



MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Laboratories Administration

Robert A. Myers, Ph.D., Director
1770 Ashland Avenue
Baltimore, Maryland 21205

July 26th, 2019

To: CT/GC NAAT Approved Submitters

From: Sarah E Langtry, PHLS Supervisor, Chlamydia Laboratory *SEL*

Through: Venkata Vepachedu, Ph.D., Chief, Division of Virology and Immunology *R*
Robert A. Myers, Ph.D., Director, Laboratories Administration

CC: Elisabeth Liebow, MPH, Center for STI Infection and Prevention *R.A.M.*
Ken Ruby III, LCSW-C, MBA, Chief, Center for STI Infection and Prevention

Re: FDA Approval of Extra-genital specimens for CT/ GC NAAT Testing

We are pleased to inform you that **throat and rectal** specimen sources are now FDA-approved for Chlamydia and Gonorrhea NAAT testing. As a result, two major changes will occur, effective **August 1st, 2019**. The time from collection to testing for all throat and rectal swab specimens is being extended from 7 days to **60 days**. Additionally, throat and rectal specimens must be collected with the Aptima Multitest Swab Collection kit. This is the **Pink swab** and the **Orange Multitest Transport Tube**.



Please contact the lab at **443-681-3937** or the Chlamydia Supervisor at **443-681-3932**, if you have any questions.

Revision of the Aptima Combo 2® Assay Package Insert**Notification of throat and rectal specimen claim for Aptima Combo 2 on the Panther® System**

For US IVD Distribution

Purpose

The purpose of this Customer Technical Bulletin (CTB) is to inform customers that clinician-collected throat and rectal samples are newly cleared specimen types for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoea* using the Aptima Combo 2 assay kit on the Panther system.

Scope

This CTB is effective upon receipt and is intended for Panther system site administrators, laboratory supervisors, physicians, and operators who use the following kit part numbers:

<u>Product Name:</u>	<u>Catalog Number:</u>
Aptima Combo 2 Assay (Panther) – 100 Test Kit	302923
Aptima Combo 2 Assay (Panther) – 250 Test Kit	303094

What is Affected

Hologic, Inc. has received FDA clearance for the use of clinician-collected throat and rectal samples with the Aptima Combo 2 assay on the Panther system. The Aptima Combo 2 assay chemistry remains the same and there is no change in data analysis on the Panther instrument.

For details regarding cleared specimen types on the Aptima Combo 2 assay, please refer to the newly revised package insert (PI No. 502446 Rev. 008) and for information on the proper collection of throat and rectal specimens, please refer to the Aptima® Multitest Swab Specimen Collection Kit package insert (PI No. AW-14413-001 Rev. 007). For the current version of each package insert, refer to www.hologic.com.

What is Required

Please share this information with those in your organization as appropriate. Ensure that departments including laboratory personnel and quality assurance are informed of the package insert revision and ordering physicians/medical office managers are aware that clinician-collected throat and rectal samples are now FDA cleared for CT/NG NAAT testing using Aptima Combo 2 on the Panther system.

If there are questions or concerns regarding this communication, please contact Hologic Technical Support at +1 888 484 4747 or +1 858 410 8511, or by e-mail at molecularsupport@hologic.com.

END OF DOCUMENT

Collection instructions for CT/GC testing using the Hologic Aptima® Combo 2 Assay

Multi-test (Pink swab) specimens sample collection, transport, and storage:

Vaginal specimens:

- Vaginal **pink** collection swab should be inserted **2 inches** into the opening of the vagina.
- Gently rotate swab clockwise for **10 to 30 seconds** to ensure adequate sampling. Ensure swab touches the walls of the vagina so moisture is absorbed by the swab. Withdraw swab carefully without touching the skin.
- Place swab into the **orange multi-test** specimen tube, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.



Rectal swabs:

- Insert **pink multi-test** swab **3 to 5 cm** into the anus and rotated for **5–10 seconds**. (If needed prior to insertion, the swab can be moistened with water or saline solution).
- Place swab into the **orange multi-test specimen tube**, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

Pharyngeal swabs:

- Use **pink unisex** swab to make contact with five key anatomic landmarks: bilateral tonsils, bilateral posterior walls, and the uvula.
- Place swab into the **orange multi-test specimen tube**, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

All Multi-test (Pink swab) specimens: After collection, transport and store the swab in the labeled swab specimen transport tube at **2°C to 30°C** until tested. Specimens must be assayed with the APTIMA COMBO 2 Assay within **60 days** of collection. If longer storage is needed, freeze at **-20°C** to **-70°C** for up to 12 months after collection.

Collection instructions for CT/GC testing using the Hologic Aptima® Combo 2 Assay

Unisex (Blue swab) specimens sample collection, transport, and storage:



Male Urethra:

- Discard white cleaning swab.
- Blue unisex collection swab should be inserted **2cm to 4cm** into the urethra.
- Gently rotate swab clockwise for **2 to 3 seconds** to ensure adequate sampling. Withdraw swab carefully.
- Place swab into the **unisex** specimen tube, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

Endocervical swabs:

- Endocervical collection **require use of a cleaning swab** prior to collection. Use the white cleaning swab to remove excess mucus from cervical and surrounding mucosa.
- Discard this swab.
- Insert the **blue** unisex collection swab into cervical canal. Gently rotate the swab clockwise for **10 to 30 seconds** to ensure adequate sampling. Withdraw swab carefully to avoid contact with vaginal mucosa.
- Place swab into the **unisex specimen** tube, carefully break swab shaft **at the score line** and re-cap **tightly**.
- Users should wash their hands and re-glove between specimen collections if collecting a specimen from more than one anatomic site.

All Unisex (Blue swab) specimens: After collection, transport and store the swab in the labeled swab specimen transport tube at **2°C to 30°C** until tested. Specimens must be assayed with the APTIMA COMBO 2 Assay within **60 days** of collection. If longer storage is needed, freeze at **-20°C** to **-70°C** for up to 12 months after collection.

Aptima® Multitest Swab Specimen Collection Kit

Clinician collection procedure guide



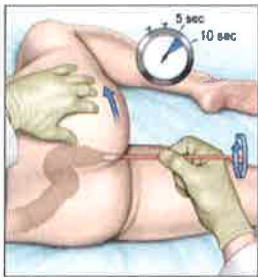
Collection for rectal swab specimens



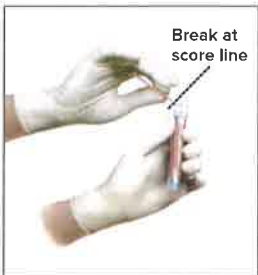
Partially open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down, or dropped, discard and use a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft covering the black score line. Do not hold the shaft below the score line.

Swab specimen collection guide for:

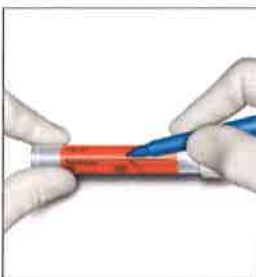
- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)



Carefully insert the swab into the rectum about 1-2 inches (3-5 cm) past the anal margin (the outside of the anus) and gently rotate the swab for 5 to 10 seconds. Withdraw the swab without touching the skin.



While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the shaft. The swab will drop to the bottom of the tube. Discard the top portion of the swab shaft.



Tightly screw the cap onto the tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for the specimen location.



Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

hologic.com | diagnostic.solutions@hologic.com | 1.888.484.4747

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Aptima® Multitest Swab Specimen Collection Kit

Clinician collection procedure guide



Collection for throat swab specimens



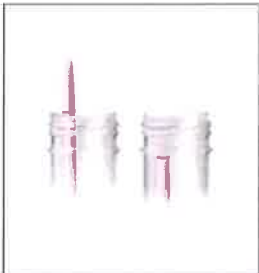
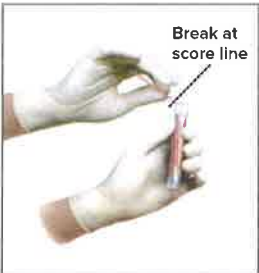
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Swab specimen collection guide for:

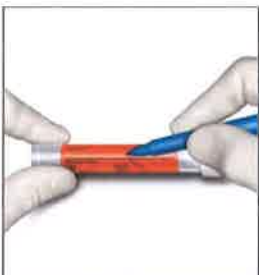
- *Chlamydia trachomatis (CT)*
- *Neisseria gonorrhoeae (NG)*



Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.



While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the shaft. The swab will drop to the bottom of the tube. Discard the top portion of the swab shaft.



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Outfit Supply Requisition

SUBMITTER: _____ DATE: _____
 NAME OF FACILITY: _____ PHONE: _____
 ADDRESS: _____

<u>KITS</u>	<u>QUANTITY</u>	<u>COMPONENTS</u>	<u>QUANTITY</u>
1. PINWORM SLIDES	_____	8. BIOHAZARD BAGS	_____
2. FLOW CYTOMETRY	_____	9. GC PLATES <input type="checkbox"/> BAGS <input type="checkbox"/> PILLS <input type="checkbox"/> SWABS	_____
3. VIRAL CULTURE KIT	_____	10. MISCELLANEOUS URINE CUPS	_____
4. SPUTUM (T B CULTURE)	_____	11. RED TOP TUBES	_____
5. VIRAL LOAD KIT	_____	12. BLOOD CULTURE	_____
6. GENO TYPING KIT	_____	13. ENTERIC PATHOGEN MEDIA (PARA PAK C&S)	_____
7. RFFIT COLLECTION KIT	_____	14. INTESTINAL PARASITE MEDIA (PARA PAK ECO, O&P)	_____
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> CHLAMYDIA/GONORRHEA NAAT </div>		<div style="border: 1px solid black; padding: 5px; display: inline-block;"> FORMS 100 PER PACK </div>	
Multi-Test Collection Kit	_____	CULTURE MEDIA	_____
UNISEX SWAB KIT	_____	16. STUART'S TRANSPORT MEDIA	_____
URINE KIT	_____	17. AMIES TRANSPORT MEDIA	_____
URINE CUPS	_____		
PIPETTES	_____		

Vaginal, Throat and Rectal specimens

Cervix and Urethral specimens

Female and Male Urine

NOTES

- 1. INFECTIOUS AGENTS/CULTURE/DETECTION-MDH 4676 _____
- 2. SEROLOGICAL TESTING MDH 4677 _____
- 3. ENVIRONMENTAL FORM MDH# _____
- 4. FLOW CYTOMETRY MDH 4393 _____
- 5. VIRAL LOAD MDH 4393-A _____
- 6. OTHER _____