

Roche launches the cobas MPX-E assay, a new 4-in-1 donor screening test to further safeguard the global blood supply

- **The cobas MPX-E test provides four critical results (for HIV, HCV, HBV, and HEV) in a single test, increasing laboratory efficiency and decreasing healthcare costs.**
- **The new test delivers faster turnaround times and allows labs to implement Hepatitis E (HEV) screening without requiring additional instrumentation.**
- **This assay is designed for use on the fully automated cobas x800 systems, enabling high-throughput screening with up to 8 hours of walk-away time.**

Basel, 30 March 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the cobas[®] MPX-E assay, a qualitative in-vitro test for the detection and discrimination of Human Immunodeficiency Virus (HIV 1 and 2) and Hepatitis C, B, and E viruses, is now available in countries accepting the CE mark. This new assay represents a significant advancement in donor screening by consolidating the detection of four major viral targets into a single, efficient workflow. By identifying these pathogens simultaneously, the cobas MPX-E assay helps laboratories streamline their operations while enhancing the safety of blood and blood products for patients.

“Safe, timely access to blood products is a cornerstone of modern healthcare,” said Matt Sause, CEO of Roche Diagnostics. “With the launch of the cobas MPX-E test, we will help ensure that patients receive the safe blood products they need by providing a fully integrated solution that includes the most critical viral pathogens and improves lab efficiency.”

The cobas MPX-E assay is designed to meet the evolving needs of modern laboratories and, through increased sensitivity and specificity, help to prevent HEV transmission through blood transfusions. Hepatitis E (HEV) alone accounts for an estimated 20 million infections and 70,000 deaths annually worldwide.¹ Because many carriers are asymptomatic, robust screening is the only way to manage risks to the blood supply.

Additionally, the new test features dual-target detection for HIV-1 group M, targeting two independent regions of the viral genome to improve sensitivity and ensure reliable results even in the presence of mutations.

Nucleic Acid Testing (NAT) blood screening is approximately 800m CHF globally with an expected Compound Annual Growth Rate of +2% from 2024 to 2029.²

The assay runs on the fully automated cobas[®] x800 systems (cobas[®] 6800/8800 and cobas[®] 5800), which are already used by laboratories worldwide to run more than 10 million tests per month.

About the cobas MPX-E assay

The cobas MPX-E assay is a multiplex real-time PCR test for the simultaneous detection and discrimination of HIV, HCV, HBV, and HEV in distinct channels. It is designed for use on the cobas x800 family of systems, offering a scalable solution that allows multiple tests to be run simultaneously at the same time. The assay offers flexible testing options, allowing laboratories to test for all four targets or select single targets based on their specific screening requirements. The ready-to-load reagents and automation allow for up to eight hours of walk-away time, freeing up laboratory staff for other critical tasks.

For laboratories currently screening for HEV, this assay offers faster turnaround times. For those looking to implement HEV screening, the cobas MPX-E provides a cost-effective solution that does not require additional floor space or instrumentation

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.

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References

[1] Klöhn M, Schrader JA, Brüggemann Y, Todt D, Steinmann E. Beyond the Usual Suspects: Hepatitis E Virus and Its Implications in Hepatocellular Carcinoma. *Cancers (Basel)*. 2021 Nov 22;13(22):5867. doi: 10.3390/cancers13225867. PMID: 34831021; PMCID: PMC8616277.

[2] FY24 IQVIA Diagnostics market book

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