Wisconsin State Laboratory of Hygiene
UNIVERSITY OF WISCONSIN–MADISON

Communicable Disease Division
2601 Agriculture Drive, P.O. Box 7904
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Dear Clinical Partners,

On Monday, **March 15th** the Wisconsin State Laboratory of Hygiene (WSLH) will begin testing for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), and *Trichomonas vaginalis* (TV) using our new Hologic Panther System. This change in testing requires different collection kits from previous methods and previous collection kits will no longer be accepted. Please refer to the included pictorial collection kit guide to determine which kits are most appropriate for your patients. The BD collection kits we previously accepted may be discarded after the change has occurred. They will no longer be accepted for testing after March 31st, 2021. Existing submitters will be sent new Aptima collection kits in the next 2 weeks in preparation for the change. If you do not receive these kits and would like them please contact our Clinical Orders Department at 1-800-862-1088 and request collection kits to meet your testing needs for up to 2 weeks at a time.

This change in testing will allow us to continue to provide highly accurate testing. And, submitters are likely to see a reduction in the time to results. This change will not result in an increase in the test cost. The new instrumentation will expand our ability to provide sexual health testing. We are working to validate additional specimen types, like male urine for *Trichomonas vaginalis* and new pathogens like *Mycoplasma genitalium*. Look for additional announcements for these news tests later this year!

WSLH Staff

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Change to CT/GC Testing

On Monday, March 15th the Wisconsin State Laboratory of Hygiene (WSLH) will begin testing for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) using the Aptima Combo 2 Assay. This new test uses different collection kits, the previous CT/GC collection kits will no longer be accepted. Male urethral specimen will no longer be accepted, urine is the preferred male specimen type. Testing will be available for patients 14 years and older.

CT and GC infections are two of the most common sexually transmitted infections worldwide. In the United States alone, 1,708,569 cases of CT and 555,608 cases of GC infections were reported to the CDC in 2017 (1). CT and GC oropharyngeal infections may present with sore throat although most are asymptomatic. Rectal infections, when symptomatic, may present with discharge, anal itching, soreness, bleeding, and painful bowel movements (2). The CDC recommends the use of molecular tests for the detection of CT and GC in men and women with and without symptoms, not only for urogenital specimens, but also for extragenital sites (3). Due to the overlap in symptoms, it may be appropriate to test for both Chlamydia and Gonorrhea at the same time.

The Aptima CT/GC assay uses nucleic acid probes and Transcription-Mediated Amplification (TMA) for the qualitative detection and differentiation of ribosomal RNA (rRNA) from CT and GC to aid in the diagnosis of chlamydial and gonococcal disease.

Test Information:

- **Chlamydia trachomatis TMA**
  - **CPT code**: 87491
  - **Test code**: SC00128
  - **Price**: $48.99

Neisseria gonorrhoeae TMA
- **CPT code**: 87591
- **Test code**: SC00122
- **Price**: $48.99

Combined CT/GC TMA
- **CPT code**: 87491+87591
- **Test code**: SC00111
- **Price**: $97.98

- **Acceptable specimen types**:
  - Aptima Multitest Swab Collection Kit (Orange) – Clinical or patient collected vaginal swabs, clinician collected throat or rectal swabs
  - Aptima Unisex Swab Collection Kit (White) – clinical collected endocervical swab
  - Aptima Urine Specimen Collection Kit (Yellow) – female and male urine
- **Specimen handling**: Swab specimens placed in Aptima Collection Kits can be stored and transported between 4-30°C, and must be analyzed within 60 days of collection. Urine in Aptima Urine Collection Kits can be stored and transported between 2-30°C and must be analyzed within 30 days.
- **Turn-around time**: 1-3 days, testing performed on weekdays
- **Possible Results**: No Chlamydia trachomatis rRNA detected, or Chlamydia trachomatis rRNA detected. No Neisseria gonorrhoeae rRNA detected, or Neisseria gonorrhoeae rRNA detected, and Equivocal or Invalid

Reference:

1. **Centers for Disease Control and Prevention.** 2017. *Sexually Transmitted Disease Surveillance 2017*. Atlanta, GA: U.S. Department of Health and Human Services. September.
2. **Centers for Disease Control and Prevention.** 2016. STD Risk and Oral Sex-CDC Fact Sheet. https://www.cdc.gov/std/healthcomm/ stdfact-stdriskandoralsex.htm.
3. **Centers for Disease Control and Prevention.** Prepared by Rapp JR, Schachter J, Gaydos CA, Van Der Pol B). Recommendations for the laboratory-based detection of Chlamydia trachomatis and Neisseria gonorrhoeae- 2014. Morb Mortal Wkly Rprots2. 2014;63(RR2):1-19.

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Change to *Trichomonas vaginalis* Testing

On Monday, March 15th the Wisconsin State Laboratory of Hygiene (WSLH) will begin testing for *Trichomonas vaginalis* using the Aptima *T. vaginalis* Assay. The new test uses different collection kits and the previous kits will no longer be accepted. Testing will be available for females 14 years and older on clinician collected vaginal or endocervical swabs and urine. We are in the process of validating additional specimen types which will become available in the future.

T. vaginalis is the most common curable sexually transmitted disease in the US, with an estimated 7.4 million new cases occurring annually (1). Infections in women cause vaginitis, urethritis, and cervicitis and has been associated with pelvic inflammatory disease, tubal infertility, and cervical cancer. Symptomatic women with trichomoniasis usually complain of vaginal discharge, dysuria, vulvovaginal soreness, and/or irritation. However, it has been estimated that 10 to 50% of *T. vaginalis* infections in women are asymptomatic, and in men the proportion may be even higher (2). Molecular detection for *T. vaginalis* is the most sensitive method available. Traditional culture methods have sensitivity that ranges from 38% to 82% compared to molecular methods (3). *T. vaginalis* can also be detected using "wet-mount" preparation which are 35% to 80% sensitive compared with culture (4). The Aptima *T. vaginalis* Assay uses nucleic acid probes and Transcription-Mediated Amplification (TMA) for qualitative detection of ribosomal RNA to aid in the diagnosis of Trichomoniasis. Reported sensitivity is 100% compared to wet-mount and culture (5).

Test Information: Trichomonas vaginalis TMA

- **CPT code**: 87661
- **Test code**: SC00201
- **Price**: $48.99 each
- **Acceptable specimen types**: Endocervical swabs in an Aptima Unisex Swab Collection Kit, clinician collected vaginal swabs in an Aptima Multitest Swab Specimen Collection Kit, and female urine in an Aptima Urine Specimen Collection Kit.
- **Specimen handling**: After collection, swab specimens placed in the appropriate Collection Kit should be stored and transported between 2°C and 30°C, and must be analyzed within 60 days of collection. Avoid temperature extremes. Urine in Aptima Collection Kits can be stored at 2-30 °C for up to 30 days.
- **Turn-around time**: 1-3 days, testing performed on weekdays
- **Possible Results**: T. vaginalis rRNA detected, No T. vaginalis rRNA detected, or Invalid

Reference

1. **Weinstock, H., S. Berman, and W. Cates Jr.** 2004. Sexually transmitted diseases among American youth: incidence and prevalence estimates, 2000. Perspect. Sex. Reprod. Health **36**(1):6-10.
2. **Niccolai, L. M., J. J. Kopicko, A. Kassie, H. Petros, R. A. Clark, and P. Kissinger.** 2000. Incidence and predictors of reinfection with *Trichomonas vaginalis* in HIV-infected women. Sex. Transm. Dis. **27**:284-288.
3. **Nye, M. B., J. R. Schwebke, and B. A. Body.** 2009. Comparison of Aptima Trichomonas vaginalis transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. Am. J. Obstet. Gynecol. **200**:188.e1-188.e7.
4. **Wendel, K. A., E. J. Erbelding, C. A. Gaydos, and A. M. Rompalo.** 2002. *Trichomonas vaginalis* polymerase chain reaction compared with standard diagnostic and therapeutic protocols for detection and treatment of vaginal trichomoniasis. Clin. Infect. Dis. **35**(5):576-580.
5. Hologic Aptima Trichomonas vaginalis Assay package insert for Panther System. 503684 Rev. 008. Pg 20. https://www.hologic.com/sites/default/files/2020-07/503684-IFU-PI_008_01.pdf

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Acceptable Specimen Types

Collection Kit	Specimen Type	Aptima Combo 2 Assay (CT/GC)	Aptima Trichomonas vaginalis Assay
Aptima Multitest Swab Collection Kit (Orange)	Clinician Collected Vaginal Swab	✓	✓
	Patient Collected Vaginal Swab	✓	
	Clinician Collected Throat Swab	✓	
	Clinician Collected Rectal Swab	✓	
Aptima Unisex Swab Collection Kit (White)	Clinician Collected Endocervical Swab	✓	✓
Aptima Urine Specimen Collection Kit (Yellow)	Female Urine	✓	✓
	Male Urine	✓	

		
Aptima Multitest Swab Collection Kit (Orange)	Aptima Unisex Swab Collection Kit (White)	Aptima Urine Specimen Collection Kit (Yellow)

Updated 2/23/21