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Performance Evaluation of Ovulation (LH) Rapid Test Midstream (Urine) for Self-Testing via Clinical Validation

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ABSTRACT

The Ovulation (LH) Rapid Test Midstream (Urine) is a chromatographic immunoassay designed for the qualitative detection of luteinizing hormone (LH) in human urine. This study evaluated its diagnostic performance using 300 urine specimens (76 positive and 224 negative) compared with a validated commercial reference test. The results demonstrated excellent accuracy, with both positive and negative coincidence rates reaching 100%. No cross-reactivity or interference was observed with related hormones, including FSH, hCG, and TSH. These findings confirm the assay's reliability, reproducibility, and suitability for home-based self-testing. The device serves as an efficient, user-friendly, and non-invasive tool for identifying the fertile window, thus facilitating family planning and conception management.

Keywords: *Ovulation; Luteinizing Hormone (LH); Rapid Immunochromatographic Assay; Self-Testing; Clinical Validation; Fertile Window.*

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1. INTRODUCTION

Luteinizing hormone (LH) plays a central role in the female reproductive cycle. A surge in LH levels occurs approximately 24–36 hours before ovulation, marking the most fertile period. Monitoring this hormonal change allows women to better plan conception or natural birth control.

Traditional ovulation detection methods, such as basal body temperature (BBT) tracking and cervical mucus observation, are indirect and often unreliable. BBT rises only after ovulation has occurred, providing retrospective rather than predictive information, while cervical mucus evaluation is subjective and prone to variability. Ultrasound monitoring, though accurate, requires clinic visits and specialized personnel, limiting its practicality for routine use.

Urinary LH testing offers a non-invasive, rapid, and accurate approach suitable for daily home use. This study evaluates the clinical performance and reproducibility of the AllTest Ovulation (LH) Rapid Test Midstream (Urine, Model FLH-103H), compared with the CE-certified ABON LH Rapid Test reference device.

2. MATERIALS AND METHODS

Specimen Collection
A total of 300 urine specimens were analyzed, comprising 76 LH-positive and 224 LH-negative samples. All specimens were handled and stored following standard laboratory protocols to prevent degradation or contamination.

Test Procedure
Two test systems were compared:
Investigational Device: AllTest Biotech Ovulation (LH) Rapid Test Midstream (Urine), Model FLH-103H
Reference Device: ABON LH Rapid Test (Urine)

Approximately 100–120 µL of urine was applied to each midstream device. The test was allowed to develop at room temperature for 3 minutes.

Interpretation:
Positive: Both test (T) and control (C) lines visible.
Negative: Only control (C) line visible.
Invalid: Absence of the control (C) line.

Performance Evaluation
Performance evaluation included:
Diagnostic agreement (positive and negative coincidence rates)
Cross-reactivity testing with hormones such as FSH, hCG, and TSH
Precision (intra- and inter-assay reproducibility) at LH concentrations of 30, 35, and 40 mIU/mL

3. RESULTS

Diagnostic Performance

Parameter	Result
Positive coincidence rate	100%
Negative coincidence rate	100%
Overall accuracy	100%

Cross-reactivity and Interference
No cross-reactivity was observed with structurally similar glycoprotein hormones (FSH, hCG, TSH). Environmental or physiological factors, such as pH variation, mild proteinuria, or medications, had no detectable effect on test results.
Precision

Both intra- and inter-assay reproducibility reached 100%, confirming consistency across test runs and operators.

4. DISCUSSION

The Ovulation (LH) Rapid Test Midstream (Urine) demonstrated high accuracy and excellent user performance characteristics. Its ease of use, non-invasive format, and rapid result time make it ideal for self-testing applications, especially for women tracking fertility at home.

Compared with conventional ovulation prediction methods, it is faster and more convenient than ultrasound, provides higher accuracy than basal temperature and mucus monitoring, and benefits from high-affinity monoclonal antibodies for enhanced sensitivity.

Clinical Implications
The test empowers women to identify their fertile window independently with laboratory-level reliability. It represents an important contribution to accessible reproductive health tools and supports family planning in both developed and resource-limited settings.

Limitations
As a qualitative test, results indicate hormonal presence but not concentration. Some menstrual cycles may lack an LH surge despite ovulation, which could confuse users. Repeat testing over several cycles is recommended for optimal results.

5. CONCLUSION

The AllTest Ovulation (LH) Rapid Test Midstream (Urine, FLH-103H) demonstrated 100% accuracy, precision, and specificity in clinical validation. It offers a reliable, rapid, and user-friendly tool for ovulation prediction, enabling women to monitor fertility easily at home. Its performance and usability confirm its suitability for integration into reproductive health management and clinical practice.

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