Media & Investor Release

Data show Roche's sixth-generation Troponin T test offers a new level of accuracy critical for diagnosing heart attacks

- **Recently granted CE Mark, the novel test delivers improved sensitivity and accuracy for faster and more reliable diagnosis in emergencies.**
- **The test helps clinicians quickly identify heart attack and rule out non-cardiac causes, ensuring patients receive the care they need at the earliest opportunity.**
- **The global TSIX clinical study involved more than 13,000 participants, validating performance across a diverse population that reflects real-world healthcare settings.[1,2]**

Basel, 30 September 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced the primary results from the TSIX Study Program, which evaluated the performance of its new sixth-generation high-sensitivity Troponin T test for diagnosing heart attacks. Presented at the European Society for Emergency Medicine (EUSEM) 2025[2] and the European Society of Cardiology (ESC) 2025[1], the study results showed that the Elecsys® Troponin T hs Gen 6 test was able to identify acute myocardial infarction (AMI), or heart attack, and identify those not having an AMI, with a high level of precision.[2,3] This supports the efficient triage of patients arriving at the emergency department, ensuring healthcare resources can be focused where they are needed most. This data announcement follows the recent CE Mark approval for the test.

As one of the top three reasons for emergency care visits,[4] chest pain creates significant anxiety and uncertainty for patients whilst putting pressure on healthcare services. Yet only one in every ten patients who presents with symptoms will actually be experiencing a heart attack.[5] With 49% of emergency departments in Europe reporting overcrowding on a frequent basis,[6] the ability to quickly and reliably identify those patients who are suffering from AMI, and to rule out those who are not, is crucial in ensuring the best possible outcomes for patients.

"Coronary artery disease continues to place an immense strain on global health systems, particularly in emergency care, where cases of chest pain are among the most challenging presentations to evaluate," said Matt Sause, CEO of Roche Diagnostics. "Our new test enables clinicians to detect even the smallest elevations in troponin levels – a critical biomarker for heart attack – with high confidence. This ensures that in a situation when every second counts, patients receive the life-saving care they need at the earliest opportunity, and emergency services can prioritise resources to deliver care effectively to those in urgent need."

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About Roche Diagnostics' commitment to heart health

With a 30-year legacy in troponin innovation, Roche was the first company in the world to introduce high-sensitivity troponin tests. And Roche's troponin test was the first to receive FDA approval. Building on this legacy, the novel test is the first in a series of anticipated approvals for Roche, reflecting the company's vision for the future of coronary artery disease (CAD) management. This includes a portfolio of innovative tests that enable consistent and precise biomarker measurements to be reliably compared across healthcare settings. It also includes future acute coronary syndrome (ACS) offerings that will combine next-generation digital algorithms, biomarkers, near-patient care devices, and laboratory analysers.

About the TSIX Study Program

Forming the basis for regulatory approval, the comprehensive TSIX study program recruited a total of over 13,000 individuals.[1,4] It is the first global clinical study program of its kind to be performed in the use of troponin testing, involving patients in the US, China, Japan and the EU, and reflects Roche's ambition to work towards more standardised care across the world.

The **REF-TSIX** study was designed to establish the standard upper reference limits (URLs) for troponin levels in the blood.[1] These limits represent the highest expected concentration of troponin in a healthy population, providing the benchmarks used to diagnose myocardial infraction. The study prospectively collected plasma and serum samples from a diverse global population to ensure the assay's accuracy across different demographics and healthcare settings. Data presented at European Society of Cardiology congress 2025 showed a 99th percentile URLs of 27 ng/L for the overall population and sex-specific URLs of 18 ng/L for females and 32 ng/L for males.[1] These findings confirm the test's consistency and accuracy, meeting the highest benchmarks for clinical diagnostics as recommended by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).[7]

To validate the clinical performance of the newly established URLs, the prospective, international, multicenter, longitudinal cohort study **PERFORM-TSIX** enrolled 5,631 patients across 50 sites,[2,4] presenting to emergency departments with symptoms of ACS. Up to five samples were collected at intervals after presentation at the emergency department, to provide a detailed assessment of the test's performance across time points.[4]

The study data demonstrated that the assay was highly effective at detecting heart attacks, meeting its primary endpoint using the universal 99th percentile URL at three hours post emergency department presentation.[3] Moreover, the study data showed that 56.6% of patients were able to be discharged in the first hours after presentation with a negative predictive value of 99.7%, underlining its excellent clinical performance.[2,4]

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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