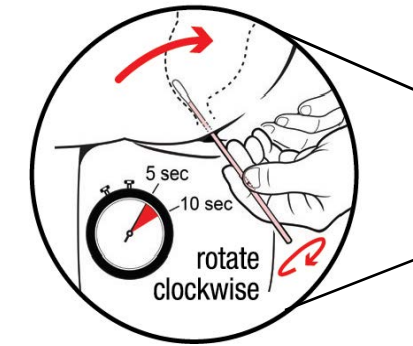
1. **Before proceeding, read the patient information and general instructions above.**
2. Partially peel open the swab package as shown in Diagram 1. Remove the swab.
Do not touch the soft tip or lay the swab down.
If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new Aptima Multitest Swab Specimen Collection Kit.
3. 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 (black line).
Do not hold the swab shaft below the score line (black line).
4. See Diagram 3 if you are circumcised (no foreskin) or Diagram 4 if you are not circumcised. Uncircumcised men will have to roll the foreskin down before starting collection. Hold the penis with your free hand (hand with no swab). Using your other hand (with the swab), **roll the swab clockwise** just at the tip or outside the opening to the penis through which you pass urine (pee). Be sure to roll the swab completely around the opening to get the best sample. It is not necessary to put the swab deep inside the opening of the penis.
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 5.
Do not spill the contents of the tube. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.
6. Immediately place the swab into the transport tube so that the score line (black line) is at the top of the tube as shown in Diagram 6.
7. Carefully break the swab shaft at the score line (black line) against the side of the tube as shown in Diagram 7.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 8.
9. Tightly screw the cap onto the tube as shown in Diagram 9. Return the tube as instructed by your health-care provider.



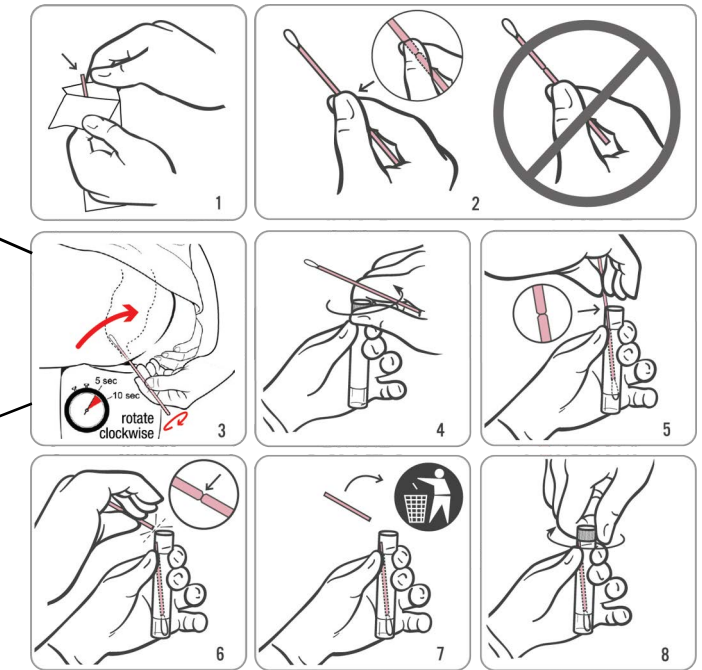
Instructions for Using the Aptima® Multitest Swab Specimen Collection Kit for Patient-Collected Specimens

RECTAL SWAB SPECIMEN COLLECTION

1. **Before proceeding, read the patient information and general instructions on page 1.**
2. 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 new Aptima Multitest Swab Specimen Collection Kit.
3. Hold the swab 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.
4. Carefully insert the swab into your rectum about 1-2 inches (3-5 cm) past the anal margin (the outside of the anus) and **gently rotate the swab clockwise** for 5 to 10 seconds as shown in Diagram 3. Withdraw the swab without touching your skin.
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4. 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.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube as shown in Diagram 5.
7. Carefully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 7.
9. Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.



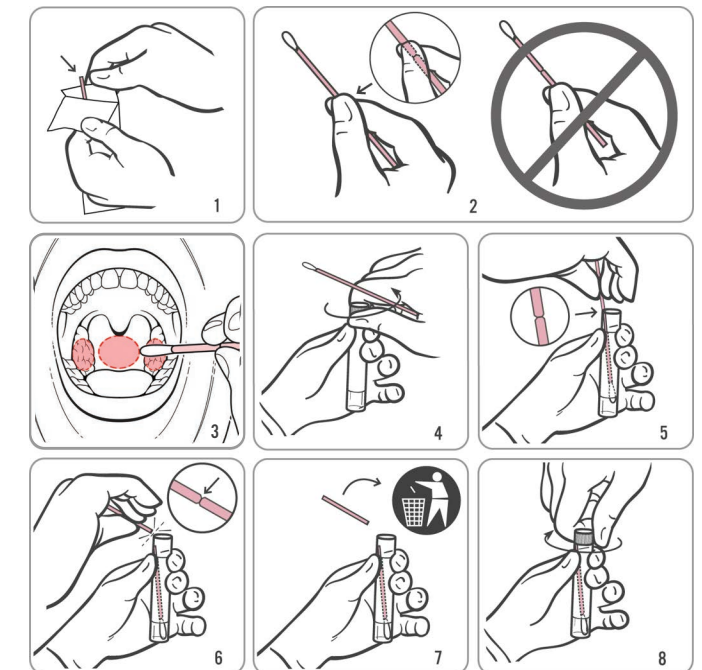
Rectal Swab Specimen Collection




THROAT SWAB SPECIMEN COLLECTION

1. **Before proceeding, read the patient information and general instructions on page 1.**
2. 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 new Aptima Multitest Swab Specimen Collection Kit.
3. Hold the swab 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.
4. Carefully insert the swab into your mouth as shown in Diagram 3, ensuring contact with bilateral tonsils (the tonsils on both sides of your mouth, unless your tonsils have been removed) and the back of your throat, then withdraw the swab without touching the inside of your cheeks or tongue.
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4. 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.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube as shown in Diagram 5.
7. Carefully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 7.
9. Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.

Throat Swab Specimen Collection



Contact Information and Revision History


Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA




Hologic BV
Da Vinciiaan 5
1930 Zaventem
Belgium

Australian Sponsor Address:
Hologic (Australia & New Zealand) Pty Ltd
Macquarie Park NSW 2113

For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.
In case of serious incident, please notify the Manufacturer and Competent Authority in your region.
Hologic, Aptima and associated logos are trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks are the property of their respective owners.
This product may be covered by one or more U.S. patents identified at www.hologic.com/patents.
©2017-2022 Hologic, Inc. All rights reserved.
AW-26254-001 Rev.001
2022-01

Revision History	Date	Description
AW-26254-001 Rev. 001	January 2022	<ul style="list-style-type: none"> Created Aptima Multitest Swab Specimen Collection Kit for Patient-Collected Specimens IFU AW-26254-001 Rev.001 based on AW-16968 Rev. 005 for regulatory compliance with IVDR Updated contact information including: EC Rep, Australian Rep information, and technical support