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Reliable Self-Testing Evaluation of Digital HCG Detection in Urine for Pregnancy Diagnosis

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ABSTRACT

The Digital hCG Pregnancy Test (Urine) is a self-administered in vitro diagnostic (IVD) device designed for qualitative detection of human chorionic gonadotropin (hCG) in urine. This study assessed its diagnostic performance using 67 urine samples (20 positive and 47 negative) compared with a validated commercial reference test. Results demonstrated 100% sensitivity, 100% specificity, and 100% overall accuracy. No cross-reactivity or interference was observed with common biological substances, and both intra-assay and inter-assay reproducibility achieved 100%. These findings confirm that the AllTest Digital hCG kit is a reliable, accessible, and user-friendly tool for home-based pregnancy self-testing.

Keywords: *Digital hCG Pregnancy Test; Urinary Human Chorionic Gonadotropin (hCG); Self-testing; Clinical Performance; Pregnancy Diagnosis.*

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1. INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by syncytiotrophoblastic cells of the developing placenta. It is a vital biomarker for confirming pregnancy and monitoring early gestational health, helping prevent complications such as ectopic pregnancy and miscarriage. Accurate and timely hCG detection is essential for ensuring early prenatal care and intervention.

Conventional laboratory methods, such as chemiluminescence immunoassay (CLIA) and enzyme-linked immunosorbent assay (ELISA), provide accurate quantitative results but require specialized facilities, equipment, and skilled personnel. These methods are less convenient for rapid or home-based applications.

The present study evaluates the diagnostic accuracy, reliability, and reproducibility of the Digital hCG Pregnancy Test (Urine, AllTest Biotech – Cat. No. FHC-E103H), comparing its performance with the Clearblue® Early Pregnancy Test as a reference method. This assessment emphasizes the potential of digital self-testing devices in expanding access to early pregnancy detection.

2. MATERIALS AND METHODS

Specimen Collection

A total of 67 urine specimens were collected, including 20 hCG-positive and 47 hCG-negative samples. All specimens were stored, labeled, and processed in accordance with clinical laboratory standards.

Test Procedure

Two devices were evaluated in parallel:
Investigational Kit: Digital hCG Pregnancy Test (Urine), AllTest Biotech Co., Ltd., Cat. No. FHC-E103H
Reference Device: Clearblue® Early Pregnancy Test

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Procedure:
The absorbent stick was placed directly into the urine stream or immersed in a urine sample for 10 seconds.
After replacing the cap, the test was laid flat on a level surface.
Results were read after 3 minutes.

Result Interpretation:
Positive: "YES+" displayed on the digital screen.
Negative: "NO–" displayed.

Invalid: No symbol or display of "?".
Performance Parameters
Evaluated criteria included:

Sensitivity, specificity, and accuracy.
Cross-reactivity with related hormones and substances.
Resistance to potential interference from medications, specimen contamination, and storage conditions.
Intra- and inter-assay precision and reproducibility.

3. RESULTS

Diagnostic Performance

Parameter	Result
Sensitivity	100%
Specificity	100%
Accuracy	100%

Cross-reactivity
No cross-reactivity was observed with over 20 potentially interfering substances, including luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH). The use of monoclonal antibodies specific to the β-subunit of hCG ensured high analytical specificity.

Interference Studies
Common pre-analytical variables, such as urine contamination or improper storage, did not affect test outcomes due to rigorous quality control measures.

Precision
The test exhibited 100% reproducibility across intra-assay and inter-assay assessments, confirming operational reliability and consistency.

4. DISCUSSION

The Digital hCG Pregnancy Test (Urine) provides a rapid, reliable, and user-friendly diagnostic option, combining clinical accuracy with convenient digital readout. Its clear "YES+/NO–" result display minimizes user interpretation errors and supports privacy-oriented home testing, especially beneficial in early pregnancy screening.

Compared with traditional lab-based techniques (ELISA, CLIA), this digital test offers comparable accuracy while eliminating the need for laboratory infrastructure. The device also surpasses conventional analog test strips in clarity and ease of use.

Clinical Implications
Facilitates early pregnancy detection in both clinical and home settings.
Enhances accessibility for users in low-resource environments.
Reduces the potential for misinterpretation of faint visual lines.

Limitations
Despite its strengths, the test remains qualitative and may yield false positives in individuals receiving hCG-based fertility treatments. Proper specimen handling and adherence to the test procedure are crucial for maintaining accuracy.

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5. CONCLUSION

The Digital hCG Pregnancy Test (Urine, AllTest Biotech – Cat. No. FHC-E103H) demonstrated perfect diagnostic performance (100% sensitivity, specificity, and accuracy) with no cross-reactivity or interference. The test's intuitive digital interface and high reliability make it an ideal solution for both self-testing and point-of-care screening, reinforcing its value as a modern and effective diagnostic tool in women's reproductive health.

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