Media Release

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First Duplex Test for Parvovirus B19 and Hepatitis A Virus Increases Safety of Human Plasma and Plasma Products

cobas® TaqScreen DPX Test offers real-time discrimination in a single assay[1]

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the **cobas**® TaqScreen DPX Test for use on the **cobas s** 201 system is now available with the CE Mark. It is the first IVD test to offer complete coverage of all human genotypes of parvovirus B19 (B19V) and hepatitis A virus (HAV) in one assay. The test is a state-of-the-art, in-vitro nucleic acid amplification technology (NAT) test which simultaneously quantifies B19V genotypes 1, 2 and 3 DNA and detects HAV genotypes I, II and III RNA in individual samples or pooled plasma samples of human origin.

The **cobas**® TaqScreen DPX Test uses multi-dye, real-time polymerase chain reaction (PCR) technology which allows for the simultaneous detection and identification of individual viral targets without the use of complementary discriminatory tests. The introduction of the **cobas**® TaqScreen DPX Test makes the **cobas s** 201 system the first commercially available NAT system for screening blood and plasma for six viruses.

"Roche is committed to providing the broadest coverage and most efficient screening tests to ensure the highest safety of blood and plasma products," said Paul Brown, Ph.D., President and CEO of Roche Molecular Diagnostics. "This new test is one more step

[1] Not available for sale in the US

toward that goal and complements our current **cobas**® TaqScreen tests for the detection of HIV, HCV, HBV and WNV."

The **cobas**® TaqScreen DPX Test can help manage the B19V burden in plasma pools and identify HAV-contaminated units. It allows plasma manufacturers to increase processing efficiency and may reduce the number of units that are discarded. The highly precise, quantitative values obtained for B19V DNA and the test's high sensitivity for HAV RNA meet current regulatory requirements for plasma intended for further manufacture.

Human plasma is fractionated into its components, such as immunoglobulins, albumin, and clotting factors, which have many therapeutic uses. These include 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.

The presence of B19V DNA in plasma pools as well as plasma products has been reported to be associated with the transmission of B19V by administration of plasma products, especially coagulation factors. There have also been reports on the transmission of HAV through blood and plasma products. Both B19V and HAV are not easily inactivated by traditional methods and so detection by NAT is an important step in ensuring the safety of blood and plasma products.

About Roche Blood Screening

Roche is a leader in the global NAT blood screening and plasma market, which is estimated at almost 900 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 225 blood banks worldwide use Roche's automated **cobas s** 201 system.

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, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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