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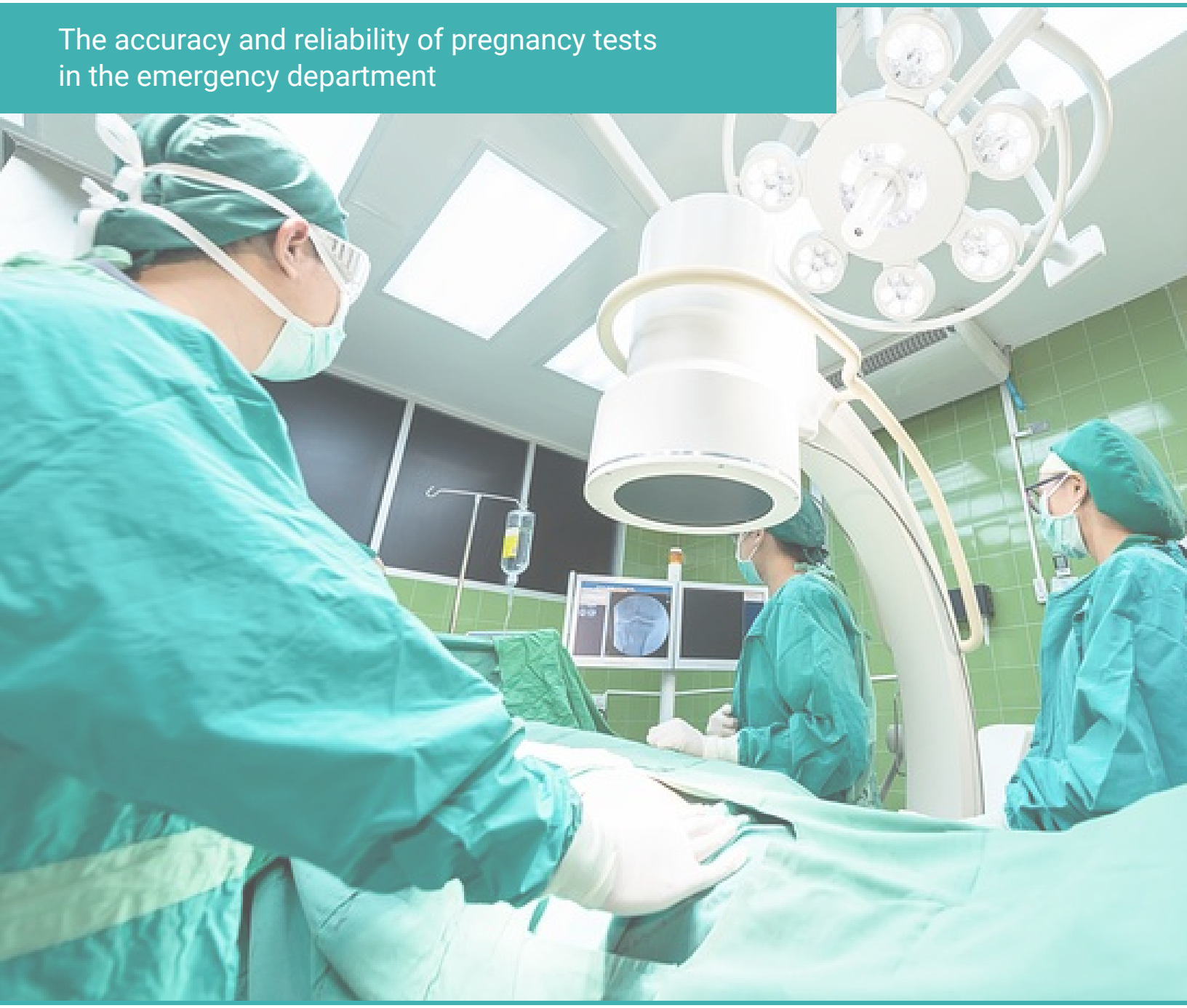
EMERGENCY ROOM: EVERY MINUTE MATTERS

The accuracy and reliability of pregnancy tests in the emergency department



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INTRODUCTION

Pregnancy Tests

Human chorionic gonadotropin (hCG) is a common hormone used to detect pregnancy. Human chorionic gonadotropin is a glycoprotein heterodimer hormone composed of an α- and β-subunit. The α-subunit is common to luteinizing hormone, follicle-stimulating hormone, and thyroid-stimulating hormone, whereas the β-subunit is unique to hCG. Early detection of pregnancy is important for caregivers to avoid certain medications and procedures that could harm a fetus.

The Challenge

Many qualitative point-of-care (POC) tests are commercially available for the detection of pregnancy. They can be classified into 3 categories based on the specific specimen required for the tests: urine, serum/plasma, and whole blood. Although urine is a noninvasive specimen, many false-negative results from POC urine-based tests have been experienced, leading to potential risk to the fetus. Recently, an investigation of 11 common POC hCG urine-based devices demonstrated that 9 of the 11 were susceptible to false-negative results. (1)Nerenz et al found that more than 60% of documented false-negative results of urine-based hCG tests were not caused by hCG βcf (2). Possible reasons include diluted urine, lower hCG levels in urine sample relative to serum, higher limit of detection of urine hCG test, and early gestational age. In certain emergency cases, a urine sample may not be readily available from a patient. Gottlieb et al recently reported that the use of whole blood in place of urine for bedside pregnancy testing resulted in a mean time savings of 21 minutes (3). One false-negative urine specimen was also observed in this study, which included 265 female patients (4) .

Quantitative serum hCG measurement is generally considered to be the most reliable method for hCG testing owing to the absence of hCG beta core fragment (βcf) interference, the presence of higher hCG concentration relative to urine specimen, and higher analytical sensitivity of the quantitative test. HCG βcf levels in serum are only 0.1% to 0.2% of intact hCG as reported by Udagawa et al (5). However, the relatively longer turnaround time makes the quantitative hCG measurement less attractive in medical settings where rapid results are preferred. Serum POC qualitative hCG tests are also not preferred in these settings because of the time required to process whole blood sample into serum. Therefore, there is a need for a rapid whole-blood hCG POC test for more reliable results. Obtaining a whole blood sample via venipuncture requires a trained health care professional. Fingerstick does not require special training and is often self-administered as in the case of blood glucose testing. Therefore, a test using a capillary sample via fingerstick could be beneficial.

02 THE SOLUTION

By providing results quickly, the ADEXUSDx® hCG test can streamline a doctor's decision-making process, which can be vital in emergency situations.

Fast
Results at the bedside within 10 minutes

Accurate
Positive Agreement: >99%
Negative Agreement: >99%

Reliable
Reduced exposure to liability from false negatives

User Friendly
No buffers, refrigeration or additional equipment required

Analytical Sensitivity
10 mIU/mL
Ability to detect low hCG levels as early as 48 hours

Sample Types
Capillary blood/whole blood/plasma/serum

To create a commercially viable capillary blood test platform, 3 technical challenges needed to be overcome. First, the test platform needed to produce valid results with minimal sample volume due to the limit of volume obtainable via fingerstick. Unlike conventional lateral flow test design, the ADEXUSDx® test platform can eliminate most of the wasted sample volume that does not contribute to test signal generation by guiding sample flow to the test strip horizontally. The second challenge was related to whole blood samples. A drop of whole blood contains only about 50% liquid. The other 50% is made up mainly of red blood cells. Therefore, the effective sample volume is only 20 µL or less. The device needed to be designed to generate equivalent sensitivity without additional solution and testing time. The final challenge was to limit the time to result, thus minimizing potential issues with blood coagulation. Reduction of strip length and widening of fiberglass region have effectively reduced the test time to 10 minutes for the hCG test.

The ADEXUSDx® hCG Test is a rapid test with demonstrated ease of use and clinical performance making the hCG test a useful POC test as well as OTC test owing to its suitability for capillary blood samples. It has a detection level at 10mIU/mL, a lower level compared with conventional urine hCG tests (20–25 mIU/mL), leading to potentially earlier detection of pregnancy.

03 REFERENCES

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