Beckman Coulter Announces FDA Clearance of New Access AccuTnI+3 Troponin I Assay for the Access 2 Immunoassay System

Delivering Diagnostic Confidence in Cardiac Disease Management

BREA, CALIF. - (June 19, 2013) - Continuing its long history of proven clinical performance in diagnosis of myocardial infarction (MI), Beckman Coulter, Inc. announces the U.S. Food and Drug Administration (FDA) 510(k) clearance of its new Access AccuTnI+3 troponin I assay for use on its Access 2 immunoassay system.

“Clinicians have depended on Beckman Coulter’s troponin I test for over 12 years and the new AccuTnI+3 assay has the proven performance to continue providing dependability to laboratories supporting emergency care,” said Arnd Kaldowski, president, Beckman Coulter Diagnostics. “Our new troponin I assay offers emergency physicians confidence in results that enable them to provide excellent care for patients at risk of MI.”

In October 2010, the FDA issued guidance to all manufacturers of troponin assays in an effort to modernize the performance evaluation and regulatory review of these critical tests. As such, the FDA requested that manufacturers conduct a clinical study in order to “modernize the labeling and claims in order to ensure that laboratories and clinicians are

-more-
informed of the true performance of troponin assays to help in result interpretation and laboratory verification of performance parameters.”

In accordance with the FDA’s new requirements, Beckman Coulter conducted a large multicenter prospective clinical trial on the AccuTnI+3 troponin I assay trial that enrolled over 1,900 subjects, and confirmed that the assay provides the clinical performance needed for optimal patient management. The data from this trial shows that the assay delivers the precision, clinical sensitivity and clinical specificity necessary to assist physicians with the diagnosis of MI.

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


Beckman Coulter, the stylized logo, Access and AccuTnI are registered trademarks of Beckman Coulter, Inc.

# # #

Link to the news release at:

https://www.beckmancoulter.com/wsrportal/page/newsDetail?id=GLB_BCI_153306