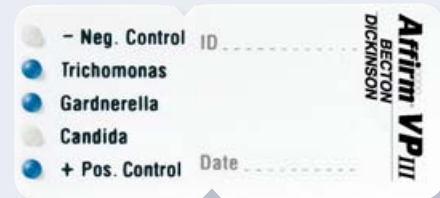


Evaluation of the Affirm™ VPIII RT Transport System for the detection and identification of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* from vaginal fluid specimens

Fuller D, H. Brown, T. Davis, J. Schwebke, and S. Hillier
Department of Obstetrics and Gynecology and Pathology, St. Vincent Hospitals and Health Services,
Indianapolis, IN.

“CONCLUSION: Data showed that the Affirm™ VPIII Ambient Temperature Transport System (ATTS) results were within the manufacturer-specified +/- 10% of the control swab (no transport reagent) at all 4 time intervals (0, 24, 48, and 72 hours) for all three organism results: *Trichomonas*, *Gardnerella*, and *Candida*. Accurate Affirm™ VPIII results can be obtained from vaginal specimens that have been delayed up to 72 hours prior to testing with the use of the Affirm™ VPIII Ambient Temperature Transport System.”

J Clin Microbiol. 2001 Sept;39(9):3197-9



Acute Obstetrics: A Practical Guide

Martha C.S. Heppard, M.D., Thomas J. Garite, M.D.

Excerpt from Obstetric Complications; Chorioamnionitis

“Affirm VPIII DNA probe testing for *Gardnerella vaginalis* may be performed if this organism is of concern and the equipment is available (45 minute turn-around time, 95% sensitivity, and 99% specificity make it extremely valuable).”

Excerpt from Obstetric Complications; Premature Rupture of the Fetal Membranes

“Whether or not these findings are present, consider obtaining a vaginal swab and testing for BV, *Trichomonas*, GBS, *Bacteroides*, and *Ureaplasma*. Affirm VPIII DNA probe testing is the preferred method of evaluation for BV and *Trichomonas* if available because of its significantly higher sensitivity and specificity than wet mount and at least equal sensitivity and specificity but more rapid turnaround time than culture.”

Excerpt from Appendices; Sexually Transmitted Disease Treatment Guidelines

“...however, the most accurate method of diagnosis is DNA testing (office testing for this is available from Becton Dickinson & Co., Affirm VPIII microbial identification test). Asymptomatic infections are common.”

Acute Obstetrics: A Practical Guide, 3rd ed. 2002. A Mosby Handbook.



BD Diagnostics
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800.638.8663
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In their own words...

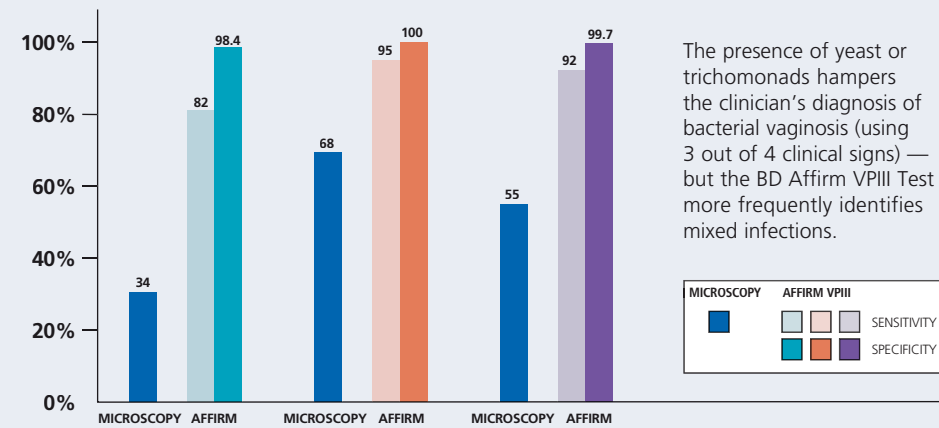
BD Affirm™ VPIII System Diagnosing Vaginal Infections

BD Diagnostics Laboratory and Healthcare Efficiency Program
● Enhancing Economic Value ● Improving Medical Outcomes ● Increasing Laboratory Efficiency

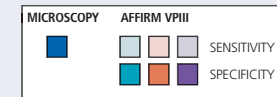


BD
Helping all people
live healthy lives

BD Affirm™ VPIII Test vs. Wet Mount Microscopy Performance



The presence of yeast or trichomonads hampers the clinician's diagnosis of bacterial vaginosis (using 3 out of 4 clinical signs) — but the BD Affirm VPIII Test more frequently identifies mixed infections.



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.

Clinical evaluation of Affirm VPIII in the detection and identification of *Trichomonas vaginalis*, *Gardnerella vaginalis*, and *Candida* species in vaginitis/vaginosis.

Brown HL, Fuller DD, Jasper LT, Davis TE, Wright JD.
Department of Obstetrics, Gynecology and Pathology, St. Vincent Hospitals and Health Service, Indianapolis, IN.

"CONCLUSIONS: The Affirm VPIII test is a more sensitive diagnostic test for detection and identification of symptomatic vaginitis/vaginosis than conventional clinical examination and wet mount testing."

Infect Dis Obstet Gynecol. 2004;12(1):17-21.

DNA hybridization test: rapid diagnostic tool for excluding bacterial vaginosis in pregnant women with symptoms suggestive of infection.

Witt A, Petricevic L, Kaufmann U, Gregor H, Kiss H.
Department of Obstetrics and Gynecology, University of Vienna Medical School, Austria.

"The DNA hybridization test compared well with Gram stain and can be used as a rapid diagnostic tool to exclude bacterial vaginosis."

J Clin Microbiol. 2002 Aug;40(8):3057-9.

"The Affirm VPIII's differential diagnosis with DNA certainty has allowed for targeted therapies to multiple organisms."

▶ Theresa Buckson, M.D.
Women's HealthCare Associates; Annapolis, Maryland



"Since putting into practice the Affirm VPIII system, we have noticed fewer return patient visits for the same symptoms as well as greater patient satisfaction."

▶ Debra Hardy-Cartwright, M.D., F.A.C.O.G.
Women's HealthCare Associates; Annapolis, Maryland



"Diagnosing vaginal infections required time consuming microscopic examinations, maintenance of the microscope, and delicate handling of the glass slide. The Affirm VPIII has helped us become more efficient in the diagnosis of vaginal infections."

◀ Dale Maynard, Office Manager
Women's HealthCare Associates; Annapolis, Maryland



"Using the Affirm VPIII, and testing for all three pathogens *Candida* species, *Gardnerella vaginalis* and *Trichomonas vaginalis*...as a panel, we found that patients who had recurring symptoms suffered from mixed infections of two or more pathogens."

◀ Loretta Trumble, C.R.N.P.
Women's HealthCare Associates; Annapolis, Maryland

