



APTIMA[®] Vaginal Swab Specimen Collection Kit

For *in vitro* diagnostic use.

Intended Use

The APTIMA Vaginal Swab Specimen Collection Kit is for use with APTIMA assays. The APTIMA Vaginal Swab Specimen Collection Kit is intended to be used for clinician and patient collection of vaginal swab specimens. Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The APTIMA Vaginal Swab Specimen Collection Kit is not for home use.

Materials Provided

50 Vaginal Swab Specimen Collection Kits (Cat. No. 301162)

Each kit contains:

Component	Quantity	Description
Swab*	1	<i>Individually wrapped, sterile swab.</i>
Transport tube	1	<i>Tube containing transport medium (2.9 mL).</i>
Patient collection instructions	1 package	<i>Pack of patient collection instructions.</i>

Warnings and Precautions

- A. For *in vitro* diagnostic use.
- B. Do not apply the 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 organisms. 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 Vaginal 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.

Kit Storage Requirements

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

Vaginal Swab Specimen Performance

The assay performance characteristics of the vaginal swab specimen are provided in the appropriate APTIMA assay package insert. The APTIMA assay package inserts may be referenced online at www.gen-probe.com. The table below identifies acceptable specimen types for each of the APTIMA assays.

APTIMA Assay for	Clinician Collected	Patient Collected
<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

Note: 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. 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 Vaginal Swab Specimen Collection Kit.
2. Remove the swab.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft.
4. Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
5. Withdraw the swab without touching the skin.
6. 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 Vaginal Swab Specimen Collection Kit.
7. Immediately place the swab into the transport tube so that the tip of the swab is visible below the tube label.
8. Carefully break the swab shaft at the scoreline against the side of the tube and discard the top portion of the swab shaft. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new APTIMA Vaginal Swab Specimen Collection Kit.
9. Tightly screw the cap onto the tube.

Specimen Transport and Storage

Vaginal swab specimens must be transported to the laboratory in the provided swab specimen transport medium and tube. Vaginal swab specimens must be transported to the laboratory at 2°C to 30°C and tested within 60 days of collection. If longer storage is needed, refer to the appropriate APTIMA assay package insert.

Note: Federal requirements for packaging must be met when specimens are transported by common land and air carriers. Refer to 42 CFR, Part 72. The most current requirements may be obtained from the Centers for Disease Control and Prevention Office of Health and Safety in Atlanta, Georgia at +1 404 636 3883.

Limitations

- A. Use this collection kit only with the APTIMA assays. Performance has not been established with other products.
- B. Vaginal swab sampling 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 patient-collected vaginal swab specimen as a replacement for a pelvic exam.
- D. The performance of vaginal swab specimen has not been evaluated in pregnant women.

- E. The performance of vaginal swab specimen has not been evaluated in teenage women less than 16 years of age.
- F. The patient-collected vaginal swab specimen application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.



Gen-Probe Incorporated
San Diego, CA 92121 USA

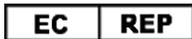
U.S. and international contact information:

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



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

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