

REV AUTHORED BY GRACE UYEKI	DATE 10/13/21	 	
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PROPRIETARY: This document contains proprietary data of Hologic, Inc. No disclosure, reproduction or use of any part thereof may be made except by written permission from Hologic.	TITLE APTIMA MULTITEST SWAB SPECIMEN COLLECTION KIT, CLINICIAN-COLLECTED, GLOBAL, IVD	DOCUMENT NUMBER AW-14413-001	REV 011
REV. RELEASE DATE: 12/22/2021		SIZE A	SHEET 1 OF 1

Aptima® Multitest Swab Specimen Collection Kit

IVD

Intended Use

The Aptima® Multitest Swab Specimen Collection Kit is intended to be used for collection of the following swab specimen types: vaginal, rectal, throat, penile meatal, and lesions. 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.

The Aptima Multitest Swab Specimen Collection Kit for Multitest Swab Specimens is also intended for use with other clinical specimen material for processing, extraction, and analysis with other Hologic products as specified in their labeling.

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

- A. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- B. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- C. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- E. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Multitest Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results.
- F. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- G. Do not use the kit after its expiration date to collect specimens.

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

Multitest Swab Specimen Performance

Assay performance characteristics using the Multitest swab specimens are provided in the appropriate Aptima assay package insert. The Aptima assay package inserts may be referenced online at www.hologic.com. The performance of the patient-collected vaginal swab specimen, patient-collected penile meatal swab specimen, rectal swab specimen, and throat swab specimen, has not been established for all Aptima assays.

When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification of each specimen.

Vaginal Swab Specimen Collection and Handling

Note: For patient-collected vaginal swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

Instructions for vaginal swab specimen collection:

1. 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.
2. Hold the 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.
3. Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus 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.
4. 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.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Penile Meatal Swab Specimen Collection and Handling

Note: For patient-collected penile meatal swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

Instructions for penile meatal swab specimen collection:

1. 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.
2. Hold the 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.

3. **Roll the swab clockwise** 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. 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.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Lesion Swab Specimen Collection and Handling

Note: Do not use disinfectants or cleaners on the lesion before the specimen is collected.

Instructions for lesion swab specimen collection:

1. 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.
2. Hold the 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.
3. If needed, expose the base of the lesion to access fluid.
4. 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.
5. 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.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
7. Carefully break the swab shaft at the score line against the side of the tube.
8. Discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

Rectal Swab Specimens Collection and Handling

Note: For patient-collected rectal swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

Instructions for rectal swab specimen collection:

1. 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.
2. Hold the 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.
3. 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. 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.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Throat Swab Specimens Collection and Handling

Note: For patient-collected throat swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

Instructions for throat swab specimen collection:

1. 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.
2. Hold the 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.
3. 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. 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.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Specimen Transport and Storage

Multitest swab specimens must be transported to the laboratory in the provided swab specimen transport medium and tube. Refer to the appropriate Aptima assay package insert for proper specimen storage conditions.

Note: Specimens must be shipped in accordance with applicable national and international regulations.

Limitations

- A. Use this collection kit only with Aptima assays and other Hologic products. Performance has not been established with other products.
- B. Use of the Multitest swab for patient-collected vaginal specimen collection is not designed to replace cervical exams and endocervical samples for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- C. Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the Multitest swab to obtain patient-collected vaginal swab specimens as a replacement for a pelvic exam.
- D. Consult assay Instructions for Use for assay specific age limitations.
- E. The patient-collected Multitest swab specimen application are limited to clinical settings where support/counseling is available to explain the procedures and precautions.



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2021-09