

## Roche launches innovative dual antigen and antibody diagnostic test supporting the fight to eliminate the hepatitis C virus

- **Elecsys HCV Duo is the first commercially available immunoassay that allows the simultaneous and independent determination of the hepatitis C virus (HCV) antigen and antibody status.**
- **The Elecsys HCV Duo immunoassay enables significantly earlier diagnosis of active HCV infection, making it possible to get patients appropriate care sooner to stop both the disease progression and transmission.**

Basel, 18 July 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of the Elecsys® HCV Duo immunoassay in countries that accept the CE Mark. Elecsys HCV Duo is the first available immunoassay that allows the simultaneous and independent determination of the hepatitis C virus (HCV) antigen and antibody status from a single human plasma or serum sample. This means that the test can be used to detect the early stage of infection, as well as when the patient is recovering from the virus, or showing signs of a chronic infection that may lead to other diseases, such as liver cancer.

By utilising the dual detection of HCV core antigen and antibodies to HCV, the Elecsys HCV Duo assay enables significantly earlier diagnosis of active hepatitis C virus infection compared to using antibody-only assays, as core antigen appears early in the course of infection and is a marker of ongoing viral replication. This can lead to earlier intervention for patients, reduction in the number of clinic visits needed to take additional test samples and can alleviate some of the testing burden on healthcare systems.

“With improved hepatitis screening, healthcare systems have the opportunity to eliminate the disease through improved prevention, testing and treatment services,” said Thomas Schinecker, CEO of Roche Diagnostics. “The addition of the Elecsys HCV Duo assay to our HCV testing portfolio can help in the fight to eliminate the hepatitis C virus. The launch of this innovative dual antigen and antibody diagnostic test underlines our commitment to support clinicians and their patients in reducing the impact of infectious diseases, where it’s needed most.”

In 2019, 58 million people were living with chronic HCV infection, but only 21% were aware of it.<sup>1</sup> 290,000 people died of hepatitis C-related causes, like cirrhosis and liver cancer, more than those due to HIV or malaria. While there is no vaccine available for HCV, there is effective treatment with antivirals that can lead to a cure in 98% of patients.<sup>1</sup> However, to find affected populations there is a greater emphasis on increased access and utilisation of testing to reduce the impact of the virus, as well as to provide better disease management for patients testing positive for HCV.<sup>3</sup>

Through early detection and intervention it is possible to get patients appropriate care sooner, stop the disease progression, as well as transmission and, potentially, reduce unnecessary healthcare costs. Addressing these factors is crucial in efforts to eradicate the disease. Currently, there are major gaps in access to hepatitis C testing and treatment in all populations, especially among economically disadvantaged populations, as well as those living in rural regions.

### **About the Elecsys HCV Duo immunoassay**

Elecsys® HCV Duo is an immunoassay for the in vitro qualitative determination of hepatitis C virus (HCV) core antigen (HCV Ag) and antibodies to HCV (anti-HCV) in human serum and plasma. The test, in conjunction with other laboratory results and clinical information, may be used to aid in the diagnosis of and the screening for HCV infection. The test can also be used as a screening test to prevent transmission of HCV to recipients of blood, blood components, cells, tissue, and organs. The subresults (HCV Ag and anti-HCV) are intended as an aid in the selection of the confirmatory testing algorithm for reactive samples.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on the cobas e 801 and cobas e 402 immunoassay analyzers.

### **About hepatitis C**

Hepatitis C is an inflammatory liver disease caused by infection with the hepatitis C virus (HCV). According to the World Health Organization, 1.5 million people were newly infected with HCV, in 2019.<sup>2</sup> Approximately 58 million people are chronic carriers of the hepatitis C virus, and most do not know they are infected.<sup>2</sup> The disease can ultimately result in cirrhosis, liver failure and hepatocellular carcinoma, which together are responsible for hundreds of thousands of deaths each year. While the momentum to address viral hepatitis is growing, progress in service delivery is still insufficient. Only 21% of people living with chronic hepatitis C infection know their status. 9.4 million people chronically infected with HCV were receiving treatment at the end of 2019, a 10-fold increase from 1 million people receiving treatment at the end of 2015, yet treatment coverage is only 13% of the people in need.<sup>2</sup> Causes of hepatitis spreading include percutaneous exposure to blood (e.g. by sharing needles, poorly sterilised medical equipment, needlestick injuries in healthcare, unsanitary tattooing/piercing, blood/blood product transfusion, hemodialysis), organ and tissue transplants and grafts, sexual contact or from being passed from an infected mother to their fetus.<sup>4</sup> These populations are the focus for existing testing protocols.

### **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 recognizing 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.

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](http://www.roche.com).

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## References

[1] Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016–2021: actions for impact. Geneva: World Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO. <https://www.who.int/publications/i/item/9789240027077>

[2] WHO. (2021). Hepatitis C factsheet. Available from: <https://www.who.int/news-room/factsheets/detail/hepatitis-c> - July 2021

[3] World Hepatitis Alliance (WHA), 2021. <https://www.worldhepatitisday.org/>

[4] World Health Organization (2021). Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016–2021: actions for impact. <https://www.who.int/publications/i/item/9789240027077>

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