

Roche Launches Improved POC Troponin Test to Diagnose Heart Attack Patients at High Mortality Risk



Roche (SIX: RO, ROG; OTCQX: RHHBY) has announced that its improved CARDIAC point-of-care Troponin T test for the cobas h 232 system is now available for countries accepting the CE Mark*. The test allows healthcare professionals to identify patients with a suspected acute myocardial infarction (AMI), termed also heart attack, with greater accuracy at low troponin concentrations, in just 12 minutes.

This hand-held, point-of-care diagnostic system requires no sample preparation or lengthy setup procedures. Therefore, it can be used in places where heart attack patients are often seen first, such as in an ambulance, emergency room, or a primary care/general practitioner's (GP's) office.

The key benefit of the improved test is that it is a quantitative test with higher accuracy at low troponin concentration (40-2000 ng/L quantitative range), compared to the former Roche POC test (100-2000 ng/L quantitative and 50-100 ng/L semi-quantitative range). This makes it possible to accurately measure lower troponin T levels between 40-100 ng/L. The test is used as an aid to rule-in patients with a suspected AMI and triage them effectively. The use of pre-hospital POC testing in the ambulance settings has been investigated in the preHAP clinical study, which showed that pre-hospital patients with a suspected AMI and a POC Troponin T ≥ 50 ng/L had a 3-10 times higher long-term mortality risk as compared with patients below that level¹.

"Point-of-care diagnostics solutions play an integral role in an effective, sustainable healthcare, and their importance will further increase", stated Roland Diggelmann, Chief Operating Officer, Roche Diagnostics Division. "The introduction of this improved test enables health care professionals to make earlier and more accurate interventions to save patients' lives."

The study results suggest that a troponin T POC test can assist the physician or paramedic on appropriate patient triage to the catheterization laboratory, acute cardiac care unit, or another emergency facility. A cardiac catheterization laboratory has dedicated diagnostic imaging equipment to visualize the arteries of the heart and allow health care professionals to make the appropriate interventions. Patients with Troponin T levels < 50 ng/L are at lower risk and can be sent to the local hospital for further investigation. The pre-hospital triage has the potential to help save time, costs and potentially lives by reducing the time to correct treatment.²

"Portable, accurate and easy-to-use, the CARDIAC point-of-care Troponin T test allows frontline healthcare providers to quickly make confident decisions where to send patients for treatment", said Jean-Claude Gottraux, Head of Roche Professional Diagnostics.

The CARDIAC point-of-care Troponin T test is standardized and compatible with the central laboratory test Elecsys cardiac Troponin T high-sensitive (cTnT-hs). After initial POC testing to diagnose patients in the ambulance (or GP's office), it can then be used in combination with further testing using the Elecsys cTnT-hs test at the central laboratory in a hospital. This means Roche can offer a standardized diagnostic solution that ranges from POC testing for the assessment of pre-hospital and hospital patients, with a suspected AMI, to central lab testing to support treatment decisions.

In Europe and the USA alone, 15-20 million patients present to the emergency department annually, with a sudden onset of chest pain and symptoms suggestive of AMI.³ Patients with chest pain and other symptoms suggestive of AMI account for approximately 10% of all emergency room consultations.⁴

AMI is a common cardiac event in which the blood supply to an area of the heart is interrupted, causing the muscle cells to die. The mortality rate of AMI is the highest within hours of onset. An early diagnosis and initiation of treatment greatly impact prognosis.⁵ The 2014 European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) 6guidelines recommend that troponin-positive (high-risk) non-ST-segment elevation acute coronary syndrome patients have coronary angiography within 24 hours, compared to the previous recommendation of 72 hours. This demands earlier triage of high-risk patients.

More about cobas h 232 POC system

The cobas h 232 point-of-care diagnostic system enables healthcare professionals to get results in just 12 minutes, thanks to a technically elaborate but easy to use system. The intuitive user interface and the easy utilization of test strips provides healthcare professionals with a smooth operation and fast results. In addition to the new CARDIAC point-of-care Troponin T test, the system can also test NT-proBNP, D-dimer, CK-MB and myoglobin, to facilitate rapid diagnosis in conditions such as acute coronary syndrome, heart failure and pulmonary embolism.

More about Troponin

Troponin is a heart muscle protein that is released into the blood stream during a heart attack. Fast and reliable heart attack diagnosis is critical as every hour of delay from the onset of symptoms to treatment, increases the mortality risk.²

More about the cardiac troponin T high-sensitivity test from Roche

The Elecsys cardiac Troponin T high-sensitive (cTnT-hs) test from Roche detects cardiac troponin which is the preferred biomarker for heart attack in clinical practice. In combination with an electrocardiogram (ECG), it has become the gold standard for the diagnosis. The high sensitivity of the Roche cTnT-hs assay significantly accelerates “rule-in” and “rule-out” decision-making, thereby maximizing the potential for effective treatment. At the same time, the faster decision-making may help to streamline the emergency room workload and lighten the burden on healthcare systems.⁷

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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