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Health Professional News

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FDA Approves Most Comprehensive System to Test Donated Blood for HIV, Hepatitis B & Hepatitis C

Advanced test for increased blood safety is first to add the detection of HIV-1 Group O RNA and HIV-2 RNA

The United States Food & Drug Administration (FDA) today approved a new nucleic acid test from Roche to screen donated blood for HIV-1 Group M RNA, hepatitis C RNA and hepatitis B DNA in a single, automated assay. The test, called the cobas TaqScreen MPX Test for use on the cobas s 201 system, is a qualitative in vitro test for comprehensive single-assay detection of HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, hepatitis C Virus RNA and hepatitis B Virus DNA in human plasma. The test, which is not intended for use as an aid in diagnosis, is designed to further increase the safety of blood supplies by identifying infections earlier than traditional serology tests.

"Roche is committed to meeting the needs of blood centers with tests and systems that ensure the highest blood safety," said Daniel O'Day, head of Roche Molecular Diagnostics, the business area of Roche Diagnostics that developed the test. "Our multiplex test has been widely adopted and has demonstrated excellent performance in blood centers worldwide. We are pleased to introduce it in the US as we continue to further invest in solutions for this critical industry."

The test runs on the fully automated, real-time PCR cobas s 201 system, designed to increase processing efficiency with a unique modular design and ready to use reagents.

"The Roche MPX test raises the blood industry to a higher level with regard to overall blood safety, process simplification and process control," said Louis M. Katz MD, Executive VP, Medical Affairs at Mississippi Valley Regional Blood Center, one of the TaqScreen MPX clinical trials sites. "Our organization looks forward to using the MPX test."

Countries that have implemented NAT testing have demonstrated a reduction in transfusion-related HIV, HBV, and HCV infections. In the U.S. alone, the Centers for Disease Control and Prevention estimates that there are more than one million people in the U.S. living with HIV/AIDS, with an additional 40,000 people being infected each year. It is estimated that 300,000 infected persons are unaware of their HIV status. More than 4 million people in the U.S. have been infected with HCV, 3.2 million of whom are chronically infected. HCV is the leading cause of liver cancer in the U.S. More than 1,200,000 people are chronically infected with HBV and about 5,000 people die of complications of HBV every year in the US. Many individuals with HBV and HCV show no symptoms of disease, and do not know that they are infected.

About Roche Blood Screening

Roche Diagnostics is the leading provider of real-time PCR-based nucleic acid tests for the international blood bank market. Nucleic acid-based tests enable earlier detection of active HIV, Hepatitis C, and Hepatitis B infections than conventional antibody or antigen assays. Roche assays have been used by the Japanese Red Cross since 1999 to screen Japan's entire blood supply. Roche launched the automated cobas s 201 system and the cobas TaqScreen MPX Test outside the United States in 2006 for the most comprehensive single-assay detection of HIV-1 Groups M & O, HIV-2, and hepatitis B and C in donated blood and plasma. The West Nile Virus test for this platform was launched in the US in 2007.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare

groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totaled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 79,000 people. Additional information is available on the Internet at www.roche.com.

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