

Roche expands hepatitis diagnostics portfolio to help clinicians diagnose and monitor patients with acute or chronic hepatitis B infection

- **Elecsys® HBeAg quant is an immunoassay that can be used as an early marker of acute hepatitis B infection, as well as an indicator of chronic active hepatitis in combination with other laboratory results and clinical information.**
- **The single test will inform clinicians if treatment is required and regimens are working in conjunction with other diagnostic assays.**
- **Almost 300 million people globally have chronic hepatitis B, causing a significant burden to health systems as it puts patients at high risk of death from cirrhosis and liver cancer.¹**

Basel, 27 November 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of Elecsys® HBeAg quant, an immunoassay that is able to determine both the presence and quantity (qualitative and quantitative) of the hepatitis B e antigen (HBeAg) in human serum and plasma. This launch means that, when combined with other laboratory results and clinical information, patients will now get confirmation on whether they have hepatitis B (HBV), and if so, to what extent, as well as treatment monitoring through one single assay. It is for use on the cobas® e analysers in countries accepting the CE Mark. HBV is the most common type of viral hepatitis affecting people of all ages, posing a significant burden on people and healthcare systems globally.¹

The new Elecsys HBeAg quant test will complement existing HBV testing markers. When a patient with suspected HBV returns a positive result of HBeAg, clinicians can determine the patient's disease phase,^{2,3} assess the activity of the virus in the liver⁴ and risk of progressive liver disease and Hepatocellular carcinoma (HCC).^{5,6}

"Hepatitis B affects millions of people each year and is a major global health burden. An accurate diagnosis is critical to ensuring timely treatment options. If hepatitis B is left untreated, it can cause chronic infections, putting people at high risk of death from cirrhosis and liver cancer," said Matt Sause, CEO of Roche Diagnostics. "The addition of the Elecsys® HBeAg quant immunoassay to our viral hepatitis testing portfolio underlines Roche's commitment to tackle healthcare's biggest challenges to support clinicians and their patients."

The new diagnostic tool reduces complexity and improves operational efficiency thanks to a leaner workflow for lab personnel. It can also simplify the experience for patients, as they only have to undergo one single test to indicate both the presence and quantity of HBeAg. The qualitative result provided by the test can help diagnose patients with HBeAg as an early

marker of acute HBV, as well as indicate chronic or active HBV. The additional quantitative answer will enhance patient management enabling the most appropriate treatment plan for patients.

The Elecsys HBeAg quant can also be used as a tool in perinatal screening⁷ and to monitor antiviral treatment response within infected patients, potentially supporting the implementation of a therapeutic plan tailored to individual patient's needs.

About the Elecsys HBeAg quant immunoassay

Elecsys[®] HBeAg quant is an immunoassay for the in vitro qualitative and quantitative determination of hepatitis B e antigen (HBeAg) in human serum and plasma. In conjunction with other laboratory results and clinical information, HBeAg quantification may be used as an aid for the diagnosis and monitoring of patients with hepatitis B viral infection. Elecsys[®] HBeAg quant reports both a qualitative and a quantitative readout, providing greater value to clinicians and patients. The test can be used for samples from patients with unknown HBeAg status (first line testing) as well as those who have previously tested positive (second line testing). The immunoassay is intended for use on all available cobas e analysers.

About hepatitis B

HBV is a viral infection that attacks the liver and can cause both acute and chronic disease.¹ It is the most common type of viral hepatitis affecting people of all ages, posing a significant burden on people and healthcare systems globally.¹ In 2019, WHO estimated that 296 million people were living with chronic hepatitis B infection, with 1.5 million new infections each year. In this same year, hepatitis B resulted in an estimated 820,000 deaths, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer). The virus is most commonly transmitted from mother to child during birth and delivery, as well as through contact with blood or other body fluids during sex with an infected partner, unsafe injections or exposures to sharp instruments.¹ While a vaccine exists to prevent HBV, there is currently no cure for patients who have been diagnosed with the infection.

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.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects

our efforts to improve access to healthcare together with local partners in every country we work.

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For more information, please visit www.roche.com.

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Roche Group 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

Simon Goldsborough

Phone: +44 797 32 72 915

Karsten Kleine

Phone: +41 79 461 86 83

Nina Mähltitz

Phone: +41 79 327 54 74

Kirti Pandey

Phone: +49 172 6367262

Rebekka Schnell

Phone: +41 79 205 27 03

Sileia Urech

Phone: +41 79 935 81 48