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Roche launches next-generation duplex test for parvovirus B19 and hepatitis A in markets accepting the CE mark

cobas® DPX assay increases safety of human plasma and plasma products

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the commercial availability of the **cobas® DPX** test for use on the **cobas® 6800/8800 Systems**—expanding the menu of the newest molecular diagnostic platforms from Roche with next generation donor screening assays. The **cobas® DPX** test is a real-time PCR duplex assay for parvovirus B19 (B19V) and hepatitis A virus (HAV) in human plasma. Using nucleic acid amplification testing (NAT) to detect these viral targets is an important step in ensuring the safety of blood and plasma products.

“Roche is committed to providing the broadest coverage and most efficient blood and plasma screening tests to ensure the highest safety for patients,” said Paul Brown, Head of Roche Molecular Diagnostics.

“Introducing **cobas® DPX** to the **cobas® 6800/8800 Systems** is an important step toward that goal, complementing our current donor screening tests for the detection of HIV, HCV, HBV, WNV and HEV.”

By utilizing **cobas® DPX**, blood and plasma testing centers are able to quickly identify and remove HAV-contaminated units, while simultaneously minimizing the B19V burden in plasma pools. Performing NAT with the **cobas® DPX** test enables testing facilities to increase the processing efficiency of donations while preserving high safety standards for plasma products used in transfusions and other therapeutic treatments for patients.

The **cobas® DPX** assay and the **cobas® 6800/8800 Systems** are commercially available in markets that recognize CE-Mark and are not currently available in the United States.

About Roche Blood and Plasma Screening

Roche is a leader in the global blood and plasma NAT screening market, which is estimated at almost 800 million CHF. Nucleic acid-based tests enable earlier detection of active viral infections than conventional antibody or antigen assays. Roche's real-time PCR-based nucleic acid assays have been used since 1998 to screen blood and plasma products. Currently, more than 250 testing centers worldwide use Roche's automated systems for blood and plasma screening.

Human plasma products are frequently used in the treatment of chronic and hereditary diseases and disorders such as hemophilia and primary immunodeficiency diseases. Plasma is also used to treat patients who have suffered severe burns or trauma, and during major surgery. To support therapeutic use, human plasma can be recovered from blood donations or collected directly from donors, and subsequently fractionated into its components, such as immunoglobulins, albumin, and clotting factors.

About the cobas® 6800/8800 Systems

The **cobas®** 6800 and 8800 Systems are fully automated solutions designed for blood donor screening, viral load monitoring, women's health and microbiology testing. They are available in medium and high throughput models, respectively. Based on the Nobel-prize winning PCR technology, the systems are designed to deliver increased automation and throughput with shorter time to results, providing users with greater testing flexibility to increase overall workflow efficiencies.

The systems provide up to 96 results in less than 3.5 hours, and a total of 384 results for the **cobas®** 6800 and 960 results for the **cobas®** 8800 in an 8 hours shift. Both systems allow for mixed batching, making it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (**cobas®** 6800) and four hours (**cobas®** 8800) of "work-away" time* with minimal user interaction.

For more information about the systems, please visit www.cobas68008800.com.

* May vary based on workflow demands

About Roche



Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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 roche.com.

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