

Mitsubishi Chemical Medience Corporation Receives 510(k) Clearance for PATHFAST® cTnI-II (cardiac Troponin I) Test in U.S.

Tokyo, Japan – June 14, 2011 – Mitsubishi Chemical Medience Corporation announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) premarketing notification clearance to the PATHFAST® cTnI-II (cardiac Troponin I) diagnostic test, clearing the way for its sale in the United States. The test is designed to be used with the PATHFAST analysis system, a unique, self-contained, bench-top chemi-luminescence immunoanalyzer that rapidly measures concentrations of emergency biomarkers from a single whole blood sample.

The PATHFAST cTnI-II test determines the quantity of cardiac troponin I, a protein that is integral to cardiac muscle contraction, which is elevated in the bloodstream after damage to the myocardium (the middle and thickest layer of the heart wall).^{1,2} Due to its absolute coronary specificity and high sensitivity, cardiac troponin I is considered the preferred biomarker for diagnosing cardiac muscle damage, particularly following a heart attack.

“We are pleased that the FDA has recognized the utility of the PATHFAST system for measuring levels of cardiac troponin I in whole blood, and are confident the test will be widely accepted in the U.S. market, in accordance with international guidelines,” commented Dr. Toshihiko Yoshitomi, President and CEO of Mitsubishi Chemical Medience. “Today’s news is also an important step in supporting our ongoing negotiations to secure a strategic distribution partnership to launch the PATHFAST product line in the U.S. by early 2012.”

The 510(k) clearance of the PATHFAST cTnI-II test completes the cardiovascular product line of the PATHFAST analysis system, which also includes tests to determine quantities of N-terminal pro brain natriuretic peptide (NT-proBNP), D-Dimer, myoglobin, creatinine kinase (CK)-MB, and high-sensitivity C-reactive protein (hsCRP). With its whole blood use capability, the PATHFAST system eliminates the need for centrifugation of the specimen preparation, and can be used with either plasma or serum. The system has a 17-minute turn around time, a feature that can significantly reduce testing time, which can be a key consideration in a clinical laboratory or point-of-care (POC) setting.

Mitsubishi Chemical Medience and Mitsubishi Chemical Europe have sold more than 1,000 units of the PATHFAST system in Asia, Europe, and Latin America. The PATHFAST cTnI-II test is considered “guideline acceptable” by virtue of its minimal imprecision, as measured by a coefficient of variance (CV) of $\leq 10\%$ at the 99th percentile.³ By generating precise, accurate, and rapid results, the PATHFAST cTnI-II test is expected to enhance patient safety by streamlining coordination between emergency POC and central laboratories. It may be particularly useful in the emergency room (ER) setting, as well as in satellite laboratories, physician laboratories, and central laboratories.

About Mitsubishi Chemical Medience Corporation

Mitsubishi Chemical Medience Corporation is a member of the Mitsubishi Chemical Holdings Corporation Group, which is headquartered in Tokyo, Japan. Mitsubishi Chemical Medience is the first company in Japan to establish a business style that combines clinical and diagnostic laboratory testing services with in vitro diagnostics (IVD) and pharmaceutical development support. One of Mitsubishi Chemical Medience’s primary business areas is

their IVD business, which includes the development, sale, export, and import of in vitro diagnostic reagents and instruments. Mitsubishi Chemical Medience's globally accepted PATHFAST system, a rapid point-of-care immunochemistry analyzer, has been exported to more than 40 countries. Throughout almost five decades of IVD business, customers in various chemical and diagnostic industry segments have come to trust and rely on Mitsubishi Chemical Medience's competence and strength, as represented by the superior quality of their products and customized solutions.

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² *Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health*, Seventh Edition. Philadelphia, PA: Saunders, 2003. <http://medical-dictionary.thefreedictionary.com/myocardium>. Accessed June 6, 2011.

³ Apple FS. A new season for cardiac troponin assays: it's time to keep a scorecard. *Clinical Chemistry* 2009;55(7):1303-1306.