

Aptima™ Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens

Instructions for Use
For *in vitro* diagnostic use
For US Export Only

Intended Use

The Aptima™ Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens is for use with Aptima assays. The Aptima Unisex Swab Specimen Collection Kit is intended to be used for the collection of female endocervical or male urethral swab specimens.

The Aptima Unisex Swab Specimen Collection Kit 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 Aptima Unisex Swab Specimen Collection Kits for Endocervical and Male Urethral Swab Specimens (Cat. No. 301041)

Each kit contains:

Component	Quantity	Description
Unisex collection swab	1	Swab for endocervical or male urethral swab specimens.
Cleaning swab	1	Female cleaning swab.
Transport tube	1	Tube containing swab transport medium (2.9 mL).

Warnings and Precautions

A. Do not apply the transport medium directly to skin or mucous membranes or take internally.

Note: Hazard Communication reflects the EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicds.com.

Kit Storage Requirements

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

Swab Specimen Performance

The assay performance characteristics of the female endocervical and male urethral 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 male urethral swab specimen has not been established for all Aptima assays.

Specimen Collection and Handling

A. Endocervical swab specimens

Note: If the tube contents are spilled, discard and replace with a new Aptima Unisex Swab transport tube.

1. Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). Discard this swab.

Note: To remove excess mucus from the cervical os, a large-tipped swab (not provided) may be used.

2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) into the endocervical canal.
3. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
4. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents.
7. Re-cap the swab specimen transport tube tightly.

B. Male urethral swab specimens

1. The patient should not have urinated for at least 1 hour prior to sample collection.
2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
3. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
4. Withdraw the swab carefully.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents.
7. Re-cap the swab specimen transport tube tightly.

Specimen Transport and Storage

After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed with the Aptima assays within 60 days of collection. If longer storage is needed, refer to the appropriate Aptima assay package insert.

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

Limitations

- A. Use this collection kit only with the Aptima assays and other Hologic products. Performance has not been established with other products.
- B. The performance of male urethral swab specimens has not been established for the Aptima *Trichomonas vaginalis* assay.

Contact Information and Revision History



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



Hologic BV
Da Vinciĳaan 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.

This product is intended for use only in the field of human *in vitro* diagnostics.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

Hologic and Aptima are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries.

All other trademarks that may appear in this package insert 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.

©2001-2022 Hologic, Inc. All rights reserved.

AW-26249-001 Rev. 001
2022-05

Revision History	Date	Description
AW-26249-001 Rev. 001	May 2022	<ul style="list-style-type: none"> Created Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens IFU AW-26249-001 Rev. 001 based on 502135EN Rev. 008 for regulatory compliance with IVDR Added Instructions for Use Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support