



## APTIMA<sup>®</sup> 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.gen-probe.com](http://www.gen-probe.com). The table below identifies the acceptable specimen types for each of the APTIMA assays.

| APTIMA Assay for   | Female Swab Specimens | Male Swab Specimens |
|--|-----------------------|---------------------|
| <i>Chlamydia trachomatis</i>   | Yes                   | Yes                 |
| <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> (APTIMA Combo 2 Assay) |                       |                     |
| <i>Neisseria gonorrhoeae</i>   |                       |                     |

## Specimen Collection and Handling

### 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 should be transported in compliance with Federal regulations for transport of etiological agents. Please refer to HHS Publication No. CDC 93-8395 or latest revision.

## Limitations

- A. Use this collection kit only with the APTIMA assays. Performance has not been established with other products.



Gen-Probe Incorporated  
San Diego, CA 92121 USA

### U.S. and international contact information

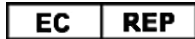
Customer Service: +1 858 410 8002  
customerservice@gen-probe.com  
Technical Support: +1 858 410 8511  
technicalsupport@gen-probe.com

Toll-free from U.S. and Canada

Customer Service: +1 800 523 5001

Technical Support: +1 888 484 4747

[www.gen-probe.com](http://www.gen-probe.com)



MLT Research Ltd  
Attn. Dr Andrew Rutter  
5 Chiltern Close  
Cardiff  
CF14 5DL  
United Kingdom

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