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Health Professional News

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New Roche Dual Target HIV-1 Test Approved for Use in European Union

Extra confidence and security with an innovative Roche solution

Roche announced today that its innovative dual-target HIV-1 test has received CE Mark certification, allowing it to be sold for clinical use in the European Union. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 utilizes a unique design to simultaneously amplify and detect two separate regions of the HIV-1 genome. This approach provides reliable test results even when mutations are present. The test uses Roche's proprietary fully automated real-time PCR technology to quantify the amount of HIV-1 RNA in a patient's blood.

"HIV mutations are a serious problem. Because it is impossible to predict when these mutations will occur, we have designed this test to detect all HIV-1 (Group M and O) strains." said Daniel O'Day, President and CEO of Roche Molecular Diagnostics. "This innovative fully-automated solution will provide reliable results for laboratories and physicians to more confidently and efficiently treat HIV-1 patients undergoing therapy."

It is critical for viral load monitoring tests to be able to quantify very low and high levels of virus, an indicator of the need for more or less aggressive treatment. The test is highly sensitive and can detect the World Health Organization HIV-1 RNA Standard in EDTA plasma as low as 20 copies per milliliter of patient sample. The test can also accurately quantify the amount of HIV in a patient sample up to 10 million copies/mL representing a broader dynamic range than previous generation tests.

About the COBAS® AmpliPrep/COBAS® TaqMan® System

The COBAS® AmpliPrep / COBAS® TaqMan® HIV Test, v2.0 is the first dual-target test to be offered on the COBAS® AmpliPrep / COBAS® TaqMan® System. The test is designed for use on the fully automated, real-time PCR platform, providing sample-in/results-out capability. The COBAS® AmpliPrep / COBAS® TaqMan® System is flexible and customizable to meet the space and workflow needs of any laboratory. In 2005, Roche received CE Mark certification for the full viral load monitoring menu (HIV-1, HBV, and HCV) on the system.

About HIV-1

According to estimates by the World Health Organization (WHO) and UNAIDS, 33.2 million people were living with HIV at the end of 2007. That same year, some 2.5 million people became newly infected, and 2.1 million died of AIDS, including 330,000 children.

The human immunodeficiency virus (HIV) is a retrovirus that infects cells of the human immune system, destroying or impairing their function. In the early stages of infection, the person has no symptoms. Within 10-15 years an HIV infection will develop into acquired immunodeficiency syndrome (AIDS); antiretroviral drugs can slow down this process even further.

HIV is transmitted through unprotected sexual intercourse (anal or vaginal), transfusion of contaminated blood, sharing of contaminated needles, and between a mother and her infant during pregnancy, childbirth and breastfeeding.

The ability of HIV to mutate itself in the presence of antiretroviral drugs can lead to treatment failure, increased direct and indirect health costs associated with the need to start more costly second-line treatment for patients, the spread of resistant strains of HIV and the need to develop new anti-HIV drugs.¹

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 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 80,000 people. Additional information is available on the Internet at www.roche.com.

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1) World Health Organization. www.who.int

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