MEDS Clinical Medicine (2025)
Clausius Scientific Press, Canada

DOI: 10.23977/medsc.2025.060409
ISSN 2616-1907 Vol. 6 Num. 4

Evaluation of the Performance of Follicle-Stimulating Hormone (FSH) Rapid Test Cassette for Self-Testing in Menopause Detection

Lei Zhang[1,*], Feng Yang[2], Junzhe Zhu[3]

[1]Zhejiang Gongshang University, Hangzhou, Zhejiang, 310018, China
[2]Community Health Service Center, Hangzhou, Zhejiang, 310000, China
[3]Wenzhou Medical University, Wenzhou, Zhejiang, 310000, China
**Corresponding author*

Keywords: Follicle-Stimulating Hormone; Rapid Test; Urine Specimen; Menopause; Chromatographic Immunoassay

Abstract: The Follicle-Stimulating Hormone (FSH) Rapid Test Cassette (Urine) is a chromatographic immunoassay specifically engineered for the qualitative detection of FSH in human urine specimens, playing a crucial role in assisting healthcare professionals in identifying perimenopause and menopause. This study was designed to conduct a comprehensive and systematic evaluation of its performance characteristics, encompassing sensitivity, specificity, accuracy, and clinical utility, by means of a direct comparison with another commercially available FSH rapid test. A total of 250 urine specimens were included in the analysis, with 85 confirmed as FSH-positive and 165 as FSH-negative through a validated reference method. The results of the evaluation revealed outstanding performance: the test achieved 100.0% relative sensitivity, meaning it correctly identified all positive specimens, 100.0% specificity, accurately ruling out all negative specimens, and 100.0% overall accuracy. Additionally, a Kappa value of 1 was obtained, which is the highest possible score for inter-method consistency, indicating perfect agreement with the reference method. Further testing confirmed that the cassette exhibits no cross-reactivity with luteinizing hormone (LH), human chorionic gonadotropin (hCG), or thyroid-stimulating hormone (TSH) at the specified concentrations, ensuring that results are not erroneously influenced by these related hormones. Moreover, the test maintained reliable and consistent performance under the recommended storage conditions, demonstrating its stability. These findings collectively confirm that the FSH Rapid Test Cassette is a reliable, rapid, and practical tool for the detection of elevated FSH levels, making it highly valuable for the timely assessment of menopausal status in clinical settings.

1. Introduction

Menopause, defined as the permanent cessation of menstruation, marks a significant physiological transition in a woman's life, typically occurring between the ages of 45 and 55[1]. The

period preceding menopause, known as perimenopause, is characterized by hormonal fluctuations, particularly a decline in estrogen levels and a subsequent rise in follicle-stimulating hormone (FSH) production [2]. FSH, a glycoprotein hormone secreted by the anterior pituitary gland, plays a key role in regulating ovarian follicle development. During perimenopause, as ovarian function declines, reduced estrogen feedback triggers increased FSH secretion, making FSH a valuable biomarker for assessing menopausal status [3].

Early identification of perimenopause and menopause is crucial for managing associated symptoms and reducing long-term health risks, such as osteoporosis, cardiovascular disease and metabolic disorders [4,5]. Traditional methods for evaluating menopausal status rely on clinical symptoms and menstrual history, which can be subjective and inconsistent. Laboratory-based FSH testing, while accurate, requires specialized equipment and professional operation, limiting its accessibility for immediate or at-home assessment[6].

The FSH Rapid Test Cassette (Urine) offers a non-invasive, user-friendly alternative for qualitative FSH detection, enabling self-testing and rapid results. This study aims to evaluate the performance of the FSH Rapid Test Cassette, including its diagnostic accuracy, cross-reactivity and practical utility, by comparing it with a commercially available reference FSH test. The goal is to validate its clinical application in aiding the detection of menopause and perimenopause.

2. Materials and Methods

2.1 Specimen Collection

A total of 250 urine specimens were collected from female patients attending outpatient clinics and hospitals who were seeking evaluation of their menopausal status. These specimens consisted of 85 FSH-positive samples and 165 FSH-negative samples, with their statuses confirmed using a validated reference method. All specimens were collected in clean, dry containers to prevent contamination and stored following standard protocols: they were refrigerated at 2-8 ℃ for a maximum of 48 hours, or frozen at -20 ℃ for longer-term storage when immediate testing was not feasible. Before testing, any frozen specimens were fully thawed and mixed thoroughly to ensure homogeneity, while those with visible precipitates were centrifuged or filtered to remove particles and achieve clarity. Additionally, all specimens were allowed to equilibrate to room temperature (15-30 ℃) to ensure optimal testing conditions, as temperature variations can affect assay performance.

2.2 Test Kits and Reference Method

The test device utilized in this study was the FSH Rapid Test Cassette (Colloidal Gold Method) manufactured by Hangzhou AllTest Biotech Co., Ltd., while the reference method employed was the commercially available FSH Rapid Test produced by ABON Biopharm (Hangzhou) Co., Ltd.—a fully validated device with well-established performance metrics for accurate FSH detection in urine specimens, widely recognized in clinical settings for its reliability.

Prior to initiating the testing procedure, several critical preparatory steps were strictly followed: first, the appropriate day for testing was carefully determined based on clinical guidelines to ensure optimal FSH concentration in urine samples, and the sealed test pouch was allowed to acclimate to room temperature (15-30 ℃) for at least 30 minutes before opening to prevent temperature-related interference with assay performance. Second, the test cassette was carefully removed from its sealed aluminum pouch and used immediately, with strict adherence to the one-hour maximum window from opening to testing to maintain reagent stability. The cassette was then positioned on a clean, level surface to ensure uniform liquid flow during the assay. Next, using a sterile sample

dropper, three drops of urine were vertically transferred into the designated specimen well, with meticulous care taken to avoid trapping air bubbles that could disrupt the chromatographic process. Finally, a timer was started immediately upon adding the urine; results were interpreted precisely at the three-minute mark when colored lines fully developed, as readings beyond ten minutes were discarded due to potential evaporation or reagent degradation that could lead to false interpretations.

To evaluate the performance of the FSH Rapid Test Cassette, a 2x2 contingency table was constructed, comparing the test results with those from the reference method. This table was used to calculate three key metrics: the positive coincidence rate (proportion of true positives correctly identified), the negative coincidence rate (proportion of true negatives correctly identified), and the total coincidence rate (overall agreement between the two methods). Additionally, Kappa consistency analysis was performed to quantify the strength of agreement beyond chance, with a pre-defined threshold of Kappa ≥0.75 indicating good consistency between the test cassette and the reference method.

3. Results and Discussion

3.1 Performance Characteristics

3.1.1 Sensitivity, Specificity, and Accuracy

A total of 250 specimens were subjected to parallel testing using the FSH Rapid Test Cassette and a validated reference method, with results revealing exceptional performance across key metrics. The positive coincidence rate stood at 100.0%, as all 85 specimens identified as positive by the reference method were correctly detected by the cassette. Similarly, the negative coincidence rate reached 100.0%, with the 165 reference-negative specimens all returning negative results via the rapid test. This consistent alignment across both positive and negative samples translated to an overall total coincidence rate of 100.0%. Further statistical validation via the Kappa coefficient yielded a value of 1.0, a score that signifies perfect agreement between the two testing approaches. Importantly, this level of consistency was maintained across all evaluated production lots, underscoring the test's reliability in different manufacturing runs. In terms of analytical performance, the test demonstrated high sensitivity, capable of detecting FSH concentrations at or above 25 mIU/mL. Additionally, it showed no cross-reactivity with other related hormones such as LH, hCG, or TSH at specified concentrations, confirming its high specificity for FSH. Collectively, these findings highlight the test's accuracy and suitability for reliable FSH detection.

3.1.2 Storage and Stability

The FSH test maintains robust stability when stored at 2-30 ℃ (36-86 ℉) in its sealed pouch, with no detectable degradation through the labeled expiration date—even under minor temperature fluctuations within this range—ensuring consistent reliability over its entire shelf life. Its non-invasive design, which requires only a simple, user-friendly sample collection (such as a urine or saliva sample), combined with an ultra-rapid three-minute turnaround time, makes it exceptionally well-suited for self-testing, allowing women to conveniently monitor key indicators of menopausal status in the comfort of their own homes and empowering them to take proactive steps in managing their reproductive health. However, the test has notable limitations: as a qualitative assay, it merely indicates the presence or absence of elevated FSH levels rather than providing precise numerical measurements, which may limit its utility for tracking gradual hormonal changes; potential hormonal interference can arise from recent use of contraceptives or hormone replacement therapies, which may skew results; and it is highly procedure-dependent, with

any deviation from step-by-step instructions—such as incorrect sample volume or timing—leading to invalid or misleading outcomes. Importantly, while a positive result signals elevated FSH, a hormonal marker often associated with menopause, it does not definitively confirm the condition on its own, and such results must always be carefully correlated with clinical symptoms (like hot flashes or irregular periods), detailed menstrual history, and a comprehensive professional medical evaluation to ensure accurate interpretation and appropriate next steps.

3.2 Discussion

3.2.1 Clinical Utility

The FSH Rapid Test Cassette's 100% accuracy relative to the reference method confirms its reliability for qualitative FSH detection. Its rapid turnaround time (3 minutes) and ease of use make it suitable for self-testing, enabling women to monitor their menopausal status conveniently. For women with irregular menstrual cycles or perimenopausal symptoms, the test provides actionable information to consult healthcare providers about lifestyle adjustments or preventive measures for conditions like osteoporosis [7].

The test's non-invasive nature (using urine specimens) improves patient compliance compared to blood tests, which require phlebotomy.

3.2.2 Limitations

The FSH Rapid Test has some limitations. Firstly, it provides qualitative rather than quantitative FSH levels, which would be beneficial for tracking hormonal trends over time. Additionally, taking oral contraceptives recently, breastfeeding or pregnancy can interfere with FSH levels, potentially impacting the test results. The test is also procedurally dependent; invalid results may occur due to improper specimen adding or timing, underscoring the importance of strict adherence to instructions. Lastly, while a positive result indicates elevated FSH, it does not confirm menopause; clinical correlation with symptoms and medical history is essential for accurate diagnosis.

3.2.3 Comparison with Other Diagnostic Methods

Compared to laboratory-based immunoassays, the FSH Rapid Test Cassette offers point-of-care convenience without compromising accuracy. Unlike serological tests, which measure FSH in blood, urine testing is more accessible for home use. The test's performance is comparable to other lateral flow immunoassays but with the added advantage of validated cross-reactivity data against LH, hCG and TSH, reducing false positives.

4. Conclusion

The FSH Rapid Test Cassette (Urine) exhibits exceptional performance, boasting 100% positive, negative, and total coincidence rates when compared to the reference method, alongside a perfect Kappa consistency score of 1.0—clear indicators of its reliability. It is highly specific, accurately detecting follicle-stimulating hormone (FSH) at concentrations of 25 mIU/mL or higher, with no cross-reactivity observed with other related hormones such as LH, hCG, or TSH, ensuring results remain trustworthy and free from interference.

Its rapid three-minute turnaround time, user-friendly design, and non-invasive urine sample requirement make it an invaluable tool for self-assessing menopausal status, enabling women to monitor hormonal changes conveniently at home and facilitating timely discussions with healthcare providers for potential clinical intervention.

While the test has limitations—including its qualitative nature (providing only presence/absence of elevated FSH rather than precise levels) and susceptibility to interference from recent contraceptive or hormone therapy use—its advantages in accessibility, speed, and ease of use make it a strong choice for primary screening. As with all diagnostic tools, results should be interpreted alongside clinical symptoms, menstrual history, and professional medical evaluation. Overall, the FSH Rapid Test Cassette stands as a robust addition to menopausal health monitoring, empowering women to take proactive control of their wellness journey.

References

[1] Turkington CA. The Perimenopause Sourcebook. Contemporary Books, New York, NY. 1998.
[2] Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
[3] Stanford JL, Weiss NS, et al. Combined Estrogen and Progestin Hormone Replacement Therapy in Relation to Risk of Breast Cancer. J. Am. Med. Assoc. 1995; 274(2): 137-142.
[4] Speroff L, Glass RH, Kase NG. Clinical Gynecologic Endocrinology and Infertility 5th Ed. Williams and Wilkins, Baltimore, MD. 1994; 588.
[5] Jacobs DS, Demott DR, Grady HJ, et al. Laboratory Test Handbook 4th Ed. Lippincott Williams and Wilkins, Baltimore, MD. 1996.
[6] North American Menopause Society. Menopause Practice: A Clinician's Guide. 6th ed. The North American Menopause Society, Cleveland, OH. 2015.
[7] Reid IR, Kanis JA. Epidemiology of osteoporosis. Osteoporosis International. 2005; 16(Suppl 3): S3-S7.