

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

For *in vitro* diagnostic use.

Intended Use

The Aptima Unisex Swab Specimen Collection Kit for Female 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.

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 Aptima 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.

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

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

A. Endocervical swab specimens

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. 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.



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

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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