Faridpur Med. Coll. J. 2026;21(2):07-12 DOI: https://doi.org/10.3329/fmcj.v21i2.90723

Original Article

Pilot Evaluation of The BVBlue® Point-of-Care Test Versus Culture for Bacterial Vaginosis Diagnosis in Pregnant Women Attending a High-Volume Clinic in Faridpur, Bangladesh

D Zeba[1], N Barai[2], S Akter[3], A Janah[4], RM Rahman[5], R Biswas[6], G Osman[7]

Abstract:

Background: *Bacterial vaginosis diagnosis remains challenging in resource-constrained settings. Point-of-care tests may enable timely management, particularly during pregnancy when bacterial vaginosis-associated complications carry substantial maternal and neonatal risks.*

Materials and Methods: *We conducted a prospective cross-sectional pilot study over two days (February 22–23, 2025) at a high-volume obstetrics-gynecology private clinic in Faridpur, Bangladesh. All pregnant women attending for routine antenatal care were enrolled. Paired vaginal specimens for concurrent BVBlue® rapid testing and standard culture were collected. We assessed bacterial vaginosis prevalence, diagnostic accuracy metrics (sensitivity, specificity, positive and negative predictive values), turnaround time and operational feasibility.*

Results: *Among 37 enrolled participants (median age 26 years, median gestational age 27 weeks), culture-confirmed bacterial vaginosis prevalence was 24.3% (9/37). Against culture as the reference standard, BVBlue® rapid test demonstrated 66.7% sensitivity (95% Confidence Interval [CI] 30.0–90.3), 100% specificity (95% CI 88.1–100.0), 100% positive predictive value (95% CI 56.1–100.0), and 90.3% negative predictive value (95% CI 75.1–96.7). Median turnaround time was 12 minutes for BVBlue® rapid testing versus 60 hours for culture. Reported per-test costs were lower for BVBlue® rapid testing (approximately 12-17 USD) than culture (approximately 20-25 USD).*

Conclusion: *In this pilot evaluation, the BVBlue® rapid test offered rapid, highly specific bacterial vaginosis detection with moderate sensitivity compared with culture. The reduction in turnaround time and reported cost advantage suggest potential utility in resource-limited settings. However, the small sample size, wide confidence intervals, and use of culture rather than the gold standard Nugent scoring as the reference standard necessitate larger validation studies.*

Keywords: Bacterial vaginosis, Point-of-care testing, BVBlue® rapid test, Pregnancy, Resource-limited settings, Diagnostic accuracy.

Introduction:

Bacterial vaginosis is the most common cause of vaginal dysbiosis in women of reproductive age, affecting up to 30% of pregnant women globally.[1–3] Beyond causing distressing symptoms such as abnormal vaginal discharge and odor, bacterial vaginosis during pregnancy is strongly associated with serious adverse outcomes, including preterm birth, low birth weight, premature rupture of membranes, and postpartum

1. Dilruba Zeba, MBBS, DGO, MCPS, FCPS (Obst & Gynae), Professor and Head of the Department of Obstetrics and Gynaecology, Faridpur Medical College, Faridpur, Bangladesh, Email: dilruba_zeba@yahoo.com.
2. Nibedita Barai, MBBS, Clinical Assistant, Peoples Diagnostic Centre, Faridpur, Bangladesh, Email: dr.nibeditabiswas@gmail.com.
3. Sajeda Akter, MBBS, FCPS Trainee, Medical Officer, Faridpur Medical College, Faridpur, Bangladesh, Email: sajedapriya007@gmail.com.
4. Afrin Jahan, MBBS, Clinical Assistant, Peoples Diagnostic Centre, Faridpur, Bangladesh, Email: afrindisha999@gmail.com.
5. Raiyan Muhibur Rahman, MBBS, Sylhet MAG Osmani Medical College, Bangladesh, Email: raiyanmuhibur@ gmail.com.
6. Rajib Biswas, MBBS, Research Investigator, International Centre for Diarrhoeal Disease Research, Bangladesh, Email: rajib.biswas@icddrb.org.
7. Md. Osman Goni, MBBS, Associate Professor & Head, Department of Surgery, Faridpur Medical College, Faridpur, Bangladesh, Email: dosmangoni@gmail.com.

Address of correspondence:

Dilruba Zeba, MBBS, DGO, MCPS, FCPS (Obst & Gynae), Professor and Head of the Department of Obstetrics and Gynaecology, Faridpur Medical College, Faridpur, Bangladesh. Phone: +88 01712 090 825, Email: dilruba_zeba@yahoo.com

endometritis.[4–8] Additionally, bacterial vaginosis increases susceptibility to sexually transmitted infections, including HIV, creating compounded health risks for both mother and infant.[5,9,10]

Despite its clinical significance, bacterial vaginosis diagnosis remains particularly challenging in resource-limited settings. The gold standard diagnostic method is Gram stain microscopy with Nugent scoring, which requires trained microscopists and laboratory infrastructure that are frequently unavailable in low- and middle-income countries.[11,12] Alternative approaches, such as Amsel's criteria, necessitate microscopy, potassium hydroxide (KOH) testing, and pH measurement, making them impractical for point-of-care use in busy antenatal clinics.[12,13] Culture-based methods, while more accessible, require 48–72 hours for results and are not considered clinically definitive for bacterial vaginosis diagnosis.[13] These limitations often result in delayed or presumptive treatment, potentially compromising maternal and neonatal outcomes.

Rapid point-of-care tests offer a promising solution to this diagnostic gap. The BVBlue® rapid test (Gryphus Diagnostics, LLC) is an enzymatic assay that detects elevated sialidase activity, an enzyme characteristically produced by bacterial vaginosis-associated pathogens such as *Gardnerella vaginalis and Bacteroides species.*[14,15] The test requires no microscopy, provides results within 10–15 minutes, and employs a simple colorimetric readout, making it potentially suitable for implementation in resource-constrained clinical environments. Previous studies have demonstrated encouraging diagnostic performance; however, validation across diverse settings and populations remains limited.[16,17]

This pilot study aimed to provide preliminary data on the diagnostic accuracy, operational feasibility and turnaround time of the BVBlue® rapid test compared with standard vaginal culture for detecting bacterial vaginosis among pregnant women attending a high-volume obstetrics-gynecology private clinic in Faridpur, Bangladesh, which is a representative setting of resource-limited healthcare environments where rapid, reliable bacterial vaginosis diagnosis could substantially improve antenatal care delivery.

Materials & Methods:

We conducted a prospective, cross-sectional pilot study over two consecutive days (February 22-23, 2025) at Peoples' Diagnostic Centre in Faridpur, Bangladesh. It is a high-volume private obstetrics and gynecology clinic that serves as a consultation center for women from Faridpur and surrounding districts, providing antenatal care to approximately 150–200 pregnant women weekly.

All pregnant women aged 18 years or older attending for routine prenatal care during the 2 days of the study period were invited to participate. Women were excluded if they reported antibiotic use within the preceding two weeks or had any medical condition that the attending clinician deemed likely to interfere with study participation or sample collection. All participants provided written informed consent prior to enrollment.

Following consent, participants completed a structured questionnaire administered by trained research assistants. The questionnaire captured demographic information (age, education level), obstetric history (gravidity, parity, gestational age), and current genitourinary symptoms (abnormal vaginal discharge, odor, irritation, or discomfort).

Two vaginal swab specimens were collected sequentially by a pre-trained clinic nurse using sterile cotton swabs. Specimens were obtained from the mid-vaginal wall, avoiding cervical contact. The first swab was immediately tested on-site using the BVBlue® rapid test (Gryphus Diagnostics, LLC, Birmingham, AL, USA) following the manufacturer's protocol. For BVBlue® rapid testing, the swab was immersed in the provided test solution, incubated at 37°C for 10 minutes, treated with chromogenic reagent, and visually assessed for color change within 3 minutes. A blue or green color indicated a positive result (elevated sialidase activity suggestive of bacterial vaginosis), while yellow indicated a negative result (Figure 1). Test results were recorded as positive, negative, or invalid. The time from sample collection to result interpretation was recorded as the turnaround time.

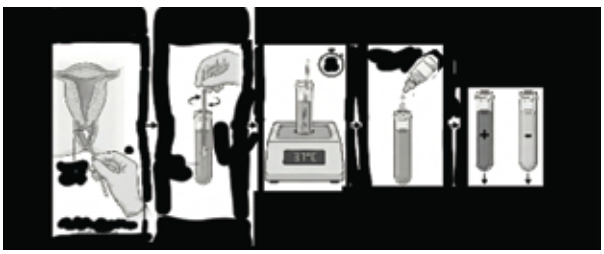

Figure 1: BVBlue® rapid testing procedure (simplified)

The second swab was immediately placed in transport medium and sent to the laboratory at Peoples' Diagnostic

Centre, Fairidpur, for standard aerobic and anaerobic vaginal culture, which served as the reference standard for this pilot evaluation. Culture results were recorded as positive (growth of bacterial vaginosis-associated organisms), negative, or inconclusive. Laboratory staff were blinded to BVBlue® rapid test results. Culture turnaround time was calculated from sample collection to result reporting.

The primary outcomes were: (1) bacterial vaginosis prevalence as determined by vaginal culture; (2) diagnostic performance of the BVBlue® rapid test compared with culture, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV); and (3) comparative turnaround time for each diagnostic method. Secondary outcomes included operational feasibility, assessed through reported per-test costs and documented technical challenges or ease-of-use observations from clinic staff. Cost in Bangladeshi Taka (BDT) was converted to USD at an exchange rate of 120 BDT/USD for reporting.

Data were analyzed using descriptive statistics. Continuous variables were summarized as medians with ranges; categorical variables as frequencies and percentages. Diagnostic accuracy metrics were calculated using standard 2×2 contingency tables, with 95% confidence intervals (CIs) computed using the Wilson score method for proportions. All analyses were performed using R version 4.5.2 (The R Foundation for Statistical Computing, Vienna, Austria) in RStudio version 2025.09.2 (Posit Software, PBC, Boston, MA, USA).

All participants provided written informed consent, and data were anonymized prior to analysis to ensure confidentiality. Participants diagnosed with bacterial vaginosis by either method received appropriate clinical management according to local antenatal care guidelines.

Results:

During the two days, 37 eligible pregnant women were enrolled and completed the study protocol. The median age was 26 years (range 19–36 years), and the median gestational age at enrollment was 27 weeks (range 13–39 weeks). Approximately 41% (15/37) of participants had completed primary education.

Using vaginal culture as the reference standard, the prevalence of bacterial vaginosis was 24.3% (9/37 participants). Symptom reporting differed substantially between culture-positive and culture-negative groups. Among women with culture-confirmed BV, 77.8% (7/9) reported abnormal vaginal discharge and 66.7% (6/9) reported abnormal odor. In contrast, among women with negative cultures, only 28.6% (8/28) reported abnormal discharge and 17.9% (5/28) reported abnormal odor.

The BVBlue® rapid test identified 6 positive cases, all of which were confirmed positive by vaginal culture (true positives). No false positive results occurred. However, 3 cases that were positive by culture were negative by the BVBlue® rapid test (false negatives), and 28 cases were concordantly negative by both methods (true negatives). No invalid results were recorded with the BVBlue® rapid test.

Compared with vaginal culture, the BVBlue® rapid test demonstrated a sensitivity of 66.7% (95% CI 30.0–90.3%) and a specificity of 100% (95% CI 88.1–100.0%). The positive predictive value was 100% (95% CI 56.1–100.0%), indicating that all positive BVBlue® rapid test results correctly identified culture-confirmed bacterial vaginosis. The negative predictive value was 90.3% (95% CI 75.1–96.7%). These diagnostic performance metrics are summarized in Table 1.

Turnaround time differed markedly between the two diagnostic methods. The BVBlue® rapid test yielded results with a median turnaround time of 12 minutes (range 10–15 minutes) from sample collection to result interpretation. In contrast, vaginal culture required a median of 60 hours (range 48–72 hours) for result reporting, representing a 300-fold difference in time to diagnosis (Table 1).

Regarding operational feasibility, reported per-test costs were lower for BVBlue® rapid testing (approximately 12-17 USD) than culture (approximately 20-25 USD). Clinic staff reported that the BVBlue® rapid test was straightforward to perform after brief training, with the primary technical requirement being access to a 37°C incubator. The principal challenges noted for culture-based diagnosis were the substantial delay in result availability and the need for specialized laboratory infrastructure (Table 1).

Table 1: Participant Characteristics and Diagnostic Performance of BVBlue® Rapid Test vs. Vaginal Culture (N=37)

Characteristic/Metric	Value
Participant demographics	
Median age, years (range)	26 (19-36)
Median gestational age, weeks (range)	27 (13-39)
Education, primary completed, n (%)	15 (42%)
Bacterial vaginosis prevalence	
Culture	9/37 (24.3%)
BVBlue® rapid test diagnostic performance vs. culture	
True Positives (TP)	6
False Positives (FP)	0
False Negatives (FN)	3
True Negatives (TN)	28
Diagnostic accuracy	
Sensitivity, % (95% CI)	66.7 (30.0 - 90.3)
Specificity, % (95% CI)	100 (88.1 - 100)
PPV, % (95% CI)	100 (56.1 - 100)
NPV, % (95% CI)	90.3 (75.1 - 96.7)
Turnaround time	
BVBlue® rapid test, median minutes (range)	12 (10-15)
Vaginal culture, median hours (range)	60 (48-72)
Reported cost per test (USD)	
BVBlue	12–17
Vaginal Culture	20-25

CI: Confidence Interval. Approximate costs in Bangladeshi Taka (BDT) was converted to USD at an exchange rate of 120 BDT/USD.

Discussion

This pilot study provides preliminary evidence on the potential utility of the BVBlue® rapid test for point-of-care diagnosis of bacterial vaginosis in pregnant women attending a high-volume antenatal clinic in a resource-limited setting in Bangladesh. The observed bacterial vaginosis prevalence of 24.3% by culture is consistent with reported rates in South Asian populations and underscores the substantial burden of this condition among pregnant women in the region.[1–3]

The most important finding was the 100% specificity of the BVBlue® rapid test in this cohort, indicating that positive results reliably identified culture-confirmed bacterial vaginosis without generating false positives. This high specificity, combined with the 300-fold reduction in turnaround time compared with culture (12 minutes versus 60 hours), offers a potential advantage for clinical decision-making.[17] The ability to provide immediate, reliable positive results during the same antenatal visit is important for prompt therapeutic intervention.[18,19]

The test's moderate sensitivity (66.7%), however, warrants careful consideration. Approximately one-third of culture-positive cases were not detected by the BVBlue® rapid test in this preliminary evaluation. While the high negative predictive value (90.3%) provides reasonable reassurance that most negative results represent a true absence of bacterial vaginosis, the potential for missed diagnoses raises important questions about optimal testing strategies. In high-prevalence settings or among symptomatic women, clinicians may need to consider retesting with alternative methods when clinical suspicion remains high.

The lower reported cost of BVBlue® rapid testing (12-17 USD) compared with culture (20-25 USD), combined with its operational simplicity, further enhances its potential feasibility for routine implementation in resource-constrained antenatal care settings. It can address a critical barrier to effective bacterial vaginosis diagnosis and management in settings where patient follow-up is challenging and treatment delays may have serious consequences.[20–22]

Previous validation studies of the BVBlue® test have reported variable diagnostic performance, with sensitivity ranging from 60% to 90% and specificity from 94% to 100% when compared with clinical criteria or Nugent scoring.[13,14,17] Our findings align with the higher end of reported specificity but fall within the lower range of sensitivity estimates. These variations likely reflect differences in reference standards, study populations, disease prevalence, and threshold effects related to microbial load or sialidase activity levels. Notably, studies using Gram stain with Nugent scoring as the reference standard have generally shown more favorable performance metrics than those using culture, suggesting that our sensitivity estimate may be conservative.

Several important limitations must be acknowledged when interpreting these preliminary findings of our study. First, the very small sample size (N=37) recruited

over only two days results in wide confidence intervals around all accuracy estimates and severely constrains generalizability. Second, vaginal culture was used as the reference standard for practical feasibility reasons, but the Gram stain with Nugent scoring is the internationally recognized reference method. Direct comparison with Nugent scoring would provide a more clinically meaningful assessment of the BVBlue® rapid test's diagnostic accuracy.

Despite these limitations, our findings suggest that the BVBlue® rapid test could serve as a useful potential point-of-care diagnostic tool for bacterial vaginosis in pregnancy within resource-limited settings. The combination of rapid results, high specificity, operational simplicity and lower cost presents a compelling value proposition for screen-and-treat strategies in high-volume antenatal clinics where conventional diagnostic methods are impractical.

Conclusion:

This pilot study demonstrates that the BVBlue® rapid test is feasible to implement in a resource-limited antenatal care setting and offers substantial advantages in turnaround time and specificity. However, the moderate sensitivity observed in our study, combined with methodological limitations, particularly the small sample size and the use of a non-gold-standard comparator, highlights the urgent need for larger, adequately powered validation studies comparing the BVBlue® rapid test with the gold-standard Nugent scoring.

Conflict of interest:

The authors declare that they have no conflicts of interest. The BVBlue® rapid test used in this research is a commercial product of Gryphus Diagnostics, LLC; however, the manufacturer had no role in the study design, data collection, data analysis, interpretation of results, or the writing of this manuscript.

Acknowledgement:

The authors would like to express their sincere gratitude to all the pregnant women who generously participated in this pilot study. We also extend our special thanks to the dedicated clinic nurses for their assistance with sample collection, as well as the laboratory staff at Peoples' Diagnostic Centre in Faridpur for their invaluable support with the microbiological culture processing.

References:

1. Zeng X, An R, Li H. Risk factors of recurrent bacterial vaginosis among women of reproductive age: A cross-sectional study. *Open Med*. 2023;18(1):20230743.

2. Swidsinski S, Moll WM, Swidsinski A. Bacterial vaginosis—Vaginal polymicrobial biofilms and dysbiosis. *Dtsch Ärztebl Int*. 2023;120(20):347.

3. van de Wijgert JH, Jespers V. The global health impact of vaginal dysbiosis. *Res Microbiol*. 2017;168(9–10): 859–64.

4. Shipitsyna E, Roos A, Datcu R, Hallén A, Fredlund H, Jensen JS, et al. Composition of the vaginal microbiota in women of reproductive age–sensitive and specific molecular diagnosis of bacterial vaginosis is possible? *PloS One*. 2013;8(4):e60670.

5. Abou Chacra L, Fenollar F, Diop K. Bacterial vaginosis: what do we currently know? *Front Cell Infect Microbiol*. 2022;11:672429.

6. Kenfack-Zanguim J, Kenmoe S, Bowo-Ngandji A, Kenfack-Momo R, Ebogo-Belobo JT, Kengne-Ndé C, et al. Systematic review and meta-analysis of maternal and fetal outcomes among pregnant women with bacterial vaginosis. *Eur J Obstet Gynecol Reprod Biol*. 2023; 289:9–18.

7. E S, L M, Js P, E S. Cost-effectiveness analysis of different screening and diagnostic strategies for sexually transmitted infections and bacterial vaginosis in women attending primary health care facilities in Cape Town. *Front Public Health*. 2023 Mar 2;11.

8. Nelson DB, Macones G. Bacterial vaginosis in pregnancy: current findings and future directions. *Epidemiol Rev*. 2002;24(2):102–8.

9. Bautista CT, Wurapa E, Sateren WB, Morris S, Hollingsworth B, Sanchez JL. Bacterial vaginosis: a synthesis of the literature on etiology, prevalence, risk factors, and relationship with chlamydia and gonorrhea infections. *Mil Med Res*. 2016;3(1):4.

10. Abou Chacra L, Ly C, Hammoud A, Iwaza R, Mediannikov O, Bretelle F, et al. Relationship between bacterial vaginosis and sexually transmitted infections: coincidence, consequence or co-transmission? *Microorganisms*. 2023;11(10):2470.

11. Gutman RE, Peipert JF, Weitzen S, Blume J. Evaluation of clinical methods for diagnosing bacterial vaginosis. *Obstet Gynecol*. 2005;105(3):551–6.

12. Rao D, Pindi D, Rani D, Sasikala DG, Kawle DV. Diagnosis of bacterial vaginosis: Amsel's criteria vs Nugent's scoring. *Sch J Appl Med Sci*. 2016;4(6): 2027–31.

13. van den Munckhof EH, van Sitter RL, Boers KE, Lamont RF, Te Witt R, le Cessie S, et al. Comparison of Amsel criteria, Nugent score, culture and two CE-IVD marked quantitative real-time PCRs with microbiota analysis for the diagnosis of bacterial vaginosis. *Eur J Clin Microbiol Infect Dis*. 2019;38(5):959–66.

14. Myziuk L, Romanowski B, Johnson SC. BVBlue test for diagnosis of bacterial vaginosis. *J Clin Microbiol*. 2003;41 (5):1925–8.

15. Akhter S, Satter H, Tarafder S, Miah RA, Sharmin S, Ahmed S. Rapid detection of Bacterial Vaginosis (BV) by BVBlue test. *Bangladesh J Med Microbiol*. 2010;4(1) :24–7.

16. Bradshaw CS, Morton AN, Garland SM, Horvath LB, Kuzevska I, Fairley CK. Evaluation of a point-of-care test, BVBlue, and clinical and laboratory criteria for diagnosis of bacterial vaginosis. *J Clin Microbiol*. 2005;43(3): 1304–8.

17. Wiguna II, Tanoto K, Hadinata V, Chan N, Santoso BI. BVBlue as a diagnostic instrument for the diagnosis of bacterial vaginosis: a systematic review. *BMC Womens Health*. 2025;25(1):90.

18. Guerra B, Ghi T, Quarta S, Morselli-Labate AM, Lazzarotto T, Pilu G, et al. Pregnancy outcome after early detection of bacterial vaginosis. *Eur J Obstet Gynecol Reprod Biol*. 2006;128(1–2):40–5.

19. Guerra B, Ghi T, Quarta S, Morselli-Labate AM, Lazzarotto T, Pilu G, et al. Pregnancy outcome after early detection of bacterial vaginosis. *Eur J Obstet Gynecol Reprod Biol*. 2006;128(1–2):40–5.

20. Martin K, Wenlock R, Roper T, Butler C, Vera JH. Facilitators and barriers to point-of-care testing for sexually transmitted infections in low- and middle-income countries: a scoping review. *BMC Infect Dis*. 2022 June 20;22(1):561.

21. Riddell MA, Vallely LM, Mengi A, Badman SG, Low N, Wand H, et al. Point-of-care testing and treatment of sexually transmitted and genital infections to improve birth outcomes in high-burden, low-resource settings (WANTAIM): a pragmatic cluster randomised crossover trial in Papua New Guinea. *Lancet Glob Health*. 2024 Apr 1;12(4):e641–51.

22. Wi TE, Ndowa FJ, Ferreyra C, Kelly-Cirino C, Taylor MM, Toskin I, et al. Diagnosing sexually transmitted infections in resource-constrained settings: challenges and ways forward. *J Int AIDS Soc*. 2019 Aug;22 Suppl 6(Suppl Suppl 6):e25343.