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User-Friendly Self-Testing Evaluation of Follicle-Stimulating Hormone (FSH) Detection in Urine

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ABSTRACT

The FSH Rapid Test Cassette (Urine) is a chromatographic immunoassay designed for qualitative detection of Follicle-Stimulating Hormone (FSH) in human urine. This study evaluated the diagnostic performance of the AllTest FSH Rapid Test Cassette using 250 urine specimens (85 positive and 165 negative) compared to a validated commercial reference test. Results demonstrated 100% diagnostic accuracy and perfect agreement with the reference device. No cross-reactivity or interference was detected with common urinary components or external factors, and intra-/inter-assay reproducibility achieved 100%. These findings establish the FSH Rapid Test Cassette as a reliable, patient-friendly, and clinically valuable tool for both screening and self-testing applications.

Keywords: *Follicle-Stimulating Hormone (FSH); Perimenopause; Menopause; Rapid Test Cassette; Urine; Immunochromatographic Assay; Diagnostic Performance*.

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1. INTRODUCTION

Menopause is a natural physiological transition occurring typically between 45 and 55 years of age, defined by the cessation of menstruation for at least 12 consecutive months. Hormonal fluctuations during perimenopause and early postmenopause often induce distressing symptoms and elevate the risk of chronic conditions. Reliable detection of menopausal status is therefore critical for timely medical guidance. Traditional diagnostic approaches, including serum FSH quantification, necessitate specialized instruments and trained personnel, thus limiting their use for home-based or low-resource environments.

Urine-based FSH testing represents a non-invasive and easily accessible alternative, with stable morning hormone concentrations and simplified handling requirements. The present study evaluates the diagnostic accuracy and reproducibility of the AllTest FSH Rapid Test Cassette (Model FFS-102H) in comparison with a validated reference device.

2. MATERIALS AND METHODS

Study Design and Sample Collection

A total of 250 urine specimens were collected for evaluation—85 positive and 165 negative for FSH. Samples were anonymized and randomly coded before testing.

Testing Procedure

Two assays were compared:
Investigational kit: AllTest FSH Rapid Test Cassette (Urine), Model FFS-102H
Reference kit: ABON FSH Rapid Test (Urine)
For each test, 100–120 µL of urine sample was applied. The results were interpreted after 3 minutes:
Positive: Both test (T) and control (C) lines visible.

Negative: Only control (C) line visible.
Invalid: Absence of the control (C) line.
Performance Parameters
Positive and negative coincidence rates
Overall accuracy
Cross-reactivity and interference studies
Reproducibility (intra- and inter-assay consistency)

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 over 20 common urinary substances, including LH, hCG, and TSH. Pre-analytical factors such as alcohol intake or non-hormonal medications showed no measurable interference.

Reproducibility
Both intra-assay and inter-assay results demonstrated 100% reproducibility, confirming consistent performance.

DISCUSSION
The FSH Rapid Test Cassette (Urine) offers a rapid, reliable, and user-friendly solution for detecting follicle-stimulating hormone, facilitating self-assessment during perimenopause and menopause. Its simplicity and non-invasive nature make it especially suitable for primary healthcare settings and low- and middle-income countries, where access to laboratory diagnostics is limited.

Compared with traditional serum-based FSH testing, the urine assay demonstrates equal diagnostic accuracy with significantly improved convenience. While ELISA remains the preferred choice for quantitative laboratory analysis, the AllTest FSH cassette provides a practical and cost-effective tool for qualitative screening and home-based monitoring.

Limitations
This test provides qualitative results only and should not be used as a standalone diagnostic measure. Accurate interpretation requires proper sample collection and adherence to instructions.

4. CONCLUSION

The AllTest FSH Rapid Test Cassette (Urine, Model FFS-102H) exhibits excellent diagnostic performance, zero cross-reactivity, and complete reproducibility, confirming its suitability for both clinical screening and individual self-testing purposes. Its ease of use and reliability support its integration into broader women's health management strategies.

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