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Roche launches next-generation viral load assay for CMV in markets accepting the CE mark

***cobas**[®] CMV assay offers unparalleled performance on the **cobas**[®] 6800/8800 Systems*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the commercial availability of the **cobas**[®] CMV assay for use on the **cobas**[®] 6800/8800 Systems—further expanding the menu on the newest molecular diagnostic platforms from Roche. The new assay offers the exceptional performance that clinicians need when treating cytomegalovirus (CMV) infection in transplant recipients receiving anti-viral therapy.

“The unparalleled performance and unmatched flexibility of the **cobas**[®] 6800/8800 Systems allows laboratories to ensure rapid turn-around time for critical tests, like **cobas**[®] CMV, while still delivering routine viral load monitoring results,” said Paul Brown, Head of Roche Molecular Diagnostics. “**cobas**[®] CMV is harmonized to the WHO standard to ensure that laboratories and clinicians can rely on this test, leading to increased quality of care and comparable results across different labs for patients infected with CMV.”

This assay will be followed in the first quarter of 2015 by the **cobas**[®] HBV assay, completing the viral load monitoring portfolio for the **cobas**[®] 6800/8800 Systems. The **cobas**[®] 6800/8800 Systems, combined with the viral load assay portfolio, are designed to improve laboratory efficiencies while providing the rapid results needed to make informed treatment decisions.

The **cobas**[®] CMV assay and the **cobas**[®] 6800/8800 Systems are commercially available in markets that recognize CE-Mark and are not currently available in the United States.

About the **cobas[®] 6800/8800 Systems**

The **cobas**[®] 6800 and 8800 Systems are fully automated solutions designed for blood donor screening, viral load monitoring, women’s health and microbiology testing. They are available in medium and high throughput models, respectively. Based on the Nobel-prize winning PCR technology, the systems are designed to deliver increased automation and throughput with shorter time to results, providing users with greater testing flexibility to increase overall workflow efficiencies.

The systems provide up to 96 results in less than 3.5 hours, and a total of 384 results for the **cobas**[®] 6800 System and 960 results for the **cobas**[®] 8800 System in an 8 hours shift.* Both systems allow for mixed batching, making it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (**cobas**[®] 6800) and four hours (**cobas**[®] 8800) of “work-away” time* with minimal user interaction.

For more information about the systems, please visit www.cobas68008800.com.

* May vary based on workflow demands

The cobas® 6800/8800 Systems are not available in all markets, including the U.S.

About the Assays for the cobas® 6800/8800 Systems

Assays for viral load monitoring

cobas® CMV is a real-time PCR test traceable to the first WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162), therefore provides consistent, reliable results across the dynamic range of the assay and across institutions.

cobas® HIV-1 is a real-time PCR test built upon the dual-target assay design from Roche. The test simultaneously amplifies and detects two separate regions of the HIV-1 genome, which are not subject to selective drug pressure, allowing for more reliable results to confidently and effectively quantify the amount of HIV-1 RNA in a patient's blood.

cobas® HCV a real-time PCR test that employs Roche's unique dual-probe approach to provide an extra layer of protection against mutations that can occur in the viral genome and is designed to accurately detect and quantify hepatitis C virus ribonucleic acid (RNA) with state-of-the-art sensitivity in order to assess a patient's response to antiviral therapy.

Assays for blood donor screening

cobas® MPX is a real-time PCR multiplex test covering five critical viral targets: HIV-1 Group M, HIV-1 Group O, HIV-2, HCV and HBV, from a single sample. It offers real-time detection and identification of HIV, HCV and HBV, eliminating both the need for discriminatory testing and the potential for discrepant results. Plus, the dual-target approach with amplification of separate regions of HIV-1, and dual probes for HCV, improve coverage of new virus variants.

cobas® WNV is a real-time PCR test for West Nile virus (WNV) that is highly sensitive for both WNV lineages 1 and 2. It also provides broad coverage of other flaviviruses that cause transfusion-transmitted infectious diseases.

cobas® HEV is a real-time PCR test for hepatitis E virus (HEV), providing broad coverage of all 4 major HEV genotypes.

About Cytomegalovirus (CMV)

CMV is a very common infection, found in the majority of adults. Once infected, the virus remains latent in the body for the rest of the person's life. The virus does not cause problems if a person's immune system is functioning normally, but it can cause severe problems in immunocompromised people such as transplant recipients, people with AIDS and newborn infants. CMV is the most common viral infection in solid organ transplant (SOT) recipients. CMV virus can be reactivated in a patient who already has the infection, or a patient can be infected through the donor organ. Approximately 20–60% of all transplant recipients develop symptomatic CMV infection, typically during the first few months after transplantation. CMV disease can affect specific organs or cause generalized illness, and is a major cause of loss of the transplanted organ and death in affected individuals.



About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. 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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