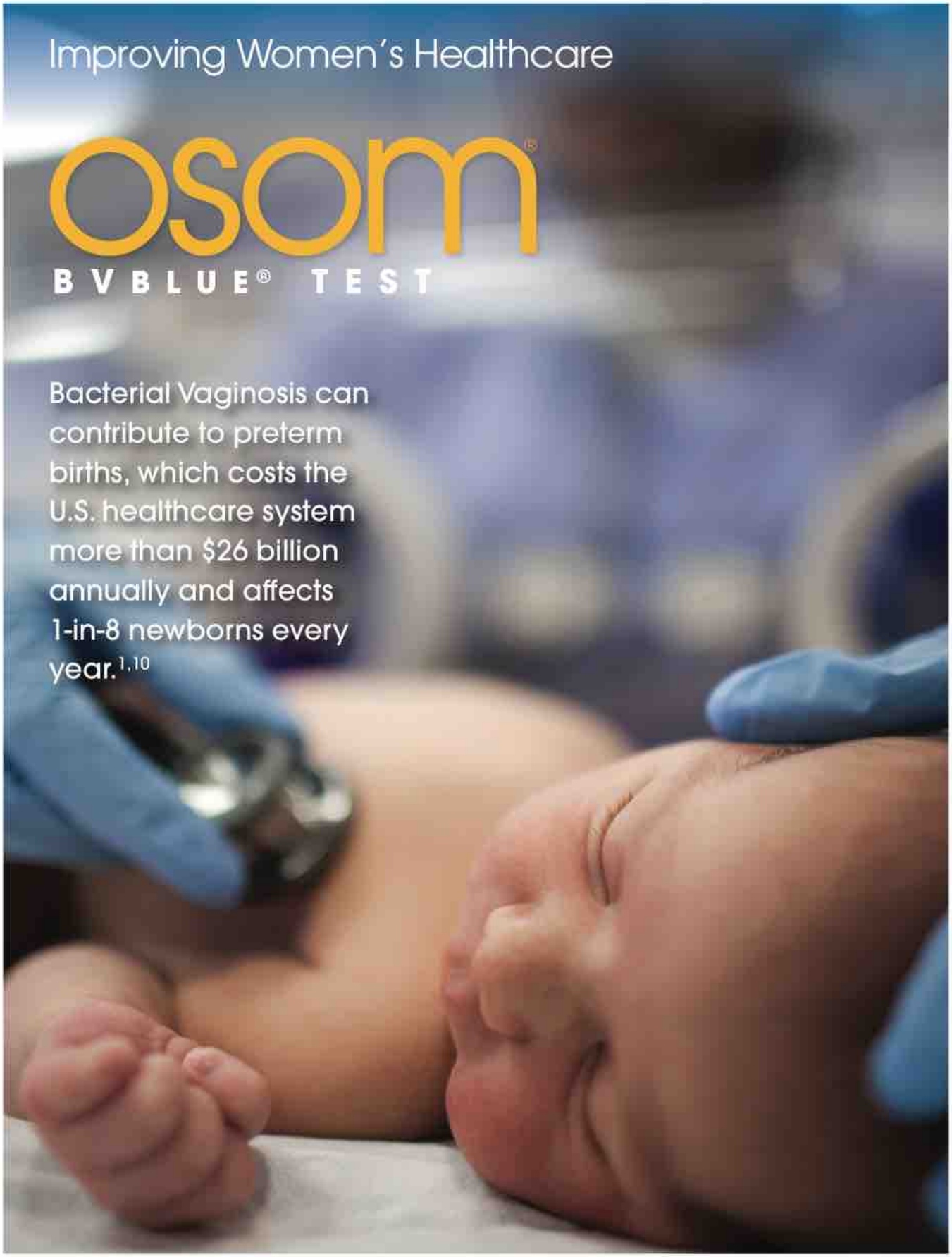

Improving Women's Healthcare
osom®
BVBLUE® TEST
Bacterial Vaginosis can contribute to preterm births, which costs the U.S. healthcare system more than $26 billion annually and affects 1-in-8 newborns every year.[1,10]

Bacterial Vaginosis

Bacterial vaginosis is the most common cause of vaginal symptoms among women of childbearing age, accounting for 40-50 percent of cases.[10] The prevalence in the U.S. is estimated to be 29% among women 14-49 years old and 51% in African-American women.[2]

The causative agents of the infection are bacterial pathogens such as *Gardnerella vaginalis, Bacteroides, Prevotella* and *Mobiluncus*. These pathogens produce an enzyme called sialidase which has been associated with an increased risk of pre-term birth.[4]

If left untreated bacterial vaginosis can lead to complications such as:

- Susceptibility to HIV and other STD's (HSV, chlamydia and gonorrhea)
- Postoperative infection after vaginal or pelvic surgery (hysterectomy or abortion)
- Increased risk of preterm delivery in pregnant women
- Endometriosis
- Upper genital tract infections such as pelvic inflammatory disease[3]

WHAT THE EXPERTS ARE SAYING

" [A] potential one-half reduction of such adverse outcomes among women who are BV-positive could have an impact in reducing overall miscarriage and preterm birth rates, which were not reduced in the last decade..."[4]

"Integrating a simple infection screening programme into routine antenatal care leads to a significant reduction in preterm births and reduces the rate of late miscarriage in a general population of pregnant women."[5]

"Elevated sialidase level that is measured at 12 weeks of gestation is associated strongly with early spontaneous preterm births and miscarriage... as the amount of vaginal sialidase activity increased, the likelihood of adverse outcome also increased."[4]

DIAGNOSTIC CHALLENGES

There are a number of diagnostic options available. However, choices may have to be made in terms of:

ACCURACY
Patient receives correct diagnosis

TIME
Patient receives correct diagnosis in a timely manner

COST
Diagnosis is obtained cost-effectively and affordably

METHOD	FEATURES

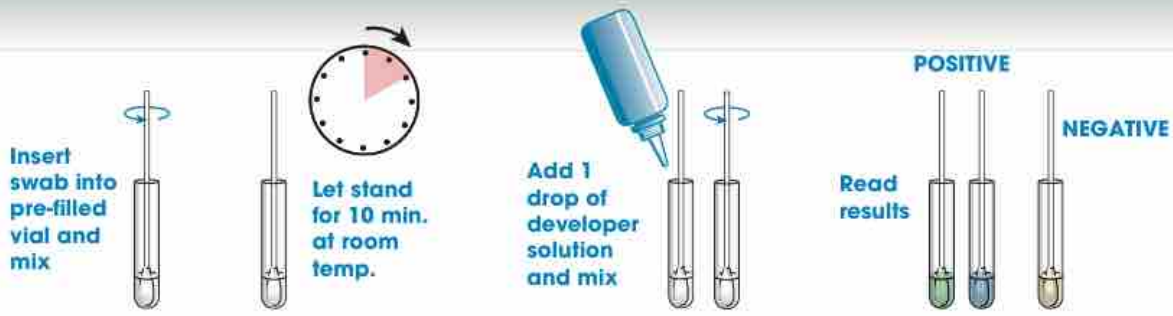
AMSEL CRITERIA	• Requires the assessment of 4 different tests/criteria. If three of these four criteria are present, a diagnosis of BV can be made:
	  • Presence of a thin gray/white vaginal discharge
	  • Vaginal pH > 4.5
	  • Positive whiff test (amines)
	  • Presence of > 20% clue cells on a wet mount
	• Requires a microscope and training

GRAM STAIN WITH NUGENT'S SCORING	• A multistep procedure in which a stained vaginal smear is examined microscopically • Bacteria are quantified and scored, with a score of ≥7 considered positive for BV • Accurate; generally considered the gold standard • Labor intensive; requires advanced skills
DNA PROBE	• Accurate • Expensive • Not CLIA waived • Does not allow for test and treat approach • Over-diagnosis is possible[9]
POINT-OF-CARE OSOM® BVBLUE® TEST	• Good sensitivity vs. Gram Stain • CLIA waived; easy-to-read, objective results in 10 minutes • No equipment or specialized training required • Actionable, diagnostic result; test-and-treat patient in one visit

WHY IS A POINT-OF-CARE TEST IMPORTANT? "The majority of women at the greatest risk for the sequelae of BV are not in settings where the conventional diagnostic methods are either practical or possible, and they would greatly benefit from access to rapid and reliable point-of-care tests to improve the diagnosis and management of BV."[6]

OSOM® BVBLUE® Procedure

- Detects elevated activity of vaginal fluid sialidase associated with 4 pathogens
- 92.8% sensitive and 98% specific vs. gram stain



Product not available in all markets.

ORDER	CONFIGURATION	CATALOG #
○ OSOM® BVBLUE® RAPID TEST KIT	25 TESTS	183
○ OSOM® BVBLUE® CONTROL KIT	---	184
○ OSOM® VAGINITIS SWAB TRANSPORT SYSTEM	50 SWAB SETS	185

The ability of the OSOM® BVBLUE® Test to accurately, quickly and cost effectively detect BV offers significant benefits to the patient and clinician alike:

- Begin immediate and proper treatment
- Provide opportunity for appropriate health education during the visit
- Help prevent recurrence and reduce associated health risks
- The performance of OSOM® BVBLUE® was better than the methods based on Amsel's Criteria (97.6% vs 67.1%).[7]
- "BVBLUE® is a useful point-of-care diagnostic tool to provide a presumptive diagnosis of BV, especially in situations where microscopic capabilities are unavailable."[8]

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