



# Women's Health

## Vaginosis Profile Q&A

### What is the Vaginosis Profile?

The Affirm™ VPIII Microbial Identification Test is a DNA probe test intended for detecting and identifying *Candida* species, *Gardnerella vaginalis* and *Trichomonas vaginalis* nucleic acid in vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis.

- *Gardnerella vaginalis* is the most common agent causing vaginitis/vaginosis.
- *Candida* species is the second most common agent - due to yeast/fungal infection.
- *Trichomonas vaginalis*, the least common agent, is a sexually transmitted disease caused by a parasitic infection.<sup>5, 8</sup>

### Potential Benefits of the Vaginosis Profile:

- Reduces repeat patient visits and complications due to improper diagnosis.
- Minimizes potential for missed diagnosis of mixed infections.

### Why is it important to test for mixed infections?

- 25% of vaginal infections are mixed infections which are frequently missed by microscopy.<sup>9, 14</sup>
- Physicians who use the Affirm VPIII can quickly detect mixed infections and provide appropriate drug combination therapy.

### Should this test be performed on pregnant patients?

#### What are the benefits?

- Screening for Bacterial Vaginosis may be considered in women at high risk for preterm labor (women with a history of preterm delivery, a low pre-pregnant weight of less than 50 kg, or both).<sup>4, 19</sup>
- The treatment of Bacterial Vaginosis in early pregnancy might reduce the incidence of premature delivery by 50%.<sup>4</sup>

#### What are the specimen transport requirements?

The Vaginosis Profile uses the Affirm VPIII Ambient Temperature Transport System (ATTS), which is a sterile ready-to-use system intended for the collection, transport and preservation of vaginal specimens for use only with the Affirm VPIII Microbial Identification Test. The ATTS should be used with those specimens where transport times are expected to exceed 1 hour at ambient temperature or 4 hours refrigerated. The ATTS enables specimen transport for up to 72 hours at ambient temperature.

#### What about difficult specimens?

Factors such as douches, lubricants or menses are present in 50% of specimens, and will obscure microscopic examinations.<sup>15</sup> The Vaginosis Profile is not hampered by these factors, thus improves accuracy of diagnosis.

### The BD Affirm VPIII detects clinically significant levels of vaginal pathogens. What does this mean?

*Gardnerella vaginalis* and *Candida* species exist as normal flora in 50% of women. The Vaginosis Profile detection threshold is set above levels of normal flora, and detects only clinically significant levels (disease state) of *Gardnerella* and *Candida* species.<sup>1, 15-17</sup> Detection thresholds as published in the Affirm VPIII package insert are:

- *Gardnerella vaginalis* - 2 X 10<sup>5</sup> - CFU/mL
- *Candida* species - 1 X 10<sup>4</sup> - CFU/mL
- *Trichomonas vaginalis* - 5 X 10<sup>3</sup> - Trichomonads/mL

### What does the *Candida* species probe detect?

*C. albicans*, *C. tropicalis*, *C. glabrata*, *C. kefyr*, *C. krusei*, *C. parapsilosis* - all are associated with vulvovaginal candidiasis.

### Organisms other than *Gardnerella vaginalis* cause BV - why aren't other microbes detected?

*Gardnerella vaginalis* is selected as the sentinel indicator for BV - when the population of this organism exceeds 2 X 10<sup>1</sup>, it is an indication of active infection caused by multiple organisms.<sup>3, 16</sup>

## References

1. Nugent et al. 1991. *J. Clin Microbiology* 29(2): 297-301.
2. Kaufman. 1988. *Am. J. Obstet. Gynecol.* 158 (4): 986-988.
3. Faro. 1966. *Int. J. Fertile Menopausal Study* 41 (2): 115-123.
4. Morales et al. 1994. *Am. J. Obstet. Gynecol.* 171 (2): 345-349.
5. Cotch et al. 1997. *Sex Transm. Dis.* 24 (6): 353-362.
6. Hautch et al. 1995. *N. Engl. J. Med.* 333 (26): 1732-1736.
7. Paige et al. 1998. *J. Nurse-Midwifery* 43 (2): 83-89.
8. McGregor, et al. 1995. *Am. J. Obstet. Gynecol.* 173 (1):157-167.
9. Master, et al. 1998. *Abstr. C-165, p. 158. Abstr. 98 "Gen.Mtg. Am. Soc. Microbiol.*
10. Briselden et al. 1998. *J. Clin. Microbiol.* 32 (1): 148-152.
11. Spiegel et al. 1983. *J. Clin. Microbiol.* 18 (1):116-132.
12. Mead. 1998. *Cont. Ob/Gyn. January*: 116-132.
13. Ferris et al. 1996. *J. Fam. Pract.* 42 (6): 595-600.
14. Ferris et al. 1996. *J. Fam. Pract.* 41 (6): 575-581.
15. BD Affirm VPIII package insert.
16. Sobel. 1990. *Med. Clinics N. Am.* 74 (6): 1573-1602.
17. Isenberg and D'Amato. 1995. In Murray et al. (ed.), *Manual of Clinical Microbiology*, 6th ed. ASM, Washington, D.C.

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## Vaginosis Profile

### Test Code:

Vaginosis Profile

### Test Synonyms:

Candida species; Gardnerella vaginalis

Trichomonas vaginalis

### Methodology:

Nucleic acid probe

### CPT Codes:

87840 Candida species DNA probe

87510 Gardnerella vaginalis DNA probe

87660 Trichomonas vaginalis DNA probe

### Turnaround Time:

2-3 days

### Specimen Requirements:

Vaginal fluid collected with BD Affirm™ VPIII Ambient Temperature Transport System (ATTS) at 20-25°C

### Specimen Stability:

Stable at 20-25°C for 3 days and refrigerated for 3 days

### Storage & Handling:

Ship specimens at ambient

### Causes for Rejection:

Frozen swab specimen; Swabs submitted in media other than ATTS

## BD Affirm™ VPIII Ambient Temperature Transport System

