

## MEMORANDUM

**TO: PHYSICIANS LABORATORY CLIENTS**

**FROM: GREGORY POST, Ph.D.  
DIRECTOR OF CLINICAL SERVICES**

**SUBJECT: AFFIRM VPIII (Test #678) – QUESTIONS AND ANSWERS**

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Beginning in October 2007, our laboratory began offering a state-of-the-art DNA probe test for the detection of bacterial vaginosis. This test detects clinically significant levels of the three most common pathogens associated with vaginitis: *Gardnerella vaginalis*, *Trichomonas vaginalis*, and *Candida species*. **Routine vaginal culture *is not recommended to diagnose vulvovaginitis or bacterial vaginosis due to large numbers of normal bacterial microflora present which can affect culture interpretation.***

The AFFIRM VPIII allows for rapid, consistent, and clinically relevant results. Here are some of the most commonly asked questions asked about this new molecular probe based system:

**Question: What makes the AFFIRM VPIII (test #678) a better method than the Wet Mount (test #630)?**

**Answer:** Compared to the AFFIRM VPIII, the wet mount test is only 50-75% sensitive for *Trichomonas*. The wet mount test needs to be performed immediately after collection. Using the "clue cells" seen on the wet mount as an indicator for bacterial vaginosis (BV) is not advised, since this can be highly variable from person to person. Wet mount results depend on the quality of the specimen, the skill of the observer, and the quality of the microscope. Approximately 25% of mixed infections are missed by microscopy. AFFIRM VPIII provides up to 60% greater sensitivity than the wet mount since it is based on direct nucleic acid probe technology and allows for superior detection of mixed infections. The AFFIRM VPII is unaffected by topical antifungal agents, lubricants, and menses which are seen in over 50% of typical wet mount specimens.

**Question: Why is this test so expensive?**

**Answer:** The cost and consequence of inadequate treatment or the inconvenience to patients misdiagnosed initially should be considered in the overall cost of the test. Failure to diagnose two of the most common causes of vaginitis (*Trichomonas vaginalis* and BV) could carry significant risks for your patient. These pathogens are associated with an increased risk of HIV infection, pre-term delivery, low birth rate delivery, and if left untreated, PID (Pelvic Inflammatory Disease). Physicians Laboratory accepts assignment from all insurers. Although the cost is higher than wet mounts or vaginal cultures, each pathogen tested in the AFFIRM VPIII has its own CPT code reimbursement.

**Question: Does the AFFIRM VPIII include testing for *Group B strep*, *Neisseria gonorrhoea*, and *Chlamydia*?**

**Answer:** No. Testing for *Group B strep*, *Neisseria gonorrhoea*, and *Chlamydia* is best performed using amplified technology rather than direct probe technology.