FDA Approves Roche’s Blood Screening Assay for Simultaneous Detection and Identification of Three Major Viral Targets

cobas TaqScreen MPX Test, v2.0 offers enhanced sensitivity and workflow advantages

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved the cobas® TaqScreen MPX Test, v2.0 for use in the detection and identification of HIV, HCV, and HBV in donations of human whole blood and blood components including source plasma. This latest version of the cobas TaqScreen MPX Test provides increased sensitivity and is the only FDA approved test to simultaneously detect and identify the most critical viral targets in one simple, ready-to-use assay. The combination of viral target detection and identification steps on a fully automated system offers workflow advantages to blood and plasma testing centers by eliminating the need for consecutive rounds of testing, and facilitating earlier donor counseling in the event of a positive result.

“Since 1998, Roche has developed assays and systems designed to protect the blood and plasma supply on a global scale,” said Roland Diggelmann, COO of Roche Diagnostics. “By continually developing these innovative products we are striving for the highest level of safety for patients and efficiency for blood and plasma centers. This latest approval supports that commitment.”

Along with CE Mark and recent approvals in Canada, Brazil, China, and India, FDA approval of the cobas TaqScreen MPX Test, v2.0 supports safety standards of blood and plasma centers worldwide. By utilizing real-time, multi-dye PCR technology, individual specimens are simultaneously detected and discriminated for HIV, HCV and HBV, reducing the sample volume required and the turnaround time for donor testing.

About the cobas TaqScreen MPX Test, v2.0

The cobas® TaqScreen MPX Test, v2.0 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) DNA in human plasma. This test is intended for use in the screening donations of human whole blood and blood components in pools of 6 samples, and source plasma donations in pools of up to 96 samples.
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 cobas s 201 system 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). 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 a 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 testing centers worldwide use Roche’s automated systems for blood and plasma screening.

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 Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 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 [www.roche.com](http://www.roche.com).

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