

BREA, Calif., Sept. 26, 2013 /PRNewswire/ -- Delivering the precision, clinical sensitivity and clinical specificity necessary to assist physicians with the diagnosis of myocardial infarction (MI), Beckman Coulter, Inc. announces the U.S. Food and Drug Administration (FDA) 510(k) clearance of its new Access AccuTnl+3 troponin I assay for use on the UniCel Dxl series of immunoassay systems.

Following the June 2013 clearance of the Access AccuTnl+3 troponin I assay on Beckman Coulter's Access 2 immunoassay analyzer, the new troponin assay is now cleared for use on all of the company's immunoassay systems, as well as the UniCel DxC integrated chemistry and immunoassay series.

"The AccuTnl+3 troponin assay has been clinically proven through a large multi-center study that enrolled more than 1,900 subjects, and it is confirmed that the test provides the clinical performance needed for optimal patient management," said Arnd Kaldowski, president, Beckman Coulter Diagnostics. "Our new troponin I assay is directly aligned with the FDA's October 2010 guidance to manufacturers of troponin assays and confirms our commitment to modernize the performance evaluation of this critical test."

The new troponin I assay continues Beckman Coulter's long history of proven clinical performance in cardiac disease management and ensures that laboratories and clinicians can optimally assist physicians with the diagnosis of MI. AccuTnl+3 delivers clinical sensitivity and specificity aligned with contemporary use of troponin set forth by the FDA and utilizes platform-specific reagents and calibrators.

About Beckman Coulter Beckman Coulter, Inc., based in Orange County, Calif., a subsidiary of Danaher Corporation (NYSE:

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), develops, manufactures and markets products that simplify, automate and innovate complex biomedical tests. More than 275,000 Beckman Coulter

systems operate in both diagnostics and life sciences laboratories on six continents. For more than 75 years, our products have been making a difference in peoples' lives by improving the productivity of medical professionals and scientists, supplying critical information for improving patient health and reducing the cost of care. For more information, visit

www.beckmancoulter.com

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