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FDA Approves New Roche West Nile Virus Blood Screening Test

Automated test helps ensure safety of blood supply by detecting virus earlier in infection cycle.

Roche Diagnostics announced that the US Food & Drug Administration (FDA) today approved its biologics license application for the company's test for direct detection of West Nile Virus in donated human blood and plasma. West Nile virus, which can cause serious health issues, is transmitted to humans most often through mosquito bites, but can also less commonly be transmitted by transfusion of infected blood or blood products. The test, called the cobas TaqScreen West Nile Virus Test, enables detection of the virus earlier in the infection cycle in donors who may show no symptoms of disease. According to the CDC, blood screening centers across the United States identified 340 donors whose blood tested positive for West Nile Virus in 2006 and 23 to date in 2007.

"We are pleased to offer US blood banks a new choice for both maximizing blood safety and optimizing efficiency," said Daniel O'Day, Head of Roche Molecular Diagnostics, the business area of Roche Diagnostics which developed the test. "The Roche test, run under an investigational new drug application by 14 clinical trial sites testing blood from a network of more than a 100 donation centers, helps blood banks streamline workflow and improve test results accuracy with reduced hands-on time, ready-to-use reagents, and full automation of each step."

The test is designed to run on the cobas s 201 system, Roche's flexible, modular instrument platform which automates each step of the real-time PCR blood screening process. The test uses Roche's highly sensitive polymerase chain reaction technology (PCR), the world's leading

nucleic acid amplification technology, to detect the genetic material of the West Nile virus directly in blood. The United States Centers for Disease Control (CDC) has stated that screening donated blood for West Nile Virus by nucleic acid amplification tests has markedly reduced the risk of transfusion transmission.

About West Nile Virus

Most people infected with West Nile Virus never show signs of illness or experience several days of flu-like symptoms, but others, especially those with compromised immune systems, can suffer serious and in some cases life threatening reactions. According to the US Centers for Disease Control, in 2002, transfusion-associated transmission (TAT) of West Nile virus (WNV) infection acquired through blood transfusion marked the emergence of a new threat to the U.S. blood supply. Although mosquito-borne transmission remains the predominant mode of WNV transmission, identification of TAT underscored the need for WNV screening of donated blood. In June 2003, blood-collection agencies implemented investigational WNV nucleic acid--amplification tests (NATs) to screen all blood donations and identify potentially infectious donations for quarantine and retrieval. This screening was performed on approximately 6 million units during June--December 2003, resulting in the removal of at least 818 viremic blood donations from the blood supply in 2003 alone.

About Roche Diagnostics Blood Screening

Roche Diagnostics is the leading provider of PCR-based nucleic acid tests for the international blood bank market. Nucleic acid-based tests enable more highly sensitive 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. In 2006, Roche launched the automated cobas s 201 system and the 5-parameter multiplex cobas TaqScreen MPX Test in Europe 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 is the first test available on the automated cobas s 201 system in the US, where the multiplex HIV, HCV, and HBV test is currently under FDA review.

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, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolic disorders and diseases of the central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invests approximately 7 billion Swiss francs a year in R&D. Worldwide, the Group employs about 75,000 people. Additional information is available on the Internet at www.roche.com.

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