

Sexual and Vaginal Health Test Update

Effective February 26, 2024

- **The Aptima® Multitest Swab Specimen Collection Kit will be the only kit required for Vaginitis, Mycoplasma genitalium, Chlamydia, and Gonorrhea testing.**
- **The Vaginitis Profile will be also offered as ala carte tests providing more diagnostic ordering options.**

We are pleased to announce that the Aptima® Multitest Swab Specimen Collection Kit (orange) has been approved to perform nucleic acid amplification tests (NAAT) for the detection of sexually transmitted infections. This one collection device supports a comprehensive testing portfolio for women's health that has been rigorously developed for highly accurate and reliable results. The assays include:

- *Chlamydia trachomatis (CT)*
- *Neisseria gonorrhoea (NG)*
- *Bacterial vaginosis (BV)*
- *Candida vaginosis (CV)/Trichomonas vaginosis (TV)*
- *Mycoplasma genitalium (Mgen)*

Benefits of the Aptima® Multitest Swab:





- Simplifies testing and provides more answers for sexual and vaginal health allowing for the flexibility to collect samples from a variety of specimen collection sites for CT and NG (vaginal*, rectal, throat).
- *The vaginal swab is the CDC's preferred collection method for these assays.^{1,2}
- Provides increased reliability in testing. Urine samples can miss up to 10% of underlying infections where vaginal samples miss fewer than 1% of infections.³⁻⁶
- Improves the patient experience with one easy collection method.
 - 90% found self-collection easy⁷
 - 76% preferred a vaginal collection over a pelvic exam⁷
 - 60% preferred a vaginal collection over a urine sample⁷
- Conveniently decreases the need for patient callbacks for recollection when reflex or add-on testing is ordered or when the cleaning swab was inadvertently submitted using the unisex swab (white).
 - *NOTE: If ordering more than 3 assays, we highly recommend using 2 collection kits to allow for repeat testing and to avoid QNS (quantity not sufficient) issues.*
- Simplifies and streamlines clinic inventory.

CLH will discontinue distribution of the Aptima® Unisex Swab Specimen Collection Kit (white) on February 26, 2024. Any specimens received in the white Unisex kit will no longer be accepted. Please refer to the updated CLH Color Media Chart for a complete listing of acceptable collection devices and/or contact your CLH representative for any media requests.

**Please note: Some insurance carriers require a prior authorization for ordering Bacterial Vaginosis testing by NAAT, and some may not cover the test at all. For this reason, CLH is offering the tests ala carte, as well as in a profile, to provide you with more options. Please consult with individual insurance carriers for coverage information and guidelines. Coverage is specific to the insurance carrier plans.

If you have any questions, please contact our Client Services Department at 808-677-7998 (Oahu) or 1-866-281-6816 (toll-free).

Sexual and Vaginal Health Media Chart:

MEDIA	TEST	TEST CODE	COLLECTION/TRANSPORT
 Aptima® Multitest Swab Collection Kit* *If collecting more than 3 tests, submit 2 kits to avoid QNS issues.	Chlamydia trachomatis (CT) Neisseria gonorrhoea (NG) Chlamydia/Gonorrhoea (CT/NG) Vaginitis Profile (BV, CV, TV) Bacterial vaginosis (BV) Candida/Trichomonas (CV, TV) Mycoplasma genitalium (Mgen)	CTNAT (0184) GCNAT (0185) CGNAT (0187) VAGPAN (4391) BVSTI (4189) CDTRIC (4190) MGENT (4163)	**Vaginal, Rectal, Throat **Vaginal, Rectal, Throat **Vaginal, Rectal, Throat Vaginal only Vaginal only Vaginal only Vaginal only <i>Vaginal- clinician or self-collected acceptable.</i> <i>**Because variety of sources are acceptable, please specify the source in your order to avoid testing delays.</i> <i>Stable 30 days at room temp.</i>
 Sterile Urine Container	Chlamydia trachomatis (CT) Neisseria gonorrhoea (NG) Chlamydia/Gonorrhoea (CT/NG) Mycoplasma genitalium (Mgen) Trichomonas- Male Trichomonas- Female	CTNAT (0184) GCNAT (0185) CGNAT (0187) MGENT (4163) TRICHM (8047) TRICF (8046)	No urination in the last hour prior to collection. Submit 20-30 ml of the initial urine stream (first catch). Do not use wipes to cleanse prior to collection. Cap tightly. <i>Refrigerate after collection.</i> <i>Stable 24 hours.</i> <i>If urine is not received within 24 hours, transfer to an Aptima® Preservative media.</i>
 Aptima® Urine Preservative Kit	Chlamydia trachomatis (CT) Neisseria gonorrhoea (NG) Chlamydia/Gonorrhoea (CT/NG) Mycoplasma genitalium (Mgen) Trichomonas- Male Trichomonas- Female	CTNAT (0184) GCNAT (0185) CGNAT (0187) MGENT (4163) TRICHM (8047) TRICF (8046)	Urine should be collected in a sterile urine container (see instructions above). Transfer 2ml of urine using pipette provided in the kit. Fill until the fluid level is between the black fill lines on the tube label. Cap tightly. <i>Stable 30 days at room temp.</i>
 ThinPrep® Vial	Chlamydia trachomatis (CT) Neisseria gonorrhoea (NG) Chlamydia/Gonorrhoea (CT/NG)	CTNAT (0184) GCNAT (0185) CGNAT (0187)	**Cervical, Vaginal <i>**Because variety of sources are acceptable, please specify the source in your order to avoid testing delays.</i> <i>Collected with Pap Smear</i> <i>Stable 2 weeks at room temp</i>

References:

1. Aptima Multitest Swab [package insert]. AW-14413, San Diego, CA; Hologic, Inc., 2019.
2. CDC. Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae. *MMWR. Recomm Rep.* 2014; 63(2). <https://www.cdc.gov/std/laboratory/2014labrec/2014-lab-rec.pdf>
3. CDC. 2015 Sexually Transmitted Diseases Treatment Guidelines. *MMWR Recomm Rep* 2015;64(3). <https://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>
4. Chernesky M, et al. Head-to-Head comparison of second-generation nucleic acid amplification tests for detection of Chlamydia trachomatis and Neisseria gonorrhoeae on urine samples from female subjects and self-collected vaginal swabs. *J Clin Microbiol.* 2014;52(7):2305-2310. doi: 10.1128/JCM.03552-13
5. Van Der Pol B, et al. Combined Testing for Chlamydia, Gonorrhoea, and Trichomonas by Use of the BD Max CT/GC/TV Assay with Genitourinary Specimen Types. *J Clin Microbiol.* 2017;55(1):155-164. doi: 10.1128/JCM.01766-16
6. Aptima Trichomonas vaginalis Assay [package insert]. 503684. San Diego, CA; Hologic, Inc., 2020
7. Chernesky MA, Hook EW, Martin DH, et al. Women find it easy and prefer to collect their own vaginal swabs which are effective for the diagnosis of Chlamydia trachomatis and Neisseria gonorrhoeae. *Sex Transm Dis.* 2005;32(12):729-33.

Thank you for choosing Clinical Labs of Hawaii.

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