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Title: Specimen Collection Instructions: Aptima Multi-Test Collection Kit (Orange Label) for CT/GC and TV: Vaginal - Clinician and patient self-collected, Rectal and Throat Clinician collected ONLY

Index: STI 11

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Version: 1.2

Authorized by: Marty Soehnlen

Authorization date: 14-Jan-2026

Next review date: 08-Jan-2028

Organizational Unit: Saginaw County Regional Laboratory

Section: High Complexity Testing

Location: High Complexity Testing

Introduction and Scope: Specimen Collection Instructions: Aptima Multi-Test Collection Kit (Orange Label) for CT/GC and TV: Vaginal - Clinician and patient self-collected, Rectal and...

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Introduction and Scope

Specimen collection instructions for vag, rectal and throat using Multitest swab



***N. gonorrhoeae, C. trachomatis, and T. vaginalis* testing**

Specimen Collection Instructions:

- **Vaginal swabs - clinician and patient self-collected**
- **Throat and Rectal swabs - clinician collected ONLY**

Use

HOLOGIC APTIMA® Multitest Swab Collection Kit (Orange Label)

I. Collection kit

- A. Collection kit for clinician & patient self-collected vaginal, clinician collected rectal and throat specimens (orange-labeled tube). This is an IATA Category B.
- B. Check the expiration date. Do not use an expired collection kit.
- C. Verify the patient's identity at the time of collection. Best practice is to ask the patient to spell their first and last name.

II. Patient preparation/sample collections for clinician-collected vaginal swabs:

- A. Ask the patient to read the collection instructions.
- B. If all the instructions are understood, provide the patient with the collection kit.
- C. Do not touch the soft tip or lay the swab down at any time during the collection. If the swab tip is touched or dropped, start with a new kit.
- D. Peel open the swab package. Hold the swab between your thumb and forefinger, covering the scored line in the middle of the shaft to remove the swab from the package
- E. Carefully insert the swab into the vagina about 2 inches past the introitus, and gently rotate the swab clockwise for 10 to 30 seconds. Make sure the swab touches the walls of the vagina and absorbs the moisture.
- F. Remove the swab without touching the skin or other surfaces and place it in the transport tube (See VI)

III. **Self-collected vaginal specimens – This is for *N. gonorrhea* and *C. trachomatis* only**

Refer to Hologic – Instructions for Obtaining Patient-Collected Aptima Vaginal Swab Specimens, at the end of this document.

IV. **Throat swab (female and male)**

- A. Use a tongue blade to hold down the patient's tongue. Look at the back of the throat and tonsils for inflammation or exudate.
- B. Do not touch the soft tip or lay the swab down at any time during the collection. If the swab tip is touched or dropped, start with a new kit.
- C. Peel open the swab package. Hold the swab between your thumb and forefinger, covering the scored line in the middle of the shaft to remove the swab from the package.
- D. Insert the specimen collection swab (orange shaft swab) and, carefully but firmly, rub the swab over the inflamed areas. If there is no inflammation or exudate, rub the swab over the tonsils and posterior pharynx.
- E. Do not touch the cheeks, teeth, or gums with the swab.
- F. Carefully remove the swab without touching the skin or other surfaces and place it in the transport tube (See VI)
- G. Do not let the swab touch the skin or other surfaces.

V. **Rectal Swab (male and female)**

- A. Do not touch the soft tip or lay the swab down at any time during the collection. If the swab tip is touched or dropped, start with a new kit.
- B. Peel open the swab package. Hold the swab between your thumb and forefinger, covering the scored line in the middle of the shaft to remove the swab from the package
- C. Insert the specimen collection swab (orange shaft swab) into the rectum
- D. Swab the anal crypts just inside the anal ring. Rotate the swab for 5 to 10 seconds.
- E. Carefully remove the swab without touching the skin or other surfaces and place it in the transport tube (See VI).
- F. Avoid fecal contamination as much as possible during the collection. If the swab is grossly contaminated with fecal material, discard it, and start with a new kit to collect another specimen.

VI. Transport Tube

- A. Remove the cap from the swab specimen transport tube. **Do not pour off the liquid preservative contents from the tube**. Immediately place the specimen collection swab into the transport tube.
- B. Carefully break the swab shaft against the side of the tube at the scored line, using care to avoid splashing of the liquid. Discard the top portion of the swab shaft, leaving the tip of the swab in the tube.
- C. Screw the cap on the transport tube as evenly and tightly as possible. Tape or Para-film® around the cap, but **DO NOT** put tape over the top of the cap.

VII. Labeling

- A. Label the transport tube with the complete patient's name and at least 1 unique identifier (For example: specimen number, date of birth, medical record number, etc.)
- B. Enter the required information on the test requisition form. The patient's name and unique identifier on the form must be entered **exactly** the same as the information on the tube.
- C. If there are multiple specimens from the same patient, please label the specimen tubes with the source also. The lab may be unable to determine the specimen source if not identified on the tube.
- D. If there are multiple specimens from the same patient, use a separate test requisition and collection kit for each specimen.

VIII. Packaging and Shipping:

- A. Specimens should be sent to the lab as soon as possible after collection.
- B. Specimens can be shipped at ambient temperature.
- C. Insert the specimen and absorbent pad into the small plastic bag provided. Make sure it is sealed. Place in the large plastic bag with the Biohazard symbol (Bio-Bag).
- D. Place the completed test requisition in the outside pocket of the Biohazard-Bag. Seal the bag.
- E. Close the box and secure with sealing tape on both sides of the flap.
- F. Attach the completed address label with the UN3733 label included in kit.
- G. Send to the Saginaw County Health Department laboratory as soon as possible (e.g. courier or 1st class mail (USPS), United Parcel Service (UPS) etc.).
- H. The specimen will not be tested if:
 1. The specimen container is received leaking.
 2. The specimen is not properly labeled, or the test requisition is not completed.
 3. The specimen label does not match the test requisition.
 4. The collection device is expired.
 5. The specimen was collected more than 60 days before receipt.
 6. Specimen is collected with the wrong collection device.

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- IX. Packaging and shipping are the responsibility of the shipper. Please be sure it complies with shipping regulations.



Chlamydia & Gonorrhea-Amplified Test-Multitest Swab

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PATIENT INFORMATION REGARDING SELF-COLLECTED SPECIMENS

- A self-collected swab is one way to test for sexually transmitted infections (STIs). Other options are available. If you have questions about the self-collected swab, other sample collection options, or STIs, consult your health care provider.
- Self-collection is an option in clinical settings if you agree to perform the procedure. Counseling from your health-care provider is available for the self-collection procedure.
- Carefully read the swab self-collection instructions below. If you feel you can perform this self-collection procedure and wish to use this method of testing for STIs, inform your health-care provider.
- Do not take the collection kit or your self-collected specimen out of the clinic.
- Some self-collected specimen types are not available with all assays. Refer to the appropriate assay package insert for appropriate specimen types.

GENERAL INSTRUCTIONS FOR ALL COLLECTION METHODS

Carefully follow procedures for reliable results. If you have any questions about any procedure, please ask your healthcare provider.

1. Wash your hands before starting.
2. In the privacy of the examination room or restroom, you will need to undress, as necessary. You will need to comfortably position yourself to maintain balance during the collection procedure.
3. Open kit package. Remove the swab and the tube. Set the tube aside before beginning instructions below to collect the specimen or specimens requested by your healthcare.

WARNING: If at any time the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your health-care provider if irritation develops. If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit. Do not take internally.

IMPORTANT INFORMATION TO CONSIDER

- IF YOU ARE PREGNANT, PLEASE INFORM YOUR HEALTH-CARE PROVIDER.
- Before you collect a vaginal swab specimen, inform your health-care provider if you have:
 - recent pelvic pain
 - pain with sexual intercourse
 - unusual vaginal discharge or bad odor

These symptoms can be due to pelvic inflammatory disease (PID). Prompt diagnosis and treatment of PID can help prevent infertility and ectopic pregnancy associated with PID.

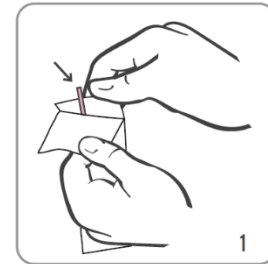
COLLECTION PROCEDURE

1) Before proceeding, read the patient information and general instructions.

- 2) Partially peel open the swab package as shown in Diagram 1. Remove the swab.

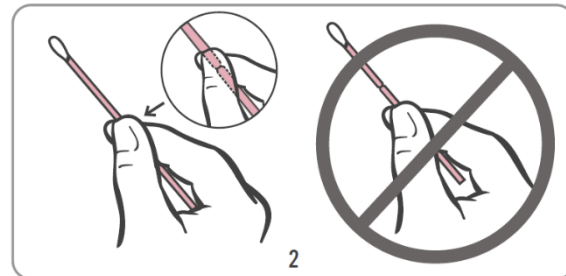
Do not touch the soft tip or lay the swab down.

If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new Aptima Multitest Swab Specimen Collection Kit.



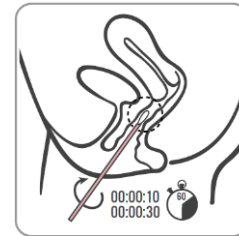
- 3) Hold the swab in your hand as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line.

Do not hold the swab shaft below the score line.



- 4) Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening of the vagina (as shown in Diagram 3) and **gently rotate the swab clockwise** for 10 to 30 seconds.

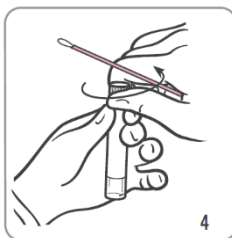
Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.



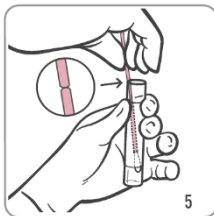
- 5) While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4.

Do not spill the contents of the tube.

If the contents of the tube are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.

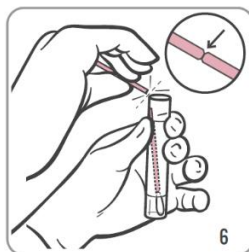


6)



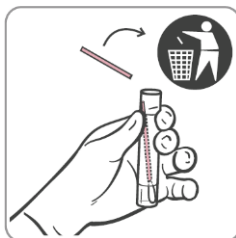
Immediately place the swab into the transport tube so that the score line is at the top of the tube as shown in Diagram 5.

7)



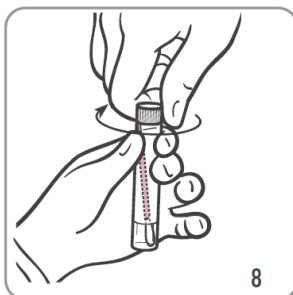
Carefully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.

8)



Immediately discard the top portion of the swab shaft as shown in Diagram 7.

9)



Tightly screw the cap onto the tube as shown in Diagram 8. Return the tube as instructed by your health-care provider.

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AW-26646-001 Rev.002

2024-02

Revision History	Date	Description
AW-26646 Rev. 002	February 2024	<ul style="list-style-type: none">Added 'Rx Only' usage at the top of the first page.Clarified that the score line is not marked with a black line.
AW-26646 Rev. 001	May 2022	<ul style="list-style-type: none">Initial Release

Appendix: Specimen Collection Instructions: Aptima Multi-Test Collection Kit (Orange Label) for CT/GC and TV: Vaginal - Clinician and patient self-collected, Rectal and Throat Clinician...

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Links

Please note: links are only correct at time of printing

Controlled Document links:

Document Revision History

Superseded on 14-Jan-2026 09:49 by Marty Soehnlen

Version 1.1 superseded by version 1.2

Document Published on 14-Jan-2026 09:49 by Marty Soehnlen

The document was published and is ready to be used.

Authorised on 14-Jan-2026 09:49 by Marty Soehnlen

Authorised version 1.2 - . The following users will be notified when a review is due for this document: Lynne Greathouse, Margaret Drayton Document was scheduled to be released on 2026-01-14 The document was originally due for review on 27-Sep-2025

Authorisation Approved on 14-Jan-2026 09:49 by Marty Soehnlen

The user Approved the authorisation request.

Set Pending Authorisation on 08-Jan-2026 12:59 by Tammy Theisen

Document was set as Pending Authorisation and authorisation requests were sent to: Marty Soehnlen

Authorisation requested on 08-Jan-2026 12:59 by Tammy Theisen

Authorisation request sent to Marty Soehnlen by Tammy Theisen on 08-Jan-2026 12:59.

Change Requested on 08-Jan-2026 12:35 by Tammy Theisen

Taylor Garcia Requested Change: 'Section 3 part I is missing a parenthesis'

Draft Created on 08-Jan-2026 12:35 by Tammy Theisen

Reason: Updated procedure

Change Requested on 04-Dec-2023 10:40 by Taylor Garcia

Taylor Garcia Requested Change: 'Section 3 part I is missing a parenthesis'

Authorisation Approved on 27-Sep-2023 14:39 by Marty Soehnlen

The user Approved the authorisation request.

Superseded on 27-Sep-2023 14:39 by Marty Soehnlen

Version 1.0 superseded by version 1.1

Document Published on 27-Sep-2023 14:39 by Marty Soehnlen

The document was published and is ready to be used.

Authorised on 27-Sep-2023 14:39 by Marty Soehnlen

Authorised version 1.1 - . The following users will be notified when a review is due for this document: Lynne Greathouse, Margaret Drayton Document was scheduled to be released on 2023-09-27 Previous version of the document didn't have a review date set.

Set Pending Authorisation on 27-Sep-2023 14:17 by Tammy Theisen

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Document was set as Pending Authorisation and authorisation requests were sent to: Marty Soehnlen

Authorisation requested on 27-Sep-2023 14:17 by Tammy Theisen

Authorisation request sent to Marty Soehnlen by Tammy Theisen on 27-Sep-2023 14:17.

Authorisation Request Deleted on 27-Sep-2023 14:17 by Tammy Theisen

Authorisation request for Marty Soehnlen was deleted by Tammy Theisen.

Reverted to Draft on 27-Sep-2023 14:17 by Tammy Theisen

Document was reverted to draft. Reason to revert: "I think I messed up. Sending again"

Set Pending Authorisation on 18-Sep-2023 13:02 by Tammy Theisen

Document was set as Pending Authorisation and authorisation requests were sent to: Marty Soehnlen

Authorisation requested on 18-Sep-2023 13:02 by Tammy Theisen

Authorisation request sent to Marty Soehnlen by Tammy Theisen on 18-Sep-2023 13:02.

Draft Created on 18-Sep-2023 12:43 by Tammy Theisen

Reason: Need to add trich to testing

Document Published on 12-Oct-2021 08:34 by Marty Soehnlen

The document was published and is ready to be used.

Authorised on 12-Oct-2021 08:34 by Marty Soehnlen

Authorised version 1.0 - . The following users will be notified when a review is due for this document: Lynne Greathouse, Margaret Drayton Document was scheduled to be released on 2021-10-12

Authorisation Approved on 12-Oct-2021 08:34 by Marty Soehnlen

The user Approved the authorisation request.

Set Pending Authorisation on 11-Oct-2021 18:48 by Tammy Theisen

Document was set as Pending Authorisation and authorisation requests were sent to: Marty Soehnlen

Authorisation requested on 11-Oct-2021 18:48 by Tammy Theisen

Authorisation request sent to Marty Soehnlen by Tammy Theisen on 11-Oct-2021 18:48.

Creation on 11-Oct-2021 18:44 by Tammy Theisen

New Document created

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Authorisation

This document was securely signed and authorised by:

Marty Soehnlen: 14-Jan-2026 09:49