U.S. FDA Clears Abbott's High Sensitivity Troponin-I Blood Test That Aids Doctors In Diagnosing Heart Attacks Faster And More Accurately

Newly cleared diagnostic test could help identify heart attacks several hours sooner than standard troponin tests and help improve diagnosis in women

ABBOTT PARK, Ill., Sept. 25, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that its ARCHITECT STAT High Sensitivity Troponin-I blood test has received clearance from the U.S. Food and Drug Administration (FDA). As one of the most researched troponin diagnostic tests, doctors in the U.S. can now utilize this proven technology to help detect heart attacks faster and more accurately than contemporary troponin tests.

Transforming cardiac disease diagnosis

An estimated 840,000 Americans die of cardiovascular diseases each year.[1] Even as cardiovascular care advances, heart disease remains the leading cause of death.[1] Timing is a critical factor in helping doctors diagnose and treat those having a potential heart attack.

When people enter the emergency room with a suspected heart attack, doctors typically use a troponin blood test to help aid in their diagnosis. Troponin-I proteins are released from the heart and can be found at elevated levels in the blood when the heart muscle has been damaged. Abbott's High Sensitivity Troponin-I blood test measures very low levels of troponin, allowing doctors to evaluate heart attack in patients within two to four hours of admission.

Women may particularly benefit from this technology as they often have lower levels of troponin than men, which could lead to an undiagnosed heart attack with contemporary troponin tests. [2]

"The addition of Abbott's high sensitivity troponin-I assay to the laboratory's diagnostic testing menu is a great step forward to help laboratory scientists and clinicians better evaluate patients suspected of having a heart attack," said Fred Apple, Ph.D., co-director of Clinical and Forensic Toxicology Laboratory at Hennepin Healthcare/Hennepin County Medical Center and professor, Laboratory Medicine and Pathology at the University of Minnesota.

"Our research using this high sensitivity assay has demonstrated it can provide doctors with the ability to detect or rule out a heart attack earlier. This ability could help hospitals with more rapid triage and management of those diagnosed with a heart attack, as well as being able to safely discharge patients earlier on, resulting in savings to the healthcare system."

Robust body of evidence supports Abbott's highly sensitive troponin-I test

Abbott's blood test, known as High Sensitive Troponin-I inEurope and Asia, has been used throughout hospitals internationally and researched in more than 200 studies for its role in identifying heart disease and cardiac events, including:

- Abbott's High Sensitive Troponin-I test was the first test outside of the U.S. to offer gender-specific cut-offs, allowing physicians to more accurately diagnose heart attacks in women. A study published in the British Medical Journal found Abbott's test uncovered twice as many heart attacks in women than standard troponin tests.[2]
- A study published in The Lancet found the test may help doctors rule out heart attack sooner for two-thirds of patients who were suspected of having a heart attack.[3] This allows doctors to discharge patients more quickly and avoid unnecessary further testing.
- Research in the Journal of the American Medical Association (JAMA) found that detecting a change in troponin levels using the high sensitivity test over the first three hours after admission could facilitate an early diagnosis of heart attacks.[4]

Doctors can also be confident in the results they receive because Abbott's core laboratory diagnostic tests, including our troponin test, are by design not affected by biotin interference. Biotin is growing in popularity as a supplement that people believe may improve hair, skin and nails. Recently, the FDA alerted the public and medical community that biotin can significantly alter some lab test results, including some cardiac tests.

"This important milestone will allow U.S. physicians to utilize the advanced, proven capabilities of this blood test as they evaluate patients suspected of a heart attack," said Agim Beshiri, M.D., senior medical director, global medical and scientific affairs, Diagnostics, Abbott. "As one of the most widely researched high sensitivity troponin tests, this technology could help address several challenges in emergency departments today, including overcrowding and more accurately identifying heart attacks in women."

As U.S. hospitals are beginning to use high sensitivity troponin blood tests, education and collaboration among emergency room physicians, lab clinicians and cardiologists are critical. To help with this effort, Abbott will be introducing the Heart Partnership Program. The new program will help hospital care teams implement the blood test into their care pathway – including utilizing technologies that can automate the process – and use the test results to help diagnose patients and better inform treatment plans.

With this clearance, the blood test may be sold in the U.S. for use on Abbott's fully-automated ARCHITECT analyzer. The ARCHITECT STAT High Sensitivity Troponin-I results should be used in conjunction with other diagnostic information such as electrocardiogram (ECG), clinical observations and information and patient symptoms to aid in the diagnosis of heart attacks.

About Abbott:
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 103,000 colleagues serve people in more than 160 countries.

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