Media & Investor Release

Roche introduces cobas Hepatitis D Virus (HDV) test, the first fully automated diagnostic solution to identify the most severe form of viral hepatitis

- **The new test enables clinicians to reliably diagnose HDV and monitor patients' treatment response.**
- **Hepatitis D affects nearly 12 million of people globally and is considered the most aggressive form of viral hepatitis, often leading to liver failure and cancer faster than other types.**
- **The cobas HDV test is the first high-throughput, fully automated HDV assay on the market, addressing the urgent need for a consistent, widely accessible solution and expanding access to critical testing just as new treatments for the disease become available.**

Basel, 14 July 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that it introduces the cobas® HDV test for use on the cobas® 5800/6800/8800 systems, a diagnostic tool for the detection and quantification of Hepatitis D Virus (HDV) RNA, in countries accepting the CE mark. Available on the industry-leading cobas 5800/6800/8800 systems, Roche aims to help healthcare providers in identifying patients and monitoring their care more effectively alongside newly available treatments.

"This is an important advancement of our commitment to improving outcomes for people living with liver disease," said Matt Sause, CEO of Roche Diagnostics. "With the cobas HDV test, we are providing clinicians with a reliable tool to aid in the identification of infected individuals and to monitor their response to treatment."

Hepatitis D, which globally affects an estimated 12 million people[1], is a unique 'satellite virus' that can only infect people who already have the Hepatitis B virus (HBV). Because of this relationship, it can occur as a co-infection, that is, being infected with both viruses at once, or a super-infection, which is being infected with HDV after already having chronic Hepatitis B. Co-infection could explain about 1 in 5 cases of liver disease[2], and super-infection being particularly dangerous with over 90% of cases becoming chronic and accelerating to liver damage[3].

Despite the severity of the disease, testing has often been limited to manual methods or lab-developed tests that can vary in consistency. The cobas HDV test is the first high-throughput, fully automated HDV assay on the market and addresses the urgent need for a consistent, widely accessible solution. This is particularly important now that specific treatments for HDV are becoming available in many markets, requiring precise monitoring to ensure they are working and to advance patient care.

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The assay runs on the fully automated cobas® 5800/6800/8800 systems. These fully automated platforms are already used in laboratories worldwide, allowing for seamless integration into existing workflows. By automating the testing process, laboratories can deliver accurate results faster and more efficiently, helping clinicians make timely decisions for their patients.

About Hepatitis D

Hepatitis D leads to faster progression toward liver failure, cirrhosis, and liver cancer compared to other forms of hepatitis. Symptoms can be severe and include jaundice (yellowing of the skin and eyes), extreme fatigue, abdominal pain, and nausea. The virus is transmitted through contact with infected blood or bodily fluids. Because it requires Hepatitis B to replicate, vaccination against Hepatitis B is the most effective way to prevent Hepatitis D infection.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

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

References

[1] World Health Organization factsheet on Hepatitis D, July 2025. https://www.who.int/news-room/fact-sheets/detail/hepatitis-d
[2] The global prevalence of hepatitis D virus infection: Systematic review and meta-analysis. Stockdale, Alexander J. et al. Journal of Hepatology, Volume 73, Issue 3, 523 - 532
[3] Bardak AE, Ozturk NB, Gurakar M, Sequeira L, Yildiz E, Ozmert EH, Idilman R, Gurakar A. Updates on Recent Advancements in Hepatitis D Virus Treatment. Viruses. 2025 Aug 10;17(8):1100. doi: 10.3390/v17081100. PMID: 40872814; PMCID: PMC12390690.

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