

Abbott's First-Of-Its-Kind Blood Test To Aid In Detecting Early Pregnancy Could Help Doctors Make Faster Treatment Decisions For Women

- Abbott receives U.S. Food and Drug Administration (FDA) clearance for its i-STAT® Total β -hCG test
- The blood test eliminates the need for a urine-based pregnancy test, which may be challenging to use in emergency situations
- Designed for use with the i-STAT® handheld blood analyzer, the β -hCG test provides results at the bedside within minutes

ABBOTT PARK, Ill., April 30, 2015 /PRNewswire/ -- Women account for nearly 60 percent of visits to emergency departments (ED) in the United States.¹ In emergency situations, it is critical for doctors to know the pregnancy status of women who are of childbearing age as soon as possible, since this influences decision-making when it comes to medications, imaging, surgery and other clinical care.

Traditionally, clinicians rely on urine-based pregnancy testing, but collecting a sample from a woman in an emergency setting can be difficult, especially if she is dehydrated, in pain or even unconscious.

Now, a simple new blood test, known as the i-STAT® Total β -hCG, can rapidly and accurately help detect the human chorionic gonadotropin (hCG) hormone that is usually used to determine whether a woman is pregnant. The test, which received U.S. FDA clearance, can detect if a woman is in the early stages of pregnancy by measuring very low levels of hCG in blood on Abbott's i-STAT® System, a handheld, portable blood analyzer. By using two to three drops of blood, the test can provide high-quality results at a person's bedside within 10 minutes.

"During a medical emergency, every minute matters," said Scott Pennington, RN, BSN, director of Critical Care Services at Gulf Coast Regional Medical Center in Panama City, Florida. "A fast blood test to help determine if a woman is pregnant can help doctors and nurses quickly decide appropriate care, which could potentially save lives."

Unlike urine testing, Abbott's β -hCG test can measure hCG in whole blood or plasma. By providing results quickly, the test can streamline a doctor's decision-making process, which can be vital in emergency situations.

The i-STAT® Total β -hCG test not only provides qualitative results that determine whether hCG hormone is present in the blood, but also quantitative results that specify the amount of hCG present. This information may help identify how far along a woman is in pregnancy while potentially reducing false-negative results by being more sensitive. This is important as data have shown that urine pregnancy tests are susceptible to false-negative results^{2,3,4}.

"In today's health care environment, clinicians are faced with a growing number of people who are seeking care," said Sharon Bracken, vice president, Point of Care Diagnostics, Abbott. "Abbott's β -hCG blood test serves as a new tool to help physicians determine pregnancy status quickly and accurately, right at the bedside, to help provide quality treatment."

In addition to the U.S., the blood test is available in Canada, Europe, the Middle East, South Africa, Australia and New Zealand. It is fully compatible with the handheld i-STAT® 1 System and the i-STAT® 1 Wireless System, which are already used in nearly 60 percent of U.S. hospitals to help improve care.

About Abbott Point of Care:

Abbott Point of Care is headquartered in Princeton, N.J., and develops, manufactures and markets critical medical diagnostic and data management products for rapid blood analysis. The company's premier product is the i-STAT® System, a market-leading handheld device capable of performing a broad menu of tests, including cardiac markers; blood gases; coagulation; lactate; chemistries/electrolytes; and hematology, using two or three drops of blood at the patient's side.

Visit Abbott Point of Care at www.abbottpointofcare.com.

About Abbott:

Abbott (NYSE: ABT) is a global health care company devoted to improving life through the development of products and technologies that span the breadth of health care. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 73,000 people.

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¹ National Hospital Ambulatory Medical Care Survey: 2011 Emergency Department Summary Tables. Emergency Department Visits. Centers for Disease Control and Prevention. Website: <http://www.cdc.gov/nchs/fastats/emergency-department.htm>. Accessed: April 15, 2015.

² Griffey RT et al. Hook-like effect causes false-negative point-of-care urine pregnancy testing in emergency patients. *J Emerg Med*. 2013;44(1):155-160.


³ Nerenz RD et al. Screening method to evaluate point-of-care human chorionic gonadotropin (hCG) devices for susceptibility to

the hook effect by hCG β core fragment: evaluation of 11 devices. *Clin Chem.* 2014;60(4):667-674.

⁴ Greene DN et al. Limitations in qualitative point of care hCG tests for detecting early pregnancy. *Clin Chim Acta.* 2013;415:317-321.

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