



# MEMO

**To:** All Regional Medical Laboratory (RML) Clients

**From:** Cindi Starkey, M.D., Ph.D., Chief of Molecular Diagnostics.  
Sonja Matthews MT (ASCP), SC, Director of Clinical Operations

**Date:** May 31, 2013

**Subject:** Vaginosis Panel Testing by B.D. Affirm™ Molecular Method

RML is pleased to announce that we are **now offering a vaginosis panel by molecular analysis**. We will be utilizing the Becton Dickinson Affirm™ test, which is a qualitative molecular test to detect the presence of *Candida* species, *Garnderella vaginalis*, and *Trichomonas vaginalis*. The detection threshold for *Candida* species and *Garnderella vaginalis* distinguish between normal flora and clinically significant levels of organisms. Microscopy detection for *Trichomonas vaginalis* can be negative in up to 50% of women with culture-confirmed trichomoniasis. The BD Affirm™ provides more accurate detection of trichomoniasis. There is a broad differential for the diagnosis of vaginitis, and successful treatment depends on an accurate diagnosis. Published performance data for the BD Affirm™ test is as follows:

	SENSITIVITY	SPECIFICITY	ACCURACY
<i>G. vaginalis</i> *	98.3%	100%	98.4%
<i>T. vaginalis</i> **	92.8%	99.9%	98.9%
<i>Candida species</i> *	82.3 %	98.4%	95.2%

\*Compared to culture (symptomatic patients)

\*\*Compared to wet mount (symptomatic and asymptomatic patients)

The CPT codes will be as follows:

	CPT codes
<i>G. vaginalis</i>	87510
<i>T. vaginalis</i>	87660
<i>Candida species</i>	87480

### Specimen requirement:

This test is validated for the following specimen type:

#### **BD Affirm™ VPIII Ambient Temperature Collection System**

This collection system consists of a sample collection tube, sterile swab, and ATTS (ambient temperature transport solution). The ATTS must be used with the sample. The sample is stable for 72 hours at ambient or refrigerated temperatures.

**NOTE: Specimens in Surepath™ media are not an acceptable specimen for this test**

**Test order name and code: VAG MOLEC [4604810]**

If you have questions, please contact Cindi Starkey, MD, PhD, Clinical Pathologist and Chief of Molecular Diagnostics, Gerald Miller, PhD, Chief of Immunology and Microbiology, or Sonja Matthews, MT (ASCP), SC, Director of Clinical Operations at 918-744-2553 or 800-722-8077.