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Health Professional News

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Improving the detection of myocardial injury: Roche launches highly sensitive diagnostic test

Roche announced today the launch of a highly sensitive Troponin T assay in Europe as well as other regions recognizing the CE Mark. The assay provides the required level of sensitivity and precision for the newest definition of myocardial infarction and has received CE approval for use on the Elecsys / cobas e electrochemiluminescence immunoassay systems.

Based on the redefinition of myocardial infarction by the joint ESC/ACCF/AHA/WHF task force ⁽¹⁾, cardiac troponin, a specific component of the contractile apparatus of the heart muscle, is the preferred marker of myocardial injury. Myocardial infarction is diagnosed when blood levels of cardiac troponin are above the 99th percentile of the reference limit of a healthy population, together with clinical evidence of myocardial ischemia. Because a small elevation in cardiac troponin may lead to clinical intervention, the new guidelines require highly sensitive troponin assays with excellent precision in the low end values (10% or less total variation at the 99th percentile of the reference control group).

"Troponin T is an established marker of cardiac injury and has already demonstrated its utility for the diagnosis and risk stratification of acute coronary syndromes", said Dr. James Creeden, Chief Medical Officer at Roche Professional Diagnostics. "With this new assay, we meet the precision recommendations stated in the ESC/ACC guidelines. The improved sensitivity of Troponin T offers diagnostic value not only in acute coronary syndromes, but also in stable patients with a variety of cardiac disorders. The Elecsys Troponin T-high sensitive assay allows the identification of cardiac injury in patients with chronic heart failure without an acute cardiac event. In these patients, Troponin T-hs has been shown to be a strong predictor of cardiac events, independent from natriuretic peptides such as NT-proBNP or BNP."

"Bringing Troponin T- high sensitive to the market helps laboratories to consolidate cardiac assays on a single integrated clinical chemistry and immunoassay system", said Dr. Dirk Ehlers, Head of Roche Professional Diagnostics. "This assay underscores Roche's commitment to provide clinicians with the full range of IVD tools for implementing evidence based medicine."

About the test

The Elecsys Troponin T - high sensitive assay reaches a level of detection of 5 pg/ml and achieves less than 10% variation at 14 pg/ml corresponding to the 99th percentile of a reference population.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2008 sales by the Pharmaceuticals Division totalled 36.0 billion Swiss francs, and the Diagnostics Division posted sales of 9.7 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested nearly 9 billion Swiss francs in R&D in 2008. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at www.roche.com.

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Reference:

1. Thygesen K, Alpert JS, White HD Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. Universal definition of myocardial infarction. Eur Heart J 2007; 28: 2525–2538; J Am Coll Cardiol 2007; 50: 2173–2195; Circulation 2007; 116: 2634–2653.

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