

Roche launches automated serology hepatitis E virus tests, including a test to detect acute HEV infections, recommended in the new WHO 2023 Essential Diagnostics List

- **It is estimated that one third of the global population could be at risk for infection with Hepatitis E virus.¹**
- **The new tests allow clinicians to diagnose acute and chronic infections amongst patients presenting with or without signs of the illness as recommended by the European Association for the Study of the Liver (EASL).²**
- **The tests complete Roche's panel used for the differential diagnosis of acute viral hepatitis caused by the hepatitis A, B, C and E viruses.**

Basel, 16 November 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of the Elecsys® Anti-HEV IgM and Elecsys Anti-HEV IgG immunoassays for the detection of hepatitis E virus (HEV) infections in countries accepting the CE mark. By testing for HEV infection, clinicians can support their patients to identify the cause of their symptoms and determine appropriate treatment, monitor for progression to severe acute HEV and prevent severe disease progression with antiviral treatment.^{1,2,6}

Recognising the value of diagnostics, the World Health Organization (WHO) has developed an “Essential Diagnostics List” which includes in-vitro diagnostics that should be available in all countries to increase timely and life-saving diagnoses. This year for the first time, tests for HEV are included to aid in the diagnosis and surveillance of HEV infection.⁵

“These tests highlight Roche’s commitment to contributing to the elimination of infectious diseases globally. Infection with HEV, a virus of significant global impact, results in 70,000 deaths and 3,000 stillbirths annually,”^{3,4} said Matt Sause, CEO of Roche Diagnostics. “The Anti-HEV IgM inclusion in the newly released WHO 2023 Essential Diagnostics List, demonstrates the important role this test plays in disease management for patients globally.

HEV testing also contributes to managing infected patients in high-risk groups and avoiding the misdiagnosis of drug-induced liver injury.^{1,2,6} They will also help to provide a more accurate estimate of the global HEV disease burden and inform governments and public health stakeholders on how to respond to the disease globally.⁵ As HEV is under-reported, the addition of these tests will support governments in managing outbreaks.

These fully automated assays will support lab personnel by enabling them to run them more efficiently compared to manual tests, as they require smaller sample volumes than manual tests, enabling results to be available within 18 minutes.

About the Elecsys Anti-HEV IgM and Anti-HEV IgG immunoassays

Elecsys Anti-HEV IgM is an immunoassay for the in vitro qualitative detection of IgM antibodies to HEV in human serum and plasma, and is used as an aid to detect an acute or recently acquired HEV infection. Elecsys Anti-HEV IgG is an immunoassay for the in vitro quantitative determination of IgG antibodies to HEV in human serum and plasma, and is used as an aid to detect a recent or past HEV infection.

The performance of both assays was evaluated in a multi-center study, which tested a total of more than 8,900 samples from presumed acute and recovered HEV infection for the determination of relative sensitivity, and from hospitalized patients, blood donors and pregnant women for the determination of relative specificity.

The overall relative sensitivity of the Elecsys Anti-HEV IgM and Elecsys Anti-HEV IgG assay was determined as 98.7% (95% CI 97.3 – 99.5%) and 99.1% (95% CI 98.0 – 99.7%), respectively. The overall specificity was determined as 99.4% (95% CI 99.2 – 99.6%) and 99.8% (95% CI 99.6 – 99.9%), respectively.

The new assays are available for use on the cobas® e 411 analyzer, cobas e 601/602 modules, and the cobas e 402 and cobas e 801 analytical modules. They expand Roche's comprehensive viral hepatitis serology test portfolio, and complete the test panel used for the differential diagnosis of acute hepatitis caused by the hepatitis A, B, C and E viruses (alongside the Elecsys Anti-HAV IgM, Elecsys Anti-HBc IgM, Elecsys HBsAg II, Elecsys Anti-HCV II, and Elecsys HCV Duo assays).

About the World Health Organisation's (WHO) 2023 Essential Diagnostics List (EDL)

The World Health Organisation's (WHO) 2023 Essential Diagnostics List (EDL) is an evidence-based register of in vitro diagnostics that supports countries to make national diagnostic choices.

Updated biennially, the EDL is intended to support national in vitro diagnostics policy development and to improve access to IVD testing and clinical laboratory services. As well as informing national EDLs, it provides advice on prioritization of IVDs at different levels of the healthcare system. Additionally, it informs United Nations agencies and non-government organizations that support the selection, procurement, supply or donation of In Vitro Diagnostics along with guidance to the private health technology and manufacturing sectors about the IVDs priorities required to address global health issues.⁵

About hepatitis E virus (HEV)

HEV is a pathogen of growing global public health concern.^{7,8} HEV includes 8 genotypes, of which HEV-1 to 4 are the most frequently detected globally. HEV-1 and HEV-2 infect only humans, whereas HEV-3 and HEV-4 can infect both humans and animals such as pigs, wild boar, rabbits and deer.⁹⁻¹⁵ It is estimated that HEV-1 and HEV-2 account for approximately

20.1 million HEV infections, 3.4 million symptomatic cases, 70,000 deaths, and 3000 stillbirths annually.³

HEV-1 and HEV-2 are commonly found in developing countries with poor sanitation, where HEV is transmitted through the fecal-oral route.^{7,10,16} HEV-3 accounts for most of the sporadic HEV infections in developed countries while HEV-4 is mainly found in Asia. Both HEV-3 and HEV-4 are transmitted zoonotically, most commonly through undercooked meat.^{7,17,18} In several countries, occasional transmission of HEV-3 and HEV-4 through blood transfusion has been reported.^{7,19,20}

HEV infection usually causes a mild or subclinical infection with a self-limiting illness that lasts from 2 to 6 weeks.^{21,22} Symptomatic hepatitis E is similar to other acute hepatitis infections (fatigue, nausea, vomiting as well as jaundice and elevated liver enzymes).²¹ High-risk populations are immunocompromised patients (specifically transplant organ recipients),^{22,21,23,24} patients with underlying liver conditions, and elderly people and pregnant women.^{9,19,13,25-27}

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 endeavour 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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Roche Global Media Relations

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

Hans Trees, PhD

Phone: +41 79 407 72 58

Simon Goldsborough

Phone: +44 797 32 72 915

Nina Mähltz

Phone: +41 79 327 54 74

Dr. Rebekka Schnell

Phone: +41 79 205 27 03

Nathalie Altermatt

Phone: +41 79 771 05 25

Karsten Kleine

Phone: +41 79 461 86 83

Kirti Pandey

Phone: +49 172 6367262

Sileia Urech

Phone: +41 79 935 81 48

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

Dr. Gerard Tobin

Phone: +41 61 68-72942

e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm

Phone: +1 650 225 3217

e-mail: kalm.loren@gene.com