Translating the power and the precision of **DNA** probe technology into better patient care.

From the complex mixture of cellular material found in a vaginal sample, only DNA probe technology has the power to selectively target organisms by their genetic “fingerprints.”

Processing a single sample, the **BD Affirm VPIII** Test uses complementary sequences of DNA that bind or hybridize only with the nucleic acid of targeted organisms. This hybridization reaction is both highly sensitive and specific, and results in the simultaneous detection and identification of multiple pathogens through clearly visible color reactions.

By helping the clinician more precisely match treatment with the disease, the **BD Affirm VPIII** Test offers an important aid to better laboratory practice and better patient care.

The **BD Affirm VPIII** Test detects and identifies vaginitis pathogens from single and mixed infection samples, to help make diagnosis and therapy more certain.

**Objective Differential Results** for **Three Vaginitis Pathogens**

- Rapid, easy-to-read results.
- Objective differential detection and identification.
- Positive and negative procedural controls in every test.

**Simple, Convenient Procedure**

- Easily reproducible by all laboratory technologists.
- Requires no advanced training.
- Less than 5 minutes total hands-on time plus walkaway convenience.

**More Sensitive and Specific Than Traditional Methods**

The **BD Affirm VPIII** Test detects and identifies vaginitis pathogens from single and mixed infection samples, to help make diagnosis and therapy more certain.

**Translating the power and the precision of **DNA** probe technology into better patient care.**

**From start to finish, the **BD Affirm VPIII** Test delivers results at your convenience.**

**The **BD Affirm VPIII** Test detects and identifies vaginitis pathogens from single and mixed infection samples, to help make diagnosis and therapy more certain.**

**Easy-to-Read Results**

**POSITIVE** result is a visible blue-colored bead. Built-in procedural controls for each sample ensure quality.

**Straightforward Procedure:**

**Sample Preparation**

Lyse action releases microbial nucleic acid in 10 minutes; requires less than 2 minutes hands-on time.

**Walkaway Automation**

DNA probe hybridization and color development occurs in just under 33 minutes.

**Easy-to-Read Results**

**POSITIVE** result is a visible blue-colored bead. Built-in procedural controls for each sample ensure quality.

**Microscopy**

**Affirm VPIII**

**Comparison to clinically significant culture.**

**Comparison to Gram Stain scored for BV in patients with BV.**

**Comparison to Diamond’s culture and wet mount.**

**Represents an overall average sensitivity.**

**BD Affirm VPIII Test vs. Wet Mount Microscopy Methodology**

**Objective Differential Results**

- Rapid, easy-to-read results.
- Objective differential detection and identification.
- Positive and negative procedural controls in every test.

**Simple, Convenient Procedure**

- Easily reproducible by all laboratory technologists.
- Requires no advanced training.
- Less than 5 minutes total hands-on time plus walkaway convenience.

**More Sensitive and Specific Than Traditional Methods**

The **BD Affirm VPIII** Test detects and identifies vaginitis pathogens from single and mixed infection samples, to help make diagnosis and therapy more certain.

**Translating the power and the precision of **DNA** probe technology into better patient care.**
The only direct specimen DNA Probe Test for Candida species, Gardnerella vaginalis and Trichomonas vaginalis.

**METHODOLOGY:**
Automated DNA probe sandwich assay.

**RESULT:**
Visible color reaction.

**PROCEDURE:**
Straightforward; requires no advanced training.

**HANDS-ON TIME:**
Total less than 5 minutes.

**TIME TO RESULT:**
Total less than 1 hour.

**SAMPLE:**
Vaginal fluid sample.

**SAMPLE COLLECTION AND TRANSPORT**

**FOR UP TO 72-HOUR STABILITY AT AMBIENT TEMPERATURE USE**
BD Affirm™ VPIII Ambient Temperature Transport System
Package of 10………………….446253
Carton of 100………………….446255

**FOR TRANSPORT TIMES < 4 HOURS:**
BD Affirm™ VPIII sample collection sets — 4 hours refrigerated; 1 hour at room temperature

For more information, contact your Local BD Representative or call BD Biosciences at 800-553-3470 today.
The BD Affirm™ VPIII Microbial Identification Test uses DNA probe technology to accurately and quickly identify Candida species, Gardnerella vaginalis and Trichomonas vaginalis.

- Results are available in less than an hour, so treatment can begin without delay
- Detects mixed infections with one vaginal swab sample
- High sensitivity and specificity

Easy as 1, 2, 3

**Sample preparation:** Lysis action releases microbial nucleic acid in 10 minutes

**Walkaway automation:** DNA probe hybridization and color development occur in just under 33 minutes

**Easy-to-read results:** Positive result is a clearly visible blue dot; built-in procedural controls for each sample ensure quality

Accurate results with DNA probe technology

**Clear results:** Provides objective results; built-in procedural control

**Detect mixed infections:** One patient sample gives you results for Candida species, G. vaginalis and T. vaginalis

**Efficient:** Up to six samples in less than an hour
Vaginal infections: The power of DNA technology for better patient care

The BD Affirm™ VPIII System

• No specialized facilities required: Unlike other molecular tests, such as PCR-based tests, BD Affirm does not require specialized facilities.

• No specialized personnel needed: Easy to learn, easy to use

• Efficient use of staff time: Hands-on time is less than 2 minutes

• Quick turnaround time: Up to six results in less than an hour

BD Affirm performance data

<table>
<thead>
<tr>
<th></th>
<th>SENSITIVITY</th>
<th>SPECIFICITY</th>
<th>ACCURACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>G. vaginalis*</td>
<td>98.3%</td>
<td>100%</td>
<td>98.4%</td>
</tr>
<tr>
<td>T. vaginalis**</td>
<td>92.8%</td>
<td>99.9%</td>
<td>98.9%</td>
</tr>
<tr>
<td>Candida species*</td>
<td>82.3%</td>
<td>98.4%</td>
<td>95.2%</td>
</tr>
</tbody>
</table>

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

Call 1-800-999-4951 ext. 3597 to get started with BD Affirm today
Or email: BD_Womenshealth@bd.com

INTENDED USE: The Affirm™ VPIII Microbial Identification Test is a DNA probe test intended for use in the detection and identification of Candida species, Gardnerella vaginalis and Trichomonas vaginalis nucleic acid in vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis.¹

¹ BD Affirm™ VPIII Microbial Identification Test [package insert]. Sparks, MD: BD Diagnostics; 2010.