**SUMMARY**
Effective Wednesday, December 12 PeaceHealth Laboratories will provide a new, highly sensitive and specific assay to detect *Trichomonas vaginalis* using the APTIMA *T. vaginalis* assay (60109). This new assay is a qualitative nucleic acid amplification test that is FDA-approved to detect *T. vaginalis* in symptomatic or asymptomatic women using urine specimens, clinician-collected endocervical and vaginal swab specimens, and ThinPrep® Liquid Pap specimens.1

**BACKGROUND**
*T. vaginalis* is the most curable common sexually transmitted infection in the U.S. More than 7.4 million new infections are estimated to occur each year.3 Infection is more common in women than in men, and older women are more likely than younger to have been infected.3

**SYMPTOMS OF INFECTION**
Most women with *T. vaginalis* infections have minimal or no symptoms.4 If symptomatic, *T. vaginalis* infections can cause vaginitis, urethritis and cervicitis.3 Symptomatic women usually complain of vaginal discharge, vulvovaginal soreness and/or irritation. Dysuria is also common.4 Complications of infection with pregnant women include a higher probability of preterm delivery and delivery of low birth weight children. Infection with *T. vaginalis* may also facilitate transmission of HIV. Men with *T. vaginalis* infection are commonly asymptomatic or present with nongonococcal urethritis.2,4

**WHEN TO TEST**
- Testing for *T. vaginalis* should be performed in women seeking care for vaginal discharge.2
- Screening for *T. vaginalis* can be performed in asymptomatic or symptomatic women at high risk for infection (women who have new or multiple partners, have a history of sexually-transmitted diseases and/or use injection drugs).2
- This test should not be used to determine therapeutic failure or success since nucleic acid may persist following appropriate antimicrobial therapy.1

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**BENEFITS**
- Nucleic acid testing by Transcription-Mediated Amplification has the highest sensitivity to detect *Trichomonas vaginalis*
- Testing is FDA-approved for use with a wide range of female specimens: endocervical and vaginal swab specimens, female urine specimens and ThinPrep® Liquid Pap specimens
- Testing may be used to test asymptomatic women
- Simplified co-testing can be done on the same specimen collected for APTIMA *Chlamydia trachomatis* TMA and *Neisseria gonorrhoeae* TMA testing

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**Trichomonas vaginalis** by Transcription-Mediated Amplification (continued)

**ACCURACY OF THE APTIMA TRICHOMONAS VAGINALIS TESTING**

The sensitivity for *T. vaginalis* testing is highest in vaginal and endocervical swab collections compared to urine specimens. The APTIMA *T. vaginalis* assay has the highest analytical sensitivity compared to other commercially available molecular diagnostic testing.3

The average sensitivity of the APTIMA *T. vaginalis* assay has been reported to be 98.1% in vaginal specimens (96.6-100%). The traditional wet mount testing sensitivity is reported to be 60.7% (43.0-83.3%) and requires immediate evaluation of wet preparation slides for optimal results. All testing methods for *T. vaginalis* have a high specificity (ranging from 96.3-100% in vaginal specimens).3

**METHODOLOGY**

*T. vaginalis* by Transcription-Mediated Amplification uses the Gen-Probe APTIMA *T. vaginalis* assay. This test is a qualitative nucleic acid amplification test that detects the ribosomal RNA from *T. vaginalis*. A single specimen may be used to test for all three (Chlamydia Trachomatis, Neisseria Gonorrhoeae, and Trichomas vaginalis, TMA Amplified) by ordering 60109 and 68363.

**ADDITIONAL TEST OPTIONS**

68362  *Neisseria Gonorrhoeae*, TMA Amplified

68360  *Chlamydia Trachomatis*, TMA Amplified

68363  *Chlamydia Trachomatis* and *Neisseria Gonorrhoeae*, TMA Amplified

60109  *Trichomonas vaginalis*, TMA Amplified

**QUESTIONS?**

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**REFERENCES**


## ORDERING INFORMATION

**60109:** *Trichomonas vaginalis* by Transcription-Mediated Amplification  

**Methodology:** Qualitative target amplification test (Nucleic Acid Amplification Test)  

**Performed:** Tuesday through Friday and Sunday  

**Released:** Same day as tested  

**CPT Code:** 87798

## SPECIMEN REQUIREMENTS

**Collect:** Clinician-collected endocervical or vaginal swab specimen using the APTIMA Unisex Swab Specimen Collection Kit, female first catch urine in sterile urine container and transferred into the APTIMA urine collection kit, or ThinPrep® cervical specimen. Carefully follow the instructions printed on the APTIMA unisex swab and APTIMA urine collection kits.

**Handling:** Urine: Using the sterile pipette provided in the APTIMA urine collection kit, transfer urine to the APTIMA transport tube so the level of the urine is visible between the minimum and maximum fill lines on the tube. If urine is transported to the laboratory in the primary collection container (not transferred), sample must reach the laboratory in time for transfer to occur within 24 hours of collection.  

ThinPrep® specimen:  
**NOTE:** *T. vaginalis* by TMA cannot be performed as an add-on after Pap testing.

**Comment:** Sensitivity may be reduced with mucoid samples. To ensure proper endocervical sampling, excess mucus should be removed. To achieve optimal sensitivity, specimens must be collected and transported with appropriate collection kits following the provided instructions.

**Stability:**  
Swab: Ambient: 2 months; Refrigerated: 2 months; Frozen: 6 months  
Urine (transferred into APTIMA transport tube): Ambient: 1 month; Refrigerated: 1 month; Frozen: 6 months. Urine (not transferred): Ambient: 24 hours; Refrigerated: 24 hours. ThinPrep® (not transferred): Ambient: 30 days; Refrigerated: 30 days. After ThinPrep® sample has been transferred into the APTIMA specimen transfer tube: Ambient: 2 weeks; Refrigerated: 1 month; Frozen: 6 months.

**Transport:** Ambient, refrigerated, or frozen if in collection kit.

**Rejection Criteria:** ThinPrep® specimen already processed for the Pap; urine older than 24 hours that has not been transferred to the APTIMA urine transport tube. APTIMA unisex swab kit received containing white cleaning swab (large white swab is for preparatory cleaning of the endocervix and is unacceptable for testing), or received containing no swab; frozen urine specimen that has not been transferred into the APTIMA urine transport tube; catheterized urine specimens; urine specimen collected with urine preservatives; specimen collected in Abbott or BD transport medium.