Media Release



Roche receives CE Mark for its Chest Pain Triage algorithm to enhance detection of Acute Coronary Syndrome (ACS)

- Roche, in collaboration with Universitätsklinikum Heidelberg, has developed a Chest Pain Triage algorithm a CE-marked IVD medical device¹ set to transform cardiac care
- This novel algorithm offers a standardised assessment, helping emergency room doctors to make confident clinical decisions in ruling in or ruling out heart attacks (acute myocardial infarction)
- Cardiovascular disease causes a third of worldwide deaths², with chest pain being the second highest reason for emergency department (ED) visits³

Basel, 23 April 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the introduction of its innovative Chest Pain Triage algorithm as part of the **navify**® Algorithm Suite. This groundbreaking algorithm is designed to more quickly and accurately detect Acute Coronary Syndrome (ACS) in patients presenting with chest pain, one of the most common reasons for Emergency Department (ED) visits. As EDs are typically one of the most crowded hospital units, leading to challenges to swiftly diagnose critical conditions, such as chest pain.⁴ This new algorithm was developed in collaboration with Universitätsklinikum Heidelberg.

The Chest Pain Triage algorithm leverages state-of-the-art diagnostic technologies, including high-sensitivity cardiac troponin testing, to provide healthcare professionals with timely and reliable data to differentiate between cardiac and non-cardiac chest pain. This advanced algorithm is part of a wider integrated offering from Roche to address ACS, including the use of the cardiac troponin T Assay and integration with existing lab solutions, offering an efficient and comprehensive approach to patient triage in emergency settings. The Chest Pain Triage algorithm also leverages the European Society of Cardiology's (ESC) guidelines, and leading cardiologists and emergency medicine experts contributed to the development of the algorithm.

"The introduction of our Chest Pain Triage algorithm underscores Roche's commitment to improving care for cardiovascular disease, one of the world's largest health burdens," said Matt Sause, CEO, Roche Diagnostics. "One of the major challenges in managing chest pain in the emergency department is the length of stay, especially since some patients aren't actually having a heart attack. Our Chest Pain Triage algorithm can help doctors quickly decide who needs urgent cardiac care and who could be discharged sooner. With an early rule-out pathway, we can cut down Emergency Department visit times by over three hours.⁵"

The new algorithm aims to identify patients genuinely at risk by accurately identifying noncardiac chest pain cases through a definitive Rule-In, Rule-Out or Observe recommendation

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according to the ESC guidelines. The algorithm simplifies decision making by automatically selecting the proper ESC 0/1, 0/2, or 0/3 accelerated pathway, based on the timing of the blood sample collection. This has the potential to reduce unnecessary hospital admissions and associated costs. The algorithm also expedites the treatment process for patients with true ACS with Rapid Assessments of chest pain onset more than three hours before the first blood sample. In addition, it includes a medical dossier for clinician support, and simplifies documentation by allowing doctors to easily copy recommendations and results into patient records. For more information, please visit the <u>Chest Pain Triage algorithm site</u>.

The development of the Chest Pain Triage algorithm is part of Roche's commitment to early identification and treatment of Cardiovascular disease. The algorithm is available in Europe, the Middle East, and Asia, with availability in the United States at a later date, through Roche's **navify** Algorithm Suite, and can be integrated into current emergency department workflows*. Roche's cardiometabolic portfolio supports faster and more accurate triage decisions, and future ACS offerings will combine next-generation digital algorithms, biomarkers, near patient care devices, and laboratory analyzers.

The **navify** Algorithm Suite is a cloud-based platform hosting clinical algorithms from Roche and partners. It provides labs and hospitals with direct workflow integration through Electronic Health Records (EHR) and Lab Information Systems (LIS) for faster and more efficient processes.

About navify

The **navify** portfolio from Roche includes more than 30 digital solutions for labs, hospitals and patients worldwide. **navify** solutions connect the healthcare community with a robust digital infrastructure to integrate data efficiently and to accelerate clinician access to innovations as well as operational and medical insights. This work includes collaborating with other innovative companies such as Fortinet in cybersecurity services. The **navify** platform is designed to deliver security at every step of the data analytical process. All data is encrypted at rest and in transit. The solution is operated in compliance with applicable laws and regulations in the USA with HIPAA (Health Insurance Portability and Accountability) as well as with GDPR (General Data Protection Regulation) regulations in Europe.

Healthcare professionals can visit <u>navify Marketplace</u> to browse and request a growing number of next generation digital solutions from Roche and other companies – all designed to drive operational and clinical excellence, built on the foundational pillars of <u>digital trust</u>. More information is also available at <u>navify.com</u>.

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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 sciencedriven 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.

All trademarks used or mentioned in this release are protected by law.

* Availability will depend on the specific market and country in some cases. Please consult a local Roche representative for the availability of the chest pain algorithm in your market

References

[1] European Union: EUR-Lex. Chest Pain Triage algorithm registration [Internet: accesses March 24, 2025] Chest Pain Triage algorithm is an in-vitro diagnostic (IVD) medical device CE-marked (NB 0123) under the requirements laid out in the <u>IVD regulation (EU) 2017/746 (IVDR)</u>.

[2] Saloni D et al. Cardiovascular Diseases. [Internet: accessed March 24, 2025]. Available from: https://ourworldindata.org/cardiovascular-diseases?insight=cardiovascular-diseases-are-the-most-commoncause-of-death-worldwide#all-charts

[3] Yukselen Z, Majmundar V, Dasari M, Arun Kumar P, Singh Y. Chest Pain Risk Stratification in the Emergency Department: Current Perspectives. Open Access Emerg Med. 2024 Feb 4;16:29-43. doi: 10.2147/OAEM.S419657. PMID: 38343728; PMCID: PMC10853047

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Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD Phone: +41 79 407 72 58

Nathalie Altermatt Phone: +41 79 771 05 25 **Sileia Urech** Phone: +41 79 935 81 48

Lorena Corfas Phone: +41 79 568 24 95

Simon Goldsborough Phone: +44 797 32 72 915 **Karsten Kleine** Phone: +41 79 461 86 83

Kirti Pandey Phone: +49 172 6367262

Yvette Petillon Phone: +41 79 961 92 50

Phone: +41 79 327 54 74

Nina Mählitz

Dr Rebekka Schnell Phone: +41 79 205 27 03

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