

Aptima® Multitest Swab Specimen Collection Kit

IVD

Intended Use

The Aptima Multitest Swab Specimen Collection Kit is for use with Aptima assays. The Aptima Multitest Swab Specimen Collection Kit is intended to be used for clinician and patient collection of vaginal swab specimens, rectal swab specimens, and throat swab specimens, and patient collection of penile meatal swab specimens. The Aptima Multitest Swab Specimen Collection Kit may also be used by a clinician to collect specimens from lesions, such as those suspected herpes simplex virus (HSV) infections.

Refer to the appropriate assay package insert for appropriate specimen types. Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection Kit has not been evaluated for home use.

Materials Provided

50 Multitest Swab Specimen Collection Kits (Cat. No. PRD-03546)

Each kit contains:

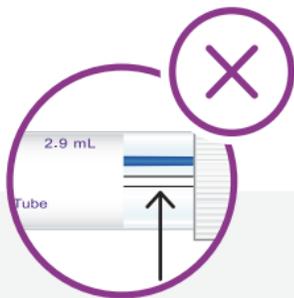
Component	Quantity	Description
Swab	1	Individually wrapped, sterile swab
Transport tube	1	Tube containing Specimen Transport Medium (STM), 2.9 mL
<i>Patient collection instructions for vaginal swab, penile meatal swab, rectal swab, and throat swab specimens</i>	1 package	Pack of patient collection instructions for vaginal swab, penile meatal swab, rectal swab, and throat swab specimens

Warnings and Precautions

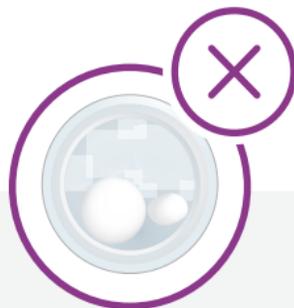
Aptima Unisex Swab Specimen collection



The **white** swab is a cleaning swab and should not be added here.
The **blue** swab is the only swab that should be sent to the lab.



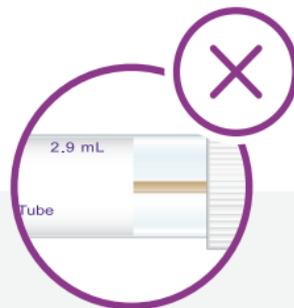
White swab
Reject



2 swabs
Reject



No swab
Reject



Wooden swab
Reject



Aptima[®]

Specimen collection and processing guide

Aptima Multitest Swab Specimen processing guide

Accept

After sample collection, immediately hold swab in the transport tube so the black score line is at top of the tube.



Align the score line with the top edge of the tube and carefully break swab shaft. Visually inspect to confirm the swab is broken at score line.



Swab will drop to bottom of the vial. Screw cap on tightly and send to lab for processing.



Reject

DO NOT break above score line.



DO NOT cut or fold swab in half.



DO NOT use wooden or any other swabs.



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 healthcare facilities 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.**

GENERAL INSTRUCTIONS FOR ALL COLLECTION METHODS

Carefully follow procedures for reliable results. If you have any questions about any procedure, please 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.

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.

RECTAL 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 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 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.




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

U.S. and international contact information:
Customer Support: +1 844 Hologic (+1 844 465 6442)
customersupport@hologic.com
Technical Support: +1 888 484 4747
molecularsupport@hologic.com


EC REP
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

For more contact information visit www.hologic.com.

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- Self-collection is an option in healthcare facilities 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.**

GENERAL INSTRUCTIONS FOR ALL COLLECTION METHODS

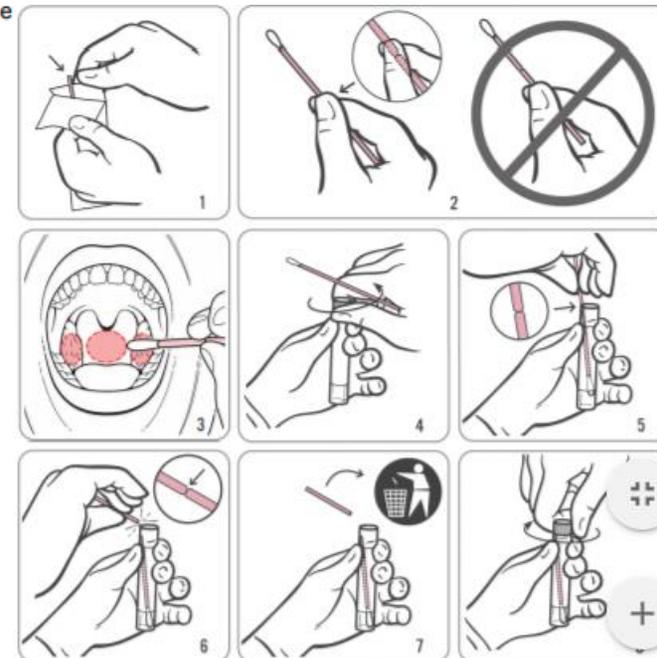
Carefully follow procedures for reliable results. If you have any questions about any procedure, please ask your health-care provider.

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.

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.

THROAT 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 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.



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

U.S. and international contact information:

Customer Support: +1 844 Hologic (+1 844 465 6442)
customersupport@hologic.com
Technical Support: +1 888 484 4747
molecularsupport@hologic.com

For more contact information visit www.hologic.com.

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Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands