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Reliable and User-Friendly Self-Testing Performance Evaluation of Vaginal pH Rapid Test Panel (Vaginal Swab)

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ABSTRACT

The Vaginal pH Rapid Test Panel (Vaginal Swab) is a dry chemical-based in vitro diagnostic (IVD) device developed for semi-quantitative determination of vaginal pH using self-collected specimens. This study assessed its diagnostic performance using 220 vaginal secretion samples (200 normal and 20 abnormal) compared with a validated reference method. Results demonstrated high sensitivity (95.0%), specificity (99.0%), and overall accuracy (98.6%). The device showed strong resistance to interference when users adhered to pre-test guidelines, and intra-/inter-assay reproducibility exceeded 98%. These results confirm the test's clinical reliability, usability, and cost-effectiveness as a self-testing tool for vaginal pH assessment and monitoring of vaginal microecological balance.

Keywords: *Vaginal pH; Rapid Test Panel; Self-testing; Bacterial Vaginosis; Clinical Performance; Vaginal Swab; Microecological Imbalance.*

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1. INTRODUCTION

Vaginal infections represent one of the most common gynecological health concerns worldwide, affecting women across all age groups. Such infections may cause discomfort and can lead to serious complications, including pelvic inflammatory disease (PID), urinary tract infections (UTIs), preterm birth, and low birth weight in pregnant women. Accurate and early detection of vaginal pH imbalance is therefore critical for preventing complications and improving women's reproductive health outcomes.

Traditional laboratory-based diagnostic methods, such as Gram staining, Nugent scoring, and microbiological culture, remain reliable but require laboratory facilities, trained personnel, and transportation of samples — limiting their accessibility and delaying results. In contrast, over-the-counter (OTC) self-testing kits for vaginal pH assessment provide a rapid, private, and accessible approach for home monitoring.

The Vaginal pH Rapid Test Panel (Vaginal Swab) evaluated in this study is designed for self-testing and semi-quantitative colorimetric detection of vaginal acidity. This research aimed to evaluate its accuracy, reproducibility, and user convenience compared with a validated reference test.

2. MATERIALS AND METHODS

Specimen Collection
A total of 220 vaginal secretion samples were collected — 200 normal and 20 abnormal based on clinical diagnosis. All samples were processed under controlled laboratory conditions and anonymized prior to analysis.

Test Procedure
Two test systems were compared:

Investigational Kit: AllTest Biotech Vaginal pH Rapid Test Panel (Vaginal Swab), Model IVPH-504H
Reference Method: A commercially validated vaginal pH rapid test (CE-certified)

Testing Procedure:
Vaginal swab specimen was collected using the sterile applicator.
The swab was gently rolled onto the detection zone of the test panel.
After 30 seconds, color changes were visually compared with the provided pH color chart.

Interpretation of Results:
Normal: pH 3.8–4.4 → yellow-green color.
Abnormal: pH > 4.4 → blue-green color; pH < 3.8 → bright yellow color.
Invalid: No color change or mismatch with color scale.

Performance Indicators
The following parameters were analyzed:
Diagnostic sensitivity, specificity, and accuracy.
Interference from external factors (e.g., menstruation, urine contamination, postmenopausal status).
Precision through intra- and inter-assay reproducibility tests (>98%).

3. RESULTS

Diagnostic Performance

Parameter	Result
Sensitivity	95.0%
Specificity	99.0%
Accuracy	98.6%

Interference Study
No significant interference was observed from post-menstrual samples, minor urine contamination, postmenopausal physiological changes, or vaginal discharge variations. These results confirm the device's robustness under typical user conditions.

Precision and Reproducibility
Intra- and inter-assay testing demonstrated over 98% reproducibility, confirming strong consistency and manufacturing quality control.

4. DISCUSSION

The Vaginal pH Rapid Test Panel (Vaginal Swab) provides a simple, fast, and non-invasive solution for evaluating vaginal acidity and detecting early signs of imbalance, such as bacterial vaginosis or candidiasis. Its colorimetric detection principle allows clear interpretation without laboratory instruments, enabling broad self-use.

Compared with traditional and laboratory-based pH meters, the Vaginal pH Rapid Test Panel is easier to use and less expensive, providing higher accuracy than general-purpose pH strips and serving as a practical alternative to laboratory assays.

Clinical Implications
Empowers users to monitor vaginal health at home with minimal training, facilitates early detection of pH imbalance, and improves privacy and accessibility — particularly in low-resource environments.

Limitations
The test is semi-quantitative and does not differentiate between infection types. Physiological false positives may occur in postmenopausal women due to naturally elevated vaginal pH levels.

5. CONCLUSION

The AllTest Biotech Vaginal pH Rapid Test Panel (Vaginal Swab, IVPH-504H) demonstrated high diagnostic performance, robust reproducibility, and excellent usability for home self-testing. Its strong correlation with reference methods confirms its validity for clinical and OTC applications. This test represents a reliable, private, and cost-effective solution for early identification of vaginal pH imbalances and can serve as an essential tool in preventive women's health

care.

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