

# OVERCOMING VAGINITIS DIAGNOSIS DIFFICULTIES

DNA probe technology identifies target organisms based on genetic fingerprints.

By John Favara

Every year, more than 10 million obstetrician-gynecologist office visits in the U.S. are attributed to vaginitis,<sup>1</sup> yet much remains misunderstood about this condition—the pathogens that cause it, its medical consequences and its diagnosis.

Vaginitis is defined by a relatively narrow spectrum of vulvovaginal symptoms, which include itching, burning, irritation and abnormal discharge. This small range of symptoms, however, belies a broad differential diagnosis. Each of the three most common diagnoses—bacterial vaginosis or BV (caused by a polymicrobial infection, which includes *Gardnerella vaginalis*), candida or yeast infection (most commonly caused by *Candida albicans*) and trichomoniasis (attributed to *Trichomonas vaginalis*)—requires a different treatment regimen.

Accurate vaginitis diagnosis, however, is often elusive. This stems from a combination of shortfalls of current methodologies, the propensity of some physicians to treat empirically based on the patient's symptoms and history alone, and the tendency of some patients to self-diagnose and self-treat, further complicating proper diagnosis. Timely diagnosis and treatment are especially important, however, in light of growing evidence linking vaginitis and susceptibility to serious medical problems.

DNA probe technology is being used in vaginitis diagnosis, helping to improve patient care and overcome laboratory workflow chal-

lenges posed by traditional diagnostic approaches. Moreover, this transformation in how vaginitis is diagnosed is further elevating the role of the clinical laboratory in delivering effective and efficient patient care.

## Vaginitis Background

Most common in women of reproductive age, vaginitis develops when the vaginal flora is altered either by the introduction of a pathogen or changes in the vaginal environment, which allows existing pathogens to proliferate. More than 90 percent of vaginitis cases are caused by Gardnerella (BV), Candida and/or Trichomonas.<sup>2,3</sup>

The condition has traditionally been viewed by women and clinicians as an annoyance rather than a source of potentially serious medical complications. Growing data, however, suggest that vaginitis should be taken more seriously.

Bacterial vaginosis, for example, which comprises 15 percent to 50 percent of vaginitis cases,<sup>4,5</sup> has been linked to the acquisition of sexually transmitted infections, pelvic inflammatory disease, human immunodeficiency virus (HIV) and infections following gynecologic surgery.<sup>6,7</sup> Several studies also have linked it to low birth weight, premature rupture of membranes and premature births.<sup>8-10</sup>

Trichomoniasis is a common sexually transmitted infection, encompassing 15 percent to 20 percent of vaginitis cases.<sup>11</sup> This infection is associated with increased risk of delivering low birth weight and preterm babies.<sup>12</sup> Studies also indicate that it increases the transmission rate of HIV,<sup>13</sup> of particular concern for African American women who have higher rates of Trichomonas infection.<sup>14</sup>

Candida, or yeast, infections account for approximately 33 percent of vaginitis cases.<sup>1</sup> Yeast infections are particularly problematic because women with symptoms often assume they have a yeast infection and begin over-the-counter (OTC) treatment. Frequently, this self-treatment is ineffective and can hamper an accurate diagnosis once the woman is evaluated by a clinician.

## Current Diagnosis

Vaginitis diagnosis typically begins with a history of the vaginal symptoms and a physical examination. Leading clinical guidelines<sup>15,16</sup> also recommend that specimens be obtained for vaginal pH determination, amine (“whiff”) test and microscopy. Some clinicians conduct this evaluation themselves, while others send samples to the laboratory for microscopy.

Microscopy is generally considered to be the clinical standard in vaginitis diagnosis; however, some clinicians skip it altogether. One study found that 42 percent



of physicians did not perform microscopy as part of any evaluation of vaginitis.<sup>17</sup> If after the above testing the diagnosis is not obvious, or if microscopy is not used, the clinician may order a culture. Additionally, a Gram stain is frequently used for BV diagnosis.

These diagnostic approaches for vaginitis have significant clinical limitations, most notably, the relatively low sensitivity of microscopy. For yeast, microscopy's sensitivity is 40 percent to 60 percent;<sup>18</sup> for Trichomonas, it is 40 percent to 80 percent;<sup>19</sup> and for BV, it is 55 percent.<sup>20</sup> Complicating matters further is that in nearly 25 percent of vaginitis cases, more than one pathogen is involved.<sup>21</sup>

While culture is more sensitive, it too has diagnostic drawbacks. BV, for example, is caused by an overabundance of organisms that are part

## The time is right for vaginitis testing to enter the age of DNA probe testing.

of the natural vaginal flora, so the mere presence of these organisms on a culture does not necessarily mean that the patient has BV. Proper diagnosis is further hampered by women self-treating using OTC medications, which can interfere with microscopy and culture

results. A review found that only 33.7 percent of women evaluated who had self-diagnosed and purchased OTC treatments for candida actually had candida.<sup>22</sup>

Beyond clinical limitations, microscopy is time consuming and typically done as a stat, which can disrupt laboratory workflow. Culture is expensive and takes several days to obtain results. As stated, some clinicians bypass both microscopy and culture, instead treating the patient based on symptoms and physical examination alone. In one study, Wiesenfeld and Macio found that treatment without adequate evaluation of etiology of the symptoms occurred in 54 percent of visits in which medication was prescribed.<sup>17</sup>

### DNA Probe Technology

DNA probe technology is available to identify target organisms based on their genetic "fingerprints." For example, the BD Affirm™ VPIII test (BD Diagnostics) uses nucleic acid hybridization technology to simultaneously test for each of the three pathogens that cause 90 percent of vaginitis cases. Laboratory-developed tests are also available, as well as tests that detect individual vaginitis-causing pathogens. These tests are polymerase chain reaction-(PCR) based, which require specialized facilities and operator skills.

Studies have shown the technology to be 92 percent sensitive in diagnosing *T. vaginalis*, 95 percent sensitive for *G. vaginalis* and 82 percent for *Candida*.<sup>23</sup> This is significantly more sensitive than microscopy, and comparable to the clinical standards of culture for *Candida*, Scored Gram Stain for *Gardnerella* and Diamond's culture for *Trichomonas*.

Some clinicians are already ordering DNA probe testing for all vaginitis cases, while others may use it for select, challenging cases. Some clinicians even perform the test in their offices.

### Technology at Work

The growing use of DNA probe testing for vaginitis diagnosis is certain to give the laboratory more prominence in providing cost-effective and enhanced care for this prevalent medical problem among women. This trend is already occurring in other clinical areas such as

STD screening and HIV monitoring, where DNA testing has become the staple in their clinical pathway.

Ochsner Health System, for example, is a nonprofit, academic, multi-specialty healthcare delivery system comprising seven hospitals and more than 35 health centers located throughout Southeastern Louisiana. After Hurricane Katrina forced other area hospitals to close in 2005, Ochsner acquired much of the shuttered hospitals' patient base.

This growth subsequently increased volumes for the microbiology laboratory at the Ochsner Medical Center Main Campus in New Orleans, which serves most of the organization's facilities. This prompted Wanda Eppling, microbiology supervisor in the Department of Pathology and Laboratory Medicine, to seek new ways to increase her staff's efficiency.

"At the time, we had too many wet preps to read for vaginitis testing, and they didn't fit into our workflow," Eppling recalls. "These wet mounts require stat handling, which meant that our tech would have to drop what he was doing to read them. It was really putting a strain on our staff."

Alfred Robichaux, III, MD, chairman of the Department of Obstetrics and Gynecology at Ochsner, learned about an automated DNA probe test for vaginitis and thought it could benefit Ochsner's patients while alleviating some of his department's workflow and other issues related to vaginitis testing.

"Up until that point, our ob/gyns and residents were doing microscopy to diagnose vaginitis cases," says Dr. Robichaux. "After the storm, our patient volumes were rising and microscopy was taking up too much time. Further, vaginitis patients would often go to our center's internists first, but they were not as experienced with microscopy or didn't have the proper equipment. So, these women would then typically have to make a separate appointment with the ob/gyn department for the microscopy. It was a very inefficient process."

The hospital adopted the DNA probe test in late 2006, and its laboratory is now running about 700 vaginitis samples per month, with testing volumes on the rise. The switch has improved patient care; it can test for three pathogens at the same time.

Adds Eppling, "Wet mounts were difficult for us because in some cases our clinics were 70 miles away. This made evaluating samples for trichomonas challenging, as these samples need to be fresh. The test eliminated that problem because it does not require fresh samples."

From a workflow standpoint, the switch has freed the staff significantly, she says. "Before, I had a parasitologist dedicated to reading the wet mounts, which was not a good use of a staffer's time—especially one with such a specialized expertise. Now, I can split the bench up," noting that the person who runs the test is also responsible for other things, such as instrument maintenance or antibiotic QC.

The time is right for vaginitis testing to enter the age of DNA probe testing. Given the medical problems it can lead to, vaginitis deserves to be higher on healthcare providers' radar screens. And having objective, proven and consistent methods for its diagnosis can help it get there. ■

*John Favara is senior marketing manager, BD Diagnostics.*



For a list of references and an additional case study on how vaginitis diagnosis was improved in an emergency department, visit our Web site at [www.advanceweb.com/labmanager](http://www.advanceweb.com/labmanager)

# VAGINITIS IN THE ED

## A case study that illustrates improved diagnosis in a hospital emergency department.

By John Favara

**P**arkview Medical Center is a licensed, 305-bed regional hospital and certified Level II Trauma Center serving Pueblo and 14 surrounding counties in southeastern Colorado. Many of the hospital's patients lack health insurance and, as a result, use the Emergency Department for more routine healthcare needs.

When it comes to vaginitis testing, Parkview's microbiology laboratory supervisor, Lana Fairbanks, MT(ASCP)SM, estimates that about 95 percent of the lab's cases come from the Emergency Department (ED). "Many of our patients come to the hospital with more serious conditions like pelvic inflammatory disease," she says. "We typically screen many of these patients for BV, Trichomonas and Candida, as well as other STDs like Chlamydia trachomatis and Neisseria gonorrhoeae."

### Mutual Frustration

The lab had been using microscopy for vaginitis detection, including the wet prep, as well as the Nugent Gram stain scoring system for BV. The ED doctors, however, had generally been frustrated by the results. "They felt that we weren't catching enough cases

of Trichomonas and the BV smear results were often ambiguous," says Fairbanks. "Because BV smear interpretation requires a certain level of expertise, the microbiology staff often found themselves amending or revising reports the next day."

A major challenge, according to Fairbanks, is in the transport time required to get the samples from the ED to the microbiology lab, which meant that trichomonas motility—key to detection—could no longer be observed under the microscope. Additionally, the smaller, night-shift staff felt even more challenged by the workload and the focused attention required for microscopy.

### Ambitious Adoption

When Fairbanks proposed adopting the Affirm VPIII DNA probe test for vaginitis diagnosis, in place of the "manual" methods the lab had been using, the ED doctors were immediately supportive. "We didn't need to talk the doctors into it," she says. "Getting information from genetic material, rather than from subjective review, is hard to argue with."

According to Candice Sobanski, MD, medical director for Parkview's Emergency Department, use of the Affirm test has improved diagnosis and overall patient management. "We've had many more positive results for BV and trichomonas, rather than 'unable to determine,'" he says. "With the number of walk-in patients who may be difficult to track down for follow-up, it's especially important to get the diagnosis right the first time so the patient can leave the facility with the proper prescription in hand."

Fairbanks says the use of DNA probe testing has also improved her staff's efficiency. "Our techs really like this test because they can walk away and perform other tasks while the test is running," she continues. "Before, they were stuck on one bench looking for something in the microscope."

### On the Rise

Parkview's microbiology lab is now doing about 90 DNA probe tests per month for vaginitis testing, and this number continues to rise each year. The hospital recently opened a satellite ED facility about eight miles away, and installed a separate Affirm VPIII test on-site. ■

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