Media Release

Roche Diagnostics

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FDA Accepts for Review New Roche Diagnostics Blood Screening Test

Automated test is designed to detect broader range of HIV and hepatitis in a single multiplex assay.

Roche Diagnostics announced today that the United States (U.S.) Food & Drug Administration has accepted for review its application for a new test designed to detect a broad range of human immunodeficiency virus (HIV) and viral hepatitis infections in donated blood and plasma. The test, called the cobas TaqScreen MPX Test, uses real-time PCR to detect HIV type 1 (Groups M & O), HIV type 2, hepatitis C virus (HCV), and hepatitis B virus (HBV) in a single multiplex assay. The test is designed for use on Roche's newly automated, modular cobas s 201 platform. Nucleic acid amplification technologies such as PCR allow earlier and more specific detection of active infections in donated blood than earlier generation serology tests, helping to ensure a safer blood supply and retention of donors who would otherwise be deferred.

"We are pleased to have reached this important milestone in bringing multiplex testing and full automation to the U.S. blood-screening market," said Daniel O'Day, head of Roche Molecular Diagnostics, a business area of Roche Diagnostics that developed the test. "We believe this automated test, with detection of HIV-1 Group O and HIV-2, may help blood banks and laboratories improve blood safety, workflow efficiency, and donor retention. In addition, the system's modular design and optional built in back-ups are designed to

minimize downtime in this highly time-sensitive industry."

The U.S. Centers for Disease Control estimates that there are more than a 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. and is the leading diagnosis in patients undergoing liver transplantation. More than 1,200,000 people are chronically infected with HBV and about 5,000 people die of complications of HBV every year. Many individuals with HBV and HCV show no symptoms of disease and do not know that they are infected. These individuals may attempt to donate blood. The cobas TaqScreen MPX assay is designed to identify infected blood from these potential donors, before they inadvertently transmit infection to others.

About HIV-1 and HIV-2[i]

Human immunodeficiency virus type 1 (HIV-1) was discovered in 1984, 3 years after the first reports of a disease that was to become known as AIDS. In 1986, a second type of HIV – less common in the U.S. - was discovered, called HIV-2. The most common form of HIV-1 is called HIV-1 Group M. In 1994, the first report confirming the identification of a different form of HIV-1, called HIV-1 Group O, was published, with the first case in the U.S. being reported in 1996.

About Roche and the Roche Diagnostics Division

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 a world leader in

diagnostics, the leading supplier of drugs for cancer and transplantation and a market leader in virology. In 2006 sales by the Pharmaceuticals Division totaled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs approximately 75,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Diagnostics Division offers a uniquely broad product portfolio and supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information about Roche, please visit our website www.roche.com.

For more information about Roche Molecular Diagnostics, please visit http://molecular.roche.com.

Tests under review by the FDA are not available for use in the United States until the agency has approved the application for each test.

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[i]Information in this section comes from the United States Centers for Disease Control website at http://www.cdc.gov and from the United States Food and Drug Administration web site at www.fda.gov/bbs/topics/ANSWERS/ANS00747.html