Since vaginitis cannot be adequately diagnosed based solely on symptoms or physical examination, additional laboratory methods are required. It is common to have more than one microbial source cause vaginitis and a vaginal examination should include appropriate laboratory testing to detect all three microorganisms.

PeaceHealth Laboratories offers the BD Affirm VPIII Microbial Identification Test (BD Affirm) to detect and identify Candida species, *Gardnerella vaginalis* and *Trichomonas vaginalis* using a vaginal fluid specimen from a patient with symptoms of vaginitis. The BD Affirm test uses DNA probes to detect all three microorganisms using cutoffs to distinguish between normal flora and levels that correlate to vaginitis.

### VAGINITIS DEFINED
Vaginitis includes a spectrum of conditions that cause vulvovaginal symptoms that may include itching, burning, irritation and abnormal discharge. It is a common medical problem for women, most often caused by:

- Bacterial vaginosis from a mixture of bacteria (22-50% of symptomatic women)
- Vulvovaginal candidiasis caused most predominantly by *Candida albicans* (17-39%)
- The protozoan *Trichomonas vaginalis* (4-35%)

*Gardnerella vaginalis* is one of the most common causes of bacterial vaginosis. Vaginal candidiasis, or “yeast infection,” is the second most common vaginal infection and afflicts three-quarters of all adult women at least once during their lifetime.

*Trichomonas vaginalis* is a single-celled protozoan parasite that is acquired most frequently by sexual transmission (*trichomoniasis*). An estimated 3 million women in the United States acquire *trichomoniasis* every year, of which a smaller subset develop symptomatic vaginitis.

Vaginitis has a broad differential diagnosis and successful treatment frequently relies on an accurate diagnosis.
ABOUT THE ASSAY
The BD Affirm test is a more sensitive diagnostic test than both conventional clinical examination and wet mount testing to detect and identify symptomatic vaginitis. One sample is used for all three microorganisms (*Candida* species, *Gardnerella vaginalis* and *Trichomonas vaginalis*).

Specimen collection is an important step and requires the correct preparation of the specimen using the BD Affirm collection device (Affirm VPIII Ambient Temperature Transport System).

The sensitivity/specificity to detect the three pathogens are:

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tbody>
<tr>
<td><em>Candida</em> species</td>
<td>82.3%</td>
<td>98.4%</td>
</tr>
<tr>
<td><em>Gardnerella vaginalis</em></td>
<td>98.3%</td>
<td>100%</td>
</tr>
<tr>
<td><em>Trichomonas vaginalis</em></td>
<td>92.8%</td>
<td>99.9%</td>
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</tbody>
</table>

*Gardnerella vaginalis* is normally found in the vagina and detection, although suggestive, is not definitive proof of bacterial vaginosis. As such, detection of *Gardnerella vaginalis* should be interpreted in conjunction with other test results and clinical findings to support a diagnosis of bacterial vaginosis (vaginal pH, clue cells, positive amine odor test).

ADDITIONAL BENEFITS OF TESTING
Bacterial vaginosis (BV) and *Trichomonas vaginalis* during pregnancy are associated with adverse pregnancy outcomes including pre-term labor and birth. *Trichomoniasis* represents the most common curable STD in young, sexually active women. Most women found to have *trichomoniasis* (85%) report no symptoms.

Additionally, the genital inflammation caused by *trichomoniasis* facilitates the sexual transmission of HIV. As many as 746 new cases of HIV infection among women each year can be attributed to *Trichomonas vaginalis* infection in the United States.
REFERENCES


ORDERING INFORMATION

VPNAT
65389
Vancouver: Vaginal Pathogens by Nucleic Acid Test
Oregon and Longview: Vaginal Pathogens DNA Direct Probes

Methodology: DNA Probe
Performed: Daily
Released: Same day as tested
CPT Code: 87800

SPECIMEN REQUIREMENTS

Supplies: Vancouver: Request from PeaceHealth Laboratories’ courier
Oregon and Longview: Order #100342

Collect: Vaginal fluid specimen using the Affirm VPIII Ambient Temperature Transport System. Follow instructions printed on the insert.

Stability: Specimen in transport system stable 72 hours ambient or refrigerated.
Specimen not in transport system stable 1 hour ambient or 4 hours refrigerated.
All specimens unstable frozen.

Transport: Ambient or refrigerated

Comments: The Affirm test is a DNA probe-based diagnostic test designed to detect the presence of Candida species, Gardnerella vaginalis, and Trichomonas vaginalis in vaginal fluid specimens.

Rejection Criteria: Delayed transport; leaking container; frozen specimen. Male specimen. Specimen source other than vaginal.

QUESTIONS?

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