

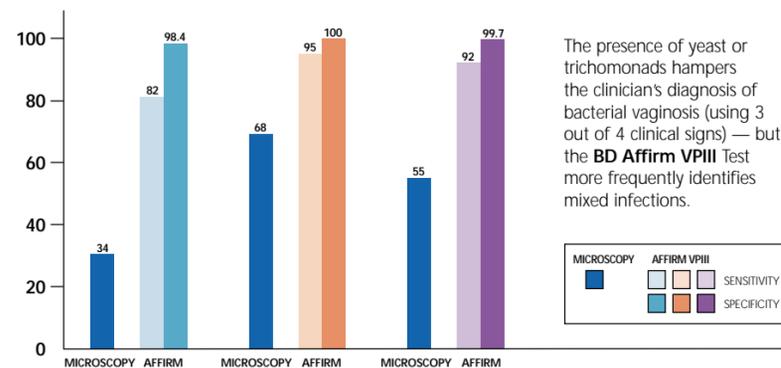
Translating the power and the precision of DNA probe technology into better patient care.

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.

BD Affirm VPIII Test vs. Wet Mount Microscopy Performance



- Candida** Comparison to clinically significant culture.
- Gardnerella** Comparison to Gram Stain scored for BV in patients with BV.
- Trichomonas** Comparison to Diamond's culture and wet mount.
- Microscopy** Represents an overall average sensitivity.

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.

Straightforward Procedure:



Sample Preparation

Lysis 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.

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.

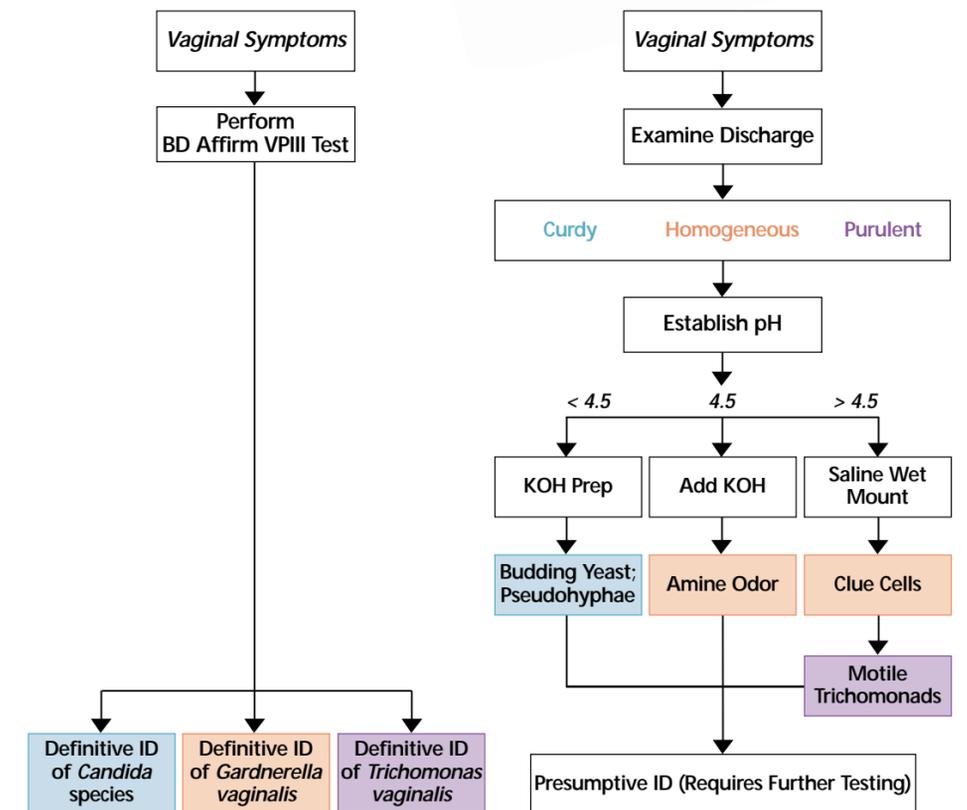
More Sensitive and Specific Than Traditional Methods

- Up to 30% more sensitive than microscopy.
- Reports only clinically significant levels of organisms.
- Equivalent to clinically significant culture for *Candida*, Scored Gram Stain for *Gardnerella* and Diamond's culture for *Trichomonas*.

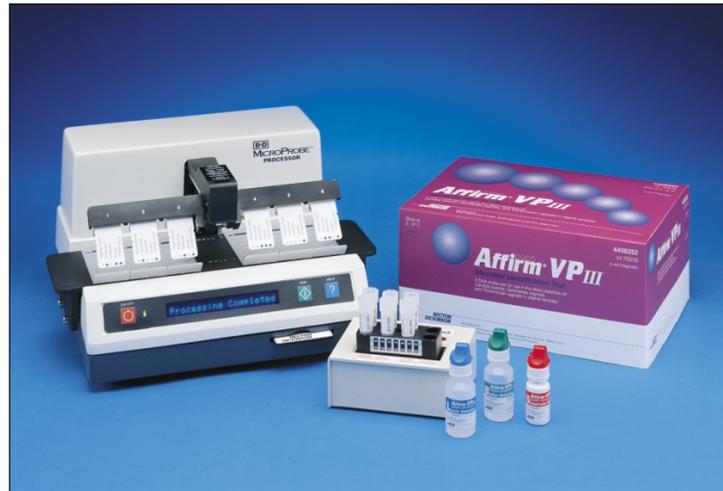
Simple, Convenient Procedure

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

BD Affirm VPIII Test vs. Wet Mount Microscopy Methodology



BD Affirm™ VPIII



The DNA Probe Test that quickly identifies *Candida*, *Gardnerella* and *Trichomonas*.

The **BD Affirm™ VPIII** Microbial Identification Test is the first diagnostic test that can objectively differentiate the three major causes of vaginitis/bacterial vaginosis (BV) from a single sample, with total time-to-results under 1 hour!

Its clearly visible color reaction eliminates the subjectivity inherent in direct microscopic methods. Plus, the straightforward procedure requires no advanced training to perform.

Best of all, the **BD Affirm VPIII** Test delivers accurate organism identification even from mixed infections, “difficult” specimens or hard-to-diagnose patients.

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: **New!**

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.



BD Biosciences

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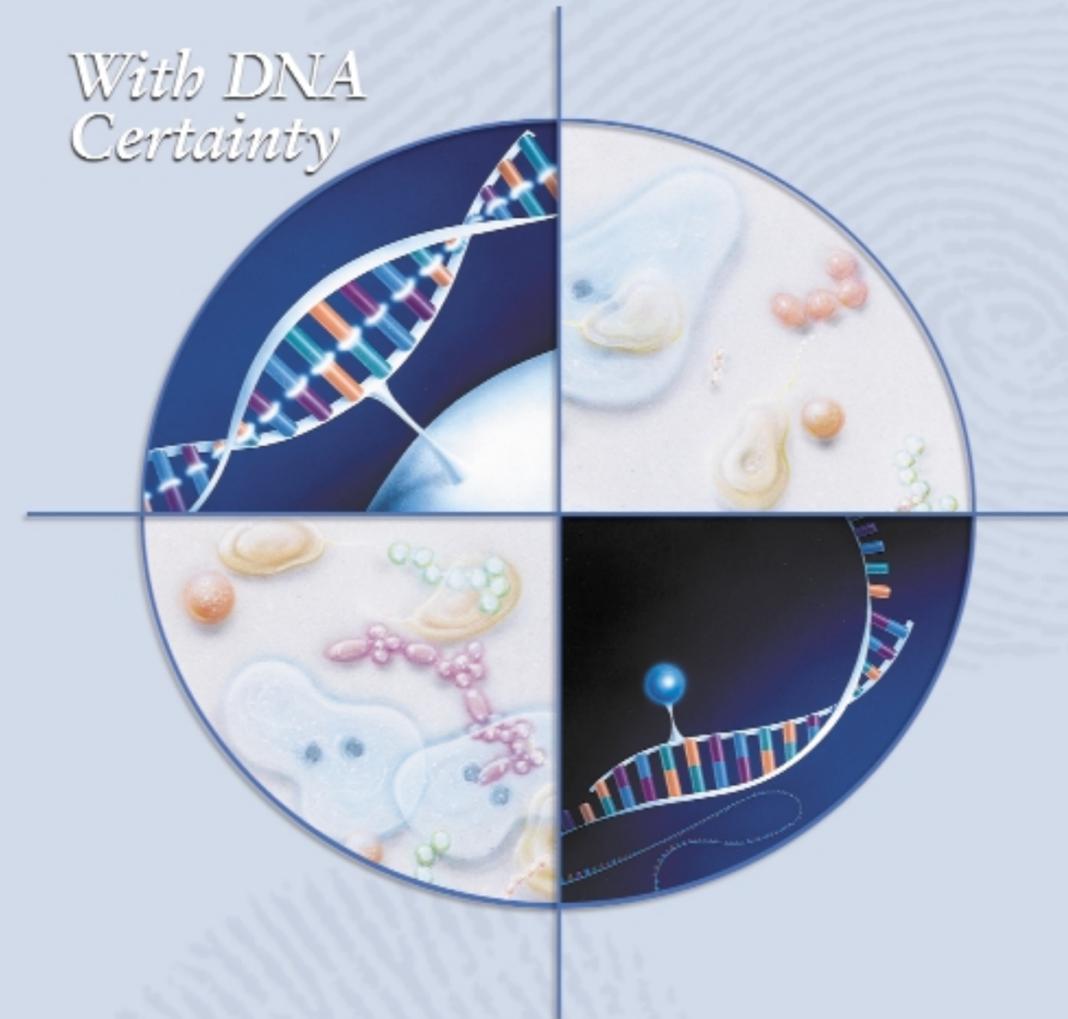
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With DNA
Certainty



Indispensable to
human health

**The Only Diagnostic Test
that Differentiates and Identifies
3 Vaginitis Pathogens from
a Single sample.**

A fast, simple way to diagnose vaginitis



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 specificity¹



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



Helping all people
live healthy lives



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 facilities¹
- **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 data¹

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

*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.

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