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Blood Screening Test That Offers Immediate Viral Discrimination for Three Major Viruses Receives CE Mark

cobas® TaqScreen MPX Test, v2.0¹ provides real-time results for HIV, HCV and HBV

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the **cobas®** TaqScreen MPX Test, version 2.0 for use on the **cobas s 201** system is now commercially available in Europe.

This latest version of the widely used **cobas®** TaqScreen MPX Test provides increased sensitivity and is the only commercially available test that provides simultaneous viral target resolution on an automated system, removing the need for further time-consuming testing of positive units.

The test is a qualitative *in vitro* test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA and Hepatitis B Virus (HBV)

¹ This product is not approved or available for use in the US.



DNA in human plasma. This test is intended for use to screen samples of donations of human whole blood and blood components including source plasma.

“Roche is the global market leader in testing sites and donations tested,” said Paul Brown, Head of Roche Molecular Diagnostics, the business area of Roche that developed the test. “By continually developing innovative products we are striving for the highest level of blood safety for patients and efficiency for blood centers. This test takes us one step closer to those goals.”

As a result of Roche’s process to globally monitor viral genome databases to track changes that may occur in viral sequences, the assay has been reformulated to include as many recent viral sequences as possible increasing the inclusivity range of viral targets.

The **cobas**[®] TaqScreen MPX Test, v2.0 also offers increased efficiencies for blood centers by removing the need for viral discriminatory testing, thereby reducing the sample volume required and the turnaround time for donor testing. By utilizing real-time, multi-dye PCR technology, results are simultaneously detected and discriminated for HIV, HCV and HBV for an individual specimen, eliminating the need for additional time-consuming discriminatory tests that other commercially available tests require.

The test runs on the fully automated **cobas s** 201 system, which is designed to increase processing efficiency in a unique modular design with ready-to-use reagents. The multi-dye technology allows signal detection in four separate channels, facilitating simultaneous monitoring of three viral targets (HIV, HCV and HBV) plus a full-process internal control. In addition to HIV, HCV and HBV, the menu of the **cobas s** 201 system includes



tests for West Nile virus, parvovirus B19 (B19V) and hepatitis A virus (HAV).² All Roche blood screening tests are based on Nucleic Acid Amplification Technology (NAT) which offers earlier detection of viruses than traditional serology testing. The **cobas s 201** system offers the most comprehensive NAT test menu available on a single automated platform.

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 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 personalized 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.

² The duplex test for B19V and HAV has been filed with the FDA under a Drug Master File. It is available to US laboratories who meet specific FDA requirements.



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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For further information please contact:

Marianne van Zeeland
Roche Molecular Diagnostics Communications
+1 925-549-1232 (Mobile)
marianne.van_zeeland@roche.com