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High-Consistency and User-Friendly Self-Testing Evaluation of hCG for Pregnancy Detection in Urine

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ABSTRACT

The Pregnancy (hCG) Rapid Test Midstream (Urine) is a rapid chromatographic immunoassay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine. This study evaluated its diagnostic performance using 608 urine specimens (231 positive, 377 negative) compared with a CE-certified reference test. Results demonstrated perfect agreement with the reference method, with both positive and negative coincidence rates reaching 100%. No cross-reactivity or interference was observed with physiological or pharmacological compounds, and intra-/inter-assay reproducibility exceeded 99%. These findings confirm that the test is a reliable, rapid, and user-friendly self-testing tool for early pregnancy detection, suitable for both clinical and home-based use.

Keywords: *Human Chorionic Gonadotropin (hCG); Pregnancy Rapid Test; Urine Specimen; Self-testing; Chromatographic Immunoassay.*

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1. INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein secreted by the placental syncytiotrophoblast shortly after fertilization, serving as a key marker for pregnancy detection. Accurate and early hCG detection is essential for confirming pregnancy, managing prenatal care, avoiding teratogenic exposure, and identifying abnormal pregnancies.

Conventional laboratory methods—such as enzyme-linked immunosorbent assay (ELISA) and chemiluminescent immunoassay (CLIA)—offer high sensitivity and specificity but require specialized equipment, technical expertise, and longer turnaround times. Consequently, they are less suitable for immediate or home-based use.

This study aimed to evaluate the diagnostic performance, reproducibility, and user-friendliness of the Pregnancy (hCG) Rapid Test Midstream (Urine) compared to a validated CE-certified reference device (ABON's hCG Rapid Test). The study focused on establishing its reliability as a point-of-care and self-testing method for pregnancy detection.

2. MATERIALS AND METHODS

Specimen Collection
A total of 608 urine specimens were collected, including 231 positive and 377 negative samples for hCG. All specimens were properly labeled, anonymized, and tested under standard laboratory conditions.

Test Procedure
Two devices were compared:
Investigational kit: AllTest Biotech Pregnancy (hCG) Rapid Test Midstream (Urine), Cat. No. FHC-103H
Reference kit: ABON's hCG Rapid Test (Urine), CE-certified

Procedure:
The midstream absorbent tip was directly exposed to the urine stream or dipped into the sample.
The cap was replaced, and the test was laid flat.
Results were interpreted after 3 minutes.

Interpretation criteria:
Positive: Both test (T) and control (C) lines visible.
Negative: Only control (C) line visible.
Invalid: No control (C) line visible.

Performance Parameters
The study evaluated:
Positive and negative coincidence rates
Diagnostic accuracy
Cross-reactivity with other hormones and substances
Interference from physiological or pharmacological factors
Intra-assay and inter-assay reproducibility

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 detected due to the use of monoclonal antibodies specific to the β-subunit of hCG. Common urinary compounds and medications did not interfere with the test results.

Reproducibility
The intra-assay and inter-assay reproducibility exceeded 99%, demonstrating strong consistency across test runs and operators.

4. DISCUSSION

The Pregnancy (hCG) Rapid Test Midstream provides fast, accurate, and highly reliable results, making it ideal for both clinical point-of-care applications and home-based self-testing. Its advantages include ease of use without additional reagents, minimal training requirements, rapid turnaround time (≤3 min), and excellent diagnostic reliability.

Compared to traditional laboratory-based methods like ELISA or CLIA, the rapid test offers similar diagnostic accuracy but far greater accessibility and convenience. In contrast to many over-the-counter (OTC) pregnancy tests, this model demonstrated higher sensitivity, reproducibility, and specificity.

Limitations
Despite its strong performance, the test provides qualitative rather than quantitative results, may yield false positives in individuals receiving hCG-containing fertility treatments, and requires proper handling and adherence to the manufacturer's instructions.

5. CONCLUSION

The Pregnancy (hCG) Rapid Test Midstream (Urine, Cat. No. FHC-103H) demonstrated 100% diagnostic agreement with the reference method, no cross-reactivity, and >99% reproducibility. It offers a simple, reliable, and cost-effective tool for early pregnancy detection and is well-suited for both clinical settings and home-based self-testing. Its robustness and user-friendliness reinforce its role as an essential instrument in women's reproductive healthcare.

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