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Roche receives FDA approval for fourth-generation HIV combination antigen-antibody assay —allowing detection of infection with high sensitivity and specificity

Elecsys® HIV combi PT assay demonstrates commitment to improving efficiency by aiding labs in consolidating testing with other routine immunoassays

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its fourth-generation HIV combination antigen-antibody assay, the Elecsys HIV combi PT assay, has received FDA PMA approval from the U.S. Food and Drug Administration (FDA).

“The approval of this highly sensitive and specific assay demonstrates our ongoing commitment of expanding Roche’s already broad testing menu for infectious diseases on the **cobas®** e 602 analyzer, including Hepatitis and ToRCH assays, said Jack Phillips, President and CEO, Roche Diagnostics Corporation. “With the addition of this assay, laboratories will be able to screen for common co-infections, such as Hepatitis C and Syphilis, which can be tested simultaneously with HIV, reducing the need for sample splitting and additional analyzers.”

About the Elecsys HIV combi PT assay

The Elecsys HIV combi PT assay is for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1 (HIV-1 groups M and O) and HIV-2 in human serum and plasma. Intended for use as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute and primary HIV-1 infection, this fourth-generation HIV immunoassay is able to detect both antigen and antibodies simultaneously. This can increase the likelihood of early detection of HIV infection, improving disease management and helping to prevent transmission of infection. The assay may be used as an aid in the diagnosis of HIV-1/HIV-2 infection in subjects greater than two years of age and in pregnant women.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims for improving patient access to medical innovations by working with all relevant stakeholders. Twenty-eight medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. 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.

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