

Roche introduces innovative Elecsys PRO-C3 test to improve precision in evaluating liver fibrosis severity

- **Elecsys PRO-C3, used with the ADAPT formula (age, diabetes status, PRO-C3, platelets), assesses liver fibrosis severity – a disease responsible for approximately one in every 25 deaths worldwide¹**
- **The test delivers results in just 18 minutes on Roche's cobas analysers, providing a fast and reliable diagnostic method.**
- **The test enables earlier identification of patients with significant liver fibrosis, potentially improving outcomes through timely management and access to emerging therapies.**

Basel, 06 May 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of its Elecsys® PRO-C3 test, a new diagnostic solution designed to assess the severity of liver fibrosis in patients showing signs of metabolic dysfunction-associated steatotic liver disease (MASLD). The test, developed in partnership with Nordic Bioscience, offers clinicians a simple and efficient method of identifying patients with liver fibrosis of varying severity, enabling timely intervention and appropriate management of the disease.

MASLD affects around 30% of the population,² and is one of the most common causes of chronic liver disease in the developed world.³ Caused mainly by diabetes, obesity and other cardiometabolic risk factors,³ a rapidly growing number of people are living with MASLD, representing a significant burden for patients and health systems worldwide. However, despite being responsible for approximately one in every 25 deaths globally,¹ the liver fibrosis associated with MASLD is often asymptomatic until the advanced stages and can go undetected for years. Unmanaged, it can lead to severe consequences such as cirrhosis, liver cancer, and liver failure.

"The Elecsys PRO-C3 test addresses an urgent need in the diagnosis, staging and management of liver fibrosis," said Matt Sause, CEO of Roche Diagnostics. "With MASLD affecting a growing number of people worldwide and new treatments emerging, it is critical to detect fibrosis accurately and early. Our innovative solution simplifies the diagnostic process and eases the burden on healthcare services, providing a clear and rapid assessment while reducing the requirement for invasive biopsies."

Until recently, no medicines were available to treat MASLD, and disease management options were focused on lifestyle interventions such as diet and exercise. New drug treatments for liver fibrosis are now emerging, giving clinicians, for the first time, a means of improving liver function and slowing disease progression.

The Elecsys PRO-C3 test requires only a single assay, which delivers results in only 18 minutes on Roche's cobas® analysers. This streamlines the process compared to currently available tests and reduces costs. Used in combination with the ADAPT formula,⁴ which includes PRO-C3 levels, platelet count, age and diabetes status, it provides a clear assessment of the severity of fibrosis, including distinguishing between different severities such as significant fibrosis (\geq F2), advanced fibrosis (\geq F3), and cirrhosis (F4). This is crucial for determining the appropriate treatment pathway for patients and identifying those who are eligible for new and emerging therapies.

Initially, the ADAPT score will be calculated manually. Later this year, Roche is planning to launch software that will automate the calculation and further streamline liver fibrosis diagnosis.

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.

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

References

- [1] Younossi ZM, Golabi P, Paik JM, Henry A, Van Dongen C, Henry L. The global epidemiology of nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH): a systematic review. *Hepatology*. 2023 Apr 1;77(4):1335-1347.
- [2] Riazzi et al. 2022, The prevalence and incidence of NAFLD worldwide: a systematic review and meta-analysis, *The Lancet Gastroenterology & Hepatology* 2022 Sep;7(9):851-861. doi: 10.1016/S2468-1253(22)00165-0. Epub 2022 Jul 5. PMID: 35798021.
- [3] EASL Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD). *J Hepatol* 2024; 81(3): 492-542.
- [4] Daniels SJ, et al. ADAPT: An Algorithm Incorporating PRO-C3 Accurately Identifies Patients With NAFLD and Advanced Fibrosis. *Hepatology*. 2019 Mar;69(3):1075-1086. doi: 10.1002/hep.30163. PMID: 30014517.

Roche Global Media Relations

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

Hans Trees, PhD

Phone: +41 79 407 72 58

Sileia Urech

Phone: +41 79 935 81 48

Nathalie Altermatt

Phone: +41 79 771 05 25

Lorena Corfas

Phone: +41 79 568 24 95

Simon Goldsborough

Phone: +44 797 32 72 915

Karsten Kleine

Phone: +41 79 461 86 83

Nina Mähltz

Phone: +41 79 327 54 74

Kirti Pandey

Phone: +49 172 6367262

Yvette Petillon

Phone: +41 79 961 92 50

Dr Rebekka Schnell

Phone: +41 79 205 27 03

Roche Investor Relations

Dr Bruno Eschli

Phone: +41 61 68-75284

e-mail: bruno.eschli@roche.com

Dr Sabine Borngräber

Phone: +41 61 68-88027

e-mail: sabine.borngraeber@roche.com

Dr Birgit Masjost

Phone: +41 61 68-84814

e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm

Phone: +1 650 225 3217

e-mail: kalm.loren@gene.com