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**A Call to Action:**

Vaginal pH Level and its Role  
in Women's Health and Safety

# Disclosure

- ✿ James C. Caillouette, MD, discloses the following:
  - ✿ Inventor – vaginal pH screening kit
  - ✿ Ownership interest – FemTek, LLC (licensing partner with Combe, Inc. for Vagisil Screening Kit)

Much like body temperature, an elevated vaginal pH level can indicate numerous serious health problems, that if identified and treated early, can significantly prevent and reduce suffering and tragedy, lengthen life spans, improve quality of life and save women and the healthcare system billions of dollars.

# An abnormal vaginal pH level can be indicative of:

- ❁ The presence of Bacterial Vaginosis ("BV")
- ❁ The presence of Sexually Transmitted Infections ("STI's")
- ❁ A risk for the presence of upper genital tract infection or pelvic inflammatory disease ("PID")
- ❁ A risk for the presence of HIV infection
- ❁ A risk for preterm rupture of the membranes (PROM) in pregnancy, for preterm labor and preterm delivery
- ❁ A risk for birth of an infant with learning deficit and/or cerebral palsy
- ❁ Estrogen deficiency in menopause
- ❁ A risk for post-operative wound infection
- ❁ A risk for development of cervical cancer

# What is Bacterial Vaginitis (“BV”)?

- ❁ A type of vaginal infection, which may be accompanied by unusual discharge, itching, burning, irritation or painful intercourse
- ❁ Bacterial Vaginitis is caused by an overgrowth of various types of infectious bacteria
- ❁ BV is the most prevalent form of vaginal infection of reproductive age women in the United States<sub>1</sub>
- ❁ BV is a condition that requires treatment, even if asymptomatic, because of its association with the later development of disease<sub>2</sub>

The other types of vaginal infection include yeast (candida) and trichomoniasis - caused by a sexually transmitted infectious parasite

# How can a woman contract BV?

- ❁ Through sexual intercourse
- ❁ Through fecal contamination (wiping the wrong way)
- ❁ With atrophic vaginitis (estrogen deficient tissue)
- ❁ Through the presence of a foreign body (retained tampon)<sub>3</sub>

# What are the symptoms of BV?

- ✿ 50% of women with BV are asymptomatic.<sup>4</sup>
- ✿ Women who are symptomatic may notice:

a thin, dark or dull grey vaginal discharge  
a fishy vaginal odor  
vaginal itching and/or vaginal burning  
painful sexual intercourse

# What is the incidence of BV?

- ❁ Vaginal infections account for more than 10 million office visits each year<sup>5</sup>
- ❁ BV has been found in 10-25% of patients in OB/GYN clinics, and in 64% of patients visiting STI clinics<sup>6</sup>
- ❁ Only 34% of women surveyed have ever heard of BV<sup>7</sup>
- ❁ In a study of 105 women, almost all of whom believed that they had a yeast infection, only 29% actually did. The rest had another form of vaginitis (BV or trichomoniasis)<sup>8</sup>
- ❁ Only 16% of women surveyed said that their physicians had discussed bacterial vaginitis with them<sup>9</sup>



# How is BV diagnosed?

## 🌸 Amsel's Criteria<sub>10</sub>

- 🌸 Through vaginal pH screening and a pH level > 4.5
- 🌸 With an abnormal vaginal discharge
- 🌸 Through detection of a fishy odor with potassium hydroxide (a "whiff" test)
- 🌸 Through microscopic identification of vaginal "clue" cells (a "wet-mount" or "Gram stain" test)

## 🌸 Gutman's Criteria<sub>11</sub>

- 🌸 A BV diagnosis is made by only two findings
  - 🌸 Vaginal pH > 4.5
  - 🌸 Positive amine "Whiff Test"

# How is BV treated?

- ❁ BV can only be diagnosed by a healthcare professional
- ❁ BV is easily treated with antibiotics
- ❁ Non-prescription medications should not be used in the treatment of BV

# How is abnormal vaginal pH and BV related to STI's?

- ❁ BV has been found in up to 64% of patients visiting STI clinics<sup>12</sup>
- ❁ Some experts believe that this incidence is so high because BV might enhance the transmittal of STI's<sup>13</sup>
- ❁ Research suggests, that without the right treatment, certain vaginal infections can lead to an increase in the chances of contracting STI's<sup>14</sup>
- ❁ Patients with repeated episodes of BV should be considered at risk for other STI's<sup>15</sup>
- ❁ Patients with recurrent episodes of BV should also be screened for gonorrhea and chlamydial infection. If either of these conditions is present, the patient should also be tested for syphilis, hepatitis B, and HIV infection<sup>16</sup>
- ❁ It can be concluded that pH screening may be appropriate not only as an indicator for BV, but also as an indicator for STI's in sexually active women

# Can vaginal pH screening help diagnose or prevent STI's?

- ❁ In sexually active women, where BV is present, STI's are more likely to be present
- ❁ Routine pH screening in sexually active women could alert them to the possibility of bacterial infection or STI
- ❁ Timely treatment and resolution of BV could reduce the incidence of or even prevent some STI's
- ❁ Routine vaginal pH screening could contribute to the overall good health of the sexually active woman

# How is abnormal vaginal pH level and BV related to PID?

- ❁ Pelvic inflammatory disease (PID) is broadly defined as infection of the female upper genital tract, including infection of:
  - ❁ the endometrial lining of the uterus (endometritis)
  - ❁ the fallopian tubes (salpingitis)
  - ❁ the ovaries (oophoritis)
  - ❁ the pelvic cavity (pelvic peritonitis)
- ❁ Diagnosis and treatment of PID are major public health problems in the U.S., with considerable economic consequences<sup>17</sup>
- ❁ Several recent studies have demonstrated an association between BV and PID<sup>18</sup>
- ❁ A 1996 Brown University study showed that the presence of BV is associated with a threefold increased risk of PID<sup>19</sup>
- ❁ A 1988 study documented a nine-fold increased risk of the clinical diagnosis of PID in women with BV<sup>20</sup>

# How can vaginal pH screening help diagnose or prevent PID?

- ❁ BV is an established risk factor for pelvic inflammatory disease
- ❁ Upper genital tract infection, or PID, can have devastating consequences such as chronic abdominal pain and infertility
- ❁ Routine vaginal pH screening will help identify the presence of BV
- ❁ If BV is diagnosed and treated early, then it is unlikely that infection will advance to the upper genital tract
- ❁ Timely treatment and resolution of BV could reduce the incidence of or even prevent PID and its consequences

# How is abnormal vaginal pH level and BV related to HIV infection?

- ❁ BV significantly increases the risk of HIV infection in women.<sup>21</sup>
- ❁ A Ugandan study found that the prevalence of HIV infection doubled among women with severe BV.<sup>22</sup>
- ❁ The authors of the Ugandan study suggested that the presence of BV may increase susceptibility to HIV, and that control of BV could reduce transmission of HIV.<sup>23</sup>
- ❁ A Malawi study found that the prevalence of HIV infection more than doubled among pregnant women with severe BV.<sup>24</sup>

# How can vaginal pH screening help diagnose or reduce HIV risk?

- ❁ In sexually active women, where BV is present, HIV infection is more likely to be present
- ❁ Routine vaginal pH screening by sexually active women could alert them to the possibility of bacterial infection or HIV
- ❁ Routine vaginal pH screening could be essential to minimizing risk of HIV infection for women with multiple partners
- ❁ Routine vaginal pH screening could contribute to the overall good health of the sexually active woman



# How is abnormal vaginal pH level and BV related to risk of premature rupture of the membranes ("PROM"), preterm labor or preterm delivery?

- ✿ It is estimated that 15-20% of pregnant women in the United States have BV<sub>25</sub>
- ✿ Seven studies have reported an increased risk of preterm birth in women with BV<sub>26</sub>
- ✿ Recent investigations have reported an association between BV and adverse pregnancy outcomes: preterm birth, preterm labor, premature rupture of the membranes, and peripartum infections<sub>27</sub>
- ✿ Infection and inflammation play primary roles in up to one-half of episodes of preterm birth and PROM<sub>28</sub>
- ✿ BV is a direct cause of adverse pregnancy outcomes<sub>29</sub>
- ✿ Clinical observations show a trend towards higher vaginal pH values in association with preterm labor and PROM<sub>30</sub>

# What is the magnitude of this problem?

- ❁ When BV was not detected and treated during pregnancy, the estimated annual costs in the U.S. in the year 2000 were \$1.4 billion<sup>31</sup>
- ❁ Direct savings by preventing BV-caused preterm birth/PROM in the U.S. are estimated at a minimum of \$150 million annually<sup>32</sup>
- ❁ Reducing the heavy economic burden associated with BV in pregnant women will require the establishment of effective screening and treatment regimens<sup>33</sup>

# How can vaginal pH screening help diagnose or prevent PROM, preterm labor, or preterm delivery?

- ❁ Screening and treatment of BV can reduce the incidence of preterm delivery<sup>34</sup>
- ❁ Important numbers of preterm births can be prevented in women considered to be at high or normal risk for preterm birth by screening and treating BV in pregnancy<sup>35</sup>
- ❁ Studies have shown that antibiotic therapy for patients with PROM can double the length of pregnancy after PROM, compared with no treatment<sup>36</sup>
- ❁ "It is time to include a test for BV among the several early prenatal screening tests"<sup>37</sup>
- ❁ Routine testing of vaginal pH, and maintenance of a healthy vaginal pH level during pregnancy can reduce the incidence of or prevent an adverse pregnancy outcome

# How is abnormal vaginal pH level and BV related to the birth of an infant with cerebral palsy?

- ❁ Intrauterine exposure to maternal infection is associated with a marked increase in risk of cerebral palsy in premature infants and infants of normal birth weight<sup>38</sup>
- ❁ Babies of normal birth weight who are exposed to infection in their mothers' wombs appear to have a nine fold increased risk of developing cerebral palsy<sup>39</sup>
- ❁ Chorioamnionitis (infection of the amniotic membrane), which is much overrepresented in children who develop cerebral palsy, is clearly established as being the result of ascending infection<sup>40</sup>
- ❁ BV is a maternal vaginal infection that can ascend into the uterus

# Can vaginal pH screening help reduce cerebral palsy risk?

- ❁ The annual cost of cerebral palsy is \$2.4 billion, representing one third of the cost of the 18 most common birth defects<sup>41</sup>
- ❁ Maternal vaginal infection is a strong risk factor for the birth of an infant with cerebral palsy
- ❁ Diagnosis and successful treatment of maternal vaginal infection, including BV, prior to delivery can reduce that risk
- ❁ Routine vaginal pH screening during pregnancy can play a role in the early detection of BV and a reduced incidence of cerebral palsy

# What does vaginal pH have to do with menopause?

- ❁ A pH level of 3.8 to 4.5 is indicative of a normal, properly estrogenized vagina<sup>42</sup>
- ❁ In the absence of infection, a vaginal pH of 6.0 to 7.5 is strongly suggestive of estrogen deficiency or menopause<sup>43</sup>
- ❁ Two estrogen-dependent mechanisms appear to play a causative role in the pathologies related to menopause: decreased pelvic blood flow and increased vaginal pH<sup>44</sup>
- ❁ Currently, approximately 45.6 million American women are post-menopausal<sup>45</sup>

# Why is estrogen replacement therapy (“ERT”) important in menopause?

- ❁ The profound estrogen deficiency that occurs with menopause may lead to a constellation of problems

Bone loss, atrophic vulvitis, vaginal itching, atrophic vaginitis, mild to severe bladder symptoms, dyspareunia, vaginal stenosis, and uterine prolapse.

- ❁ Symptoms related to menopause persist for life unless relieved by estrogen replacement therapy
- ❁ Women now spend one-third of their life in menopause

# What are the common side-effects of ERT?

- ❁ The overall compliance rate for postmenopausal women prescribed various forms of ERT has been 30%<sup>46</sup>, primarily due to unpleasant side-effects, the Women's Health Initiative and related media reports, as well as irregular bleeding, breast tenderness, cramps, and genital swelling.
- ❁ In spite of better understanding of menopause, many physicians have a "one size fits all" attitude toward estrogen dosing<sup>47</sup>.



# Can vaginal pH screening play a role in ERT compliance?

- ✿ Vaginal pH is a low-cost, effective screening tool that can help ob-gyns tailor hormone replacement therapy in post-menopausal women<sup>48</sup>
- ✿ The goal of ERT is to achieve patient compliance, resulting in a vaginal pH of 4.5, with relief of menopausal symptoms and side effects<sup>49</sup>
- ✿ Titration of estradiol level by vaginal pH during ERT may help menopausal women avoid side effects or cessation of therapy<sup>50</sup>
- ✿ The importance of the vaginal pH test in confirming estrogen deficiency cannot be overemphasized<sup>51</sup>
- ✿ A major advantage of a vaginal pH test is that it often facilitates the immediate evaluation of baseline estrogen status<sup>52</sup>
- ✿ The vaginal pH test can also be used to monitor therapeutic efficacy of and patient compliance with ERT<sup>53</sup>

# How is abnormal pH level and BV related to risks for post-operative infection in pelvic surgeries?

- ❁ A causal relationship has been established between BV and post-hysterectomy infection<sup>54</sup>
- ❁ BV has been associated with post-operative infections<sup>55</sup>
- ❁ BV is a risk factor for postcesarean endometritis (infection of the lining of the uterus)<sup>56</sup>
- ❁ BV has been associated with pelvic infection following invasive procedures such as endometrial biopsy, hysterectomy, hysterosalpingography, placement of IUD, cesarean section, or uterine curettage<sup>57</sup>
- ❁ If vaginal infection exists, there is a risk for transmission to other pelvic organs during surgery
- ❁ Because an elevated vaginal pH level may be indicative of BV, it may also be indicative of risk for pelvic infection as a post-surgical condition

# How can vaginal pH screening help reduce the risk of operative infection?

- ❁ "It is important that pH levels are normal before reproductive-tract surgeries"<sup>58</sup>
- ❁ Testing for BV is indicated for any woman who may undergo pelvic surgery. Treatment prior to pelvic operations can reduce the risk of postoperative infections<sup>59</sup>
- ❁ An elevated vaginal pH and or the presence of BV places a woman at higher risk for infection after surgery
- ❁ Vaginal pH should be checked prior to surgery, and if elevated, further tests should be conducted to identify infection for treatment and resolution

# How is abnormal pH level and BV related to risk of cervical cancer?

- ❁ BV may be a cofactor in the development of cervical intraepithelial neoplasia (CIN), a precursor of cervical cancer<sup>60</sup>
- ❁ A Swedish study of women with BV found that CIN was present 5 percent of the time, vs. 1.4 percent of the time for women without BV<sup>61</sup>
- ❁ In the same study, second and third stage CIN (more advanced) occurred in 2.9 percent of subjects with BV, compared to 0.4 percent of those without BV<sup>62</sup>

# Can vaginal pH screening help reduce the risk of cervical cancer?

- ❁ Routine vaginal pH screening could help identify the presence of BV
- ❁ Routine vaginal pH screening, in concert with regular PAP smears, could play a role in the further reduction of the incidence of cervical cancer
- ❁ Women at risk for cervical cancer may benefit from frequent vaginal pH screening
- ❁ It is now known that cervical cancer is due to human papilloma virus (HPV) infection - immunization is now available

Normal vaginal pH is  
an important determinant  
of good health in women

# BV Screening Kit

- ❁ The first OTC vaginal pH screening device is now sold across America in most pharmacies and mass retail stores
- ❁ The first and only OTC vaginal pH screening device that can be used by women of all ages
- ❁ The first and only OTC vaginal pH screening device for vaginal infections
- ❁ The first and only OTC vaginal pH screening device to play a role in the prevention of preterm rupture of the membranes, preterm labor and preterm birth

# Indications for use of the BV Screening Kit

- ❁ To screen for BV\*, and more advanced pelvic infections
  - ❁ To screen for sexually transmitted infections (STI's)
  - ❁ To screen for sexually transmitted infections before conception
  - ❁ To screen for BV to help prevent preterm birth
  - ❁ To screen for prevention of operative wound infections
  - ❁ To complement the PAP smear in screening for cervical abnormalities
- ❁ To test for ruptured membranes during pregnancy

\* in conjunction with other tests and procedures










# Who should use a BV Screening Kit?

- ❁ Physicians and health care professionals
  - ❁ during routine well-woman exams
  - ❁ during preconception and pregnancy exams
  - ❁ to confirm rupture of the membranes in pregnancy
  - ❁ when a patient presents with symptoms of vaginal infection
  - ❁ during all STI clinic visits
  - ❁ upon diagnosis of PID
  - ❁ upon abnormal pap smear result
  - ❁ with all patients undergoing hysterectomy or hysteroscopy
  - ❁ before inserting an IUD
  - ❁ when pelvic surgery is advised

# Who should use a BV Screening Kit?

## Women of all ages

-  when planning a pregnancy and during pregnancy
-  to confirm rupture of the membranes in pregnancy
-  with symptoms of a vaginal infection
-  after sexual intercourse with a new partner
-  with the onset of menopause and during ERT
-  routinely after recurrent infections, or the presence of any risk factor for infection
-  best time to test is mid-cycle and at least 48 hours after intercourse

# A call to action that can significantly improve women's health

- ❁ Reduced incidence of BV
- ❁ Reduced incidence of STI's
- ❁ Reduced incidence of upper genital tract infection, or PID
- ❁ Earlier detection of HIV and CIN - the precursor to cervical cancer
- ❁ Reduced incidence of PROM, preterm labor and preterm delivery
- ❁ Reduced incidence of cerebral palsy
- ❁ Reduced incidence of pre and post-operative infections

# A call to Action . . .

## Recommending ...

Routine vaginal pH screening with Vagisil® Screening Kit



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# James C. Caillouette, MD

Dr. Caillouette completed his pre med training at the College of Puget Sound in Tacoma, and his MD degree with honors at the University of Washington. His internship and residency were at the Los Angeles County General Hospital where he was president of the Interns / Residents Association his last two years.

Dr. Caillouette had a successful medical practice in Pasadena and is board certified in Obstetrics and Gynecology delivering some 7000 babies during his medical career. He retired after 43 years in 2002. He was chair of the department of OB/Gyn at Huntington Hospital (Pasadena, CA) on two occasions and continues to serve on hospital committees. At Keck / USC School of Medicine he began as a clinical instructor in 1959, and moved to clinical professor in 1978. He served on the Board of Councilors from 1979 to 1992. He was president of the Professional Staff Association and Attending Staff Association at LAC/USC Medical Center from 1988-90. He is a member of numerous medical associations and has been chairman or president of many of them including: the Los Angeles OB/Gyn Society, Pacific Coast OB/Gyn Society, the Obstetrical and Gynecological Assembly of LA. He chaired the Pasadena March of Dimes, is on the Scripps Home board, and was on the Board of the Caltech Associates.

He has authored or coauthored 35 scientific papers, served on twelve boards and has been a consultant to many companies. He has been issued over 31 patents and has 7 pending. Dr. Caillouette has invented medical devices since he was a junior in medical school. His first device was a bedside chemistry kit for the renal dialysis team. After many other medical devices, he invented the instant Hot / Cold packs in 1965 that are still commonly used items for home, sports, paramedics, ERs and hospitals. His company, FemTek, LLC has developed a device for both professional and home screening for vaginal infection, a warning for possible preterm birth, a test for ruptured membranes in pregnancy, and a screen for estrogen level and risk for osteoporosis in menopause.

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