

June 5, 2017

## **Roche receives FDA approval for CMV viral load testing on cobas®6800/8800 Systems**

- ***The cobas®CMV test provides fast, reproducible, high-quality results for clinical decision-making***
- ***CMV is the most common and serious viral infection in transplant patients***
- ***CMV viral load testing is used to assess how solid organ and hematopoietic stem cell transplant patients on therapy are responding to treatment***

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received FDA approval for the **cobas®** CMV (cytomegalovirus) test for use on the fully automated **cobas®** 6800 and **cobas®** 8800 Systems. Health care professionals use the CMV test to assess how transplant patients on therapy are responding to treatment. The test is standardized to the 1st WHO International Standard for improving harmonization in CMV testing results across hospital institutions.

The fully automated cobas 6800 and cobas 8800 Systems offer laboratories the fastest time to results, the highest throughput and the longest walk-away time available among automated molecular platforms.

“Transplant patients and their caregivers rely on consistent, accurate test results to successfully manage patients on anti-viral therapy for CMV,” said Uwe Oberlaender, head of Roche Molecular Diagnostics. “With this second generation test, clinicians can now receive faster, more reliable, standardized results aligned across institutions. This is a required and important step towards optimizing CMV management decisions for transplant patients.”

In addition to the CMV assay, Roche has FDA-approved viral load tests for HIV-1, HCV and HBV for the cobas 6800/8800 Systems, representing a complete portfolio of viral load monitoring tests. Further menu includes qualitative donor screening with expansion plans in

the United States for women's health and microbiology.

### **About the cobas CMV viral load test for use on the cobas 6800/8800 Systems**

cobas CMV is a real-time PCR (polymerase chain reaction) test designed to offer an expanded linear range from 34.5 IU/mL to 1E+07 IU/mL with robust coverage across genotypes. The test minimizes variability and complexity in testing offering an alternative to lab-developed tests (LDTs) reducing workload and alleviating risk for laboratories. The cobas CMV Test provides reproducible, high-quality results for clinical decision-making with demonstrated clinical utility to support the goal of result standardization across institutions.

The fully automated cobas CMV Test can be run simultaneously with HIV-1 or HCV assays on the cobas 6800/8800 Systems, streamlining workflow while increasing flexibility for patient sample management.

### **About Cytomegalovirus (CMV)**

CMV is the most common and serious viral infection in transplant patients. The virus can be transmitted through the donor organ, resulting in CMV infection and leading to the development of CMV disease, or can be reactivated in transplant recipients with previous CMV infection. CMV disease in hematopoietic transplant recipients can cause life-threatening damage to many organs including the lung, liver, kidney, gastrointestinal tract and eye. Between 50 and 80 percent of the adult population in the U.S. are infected with CMV. Although healthy persons usually have few symptoms at the time of initial infection, after infection the virus remains in a latent state in the body for the rest of a person's life. If a person becomes immunosuppressed, as happens in transplantation, the virus can become reactivated and cause symptomatic disease.

### **About the cobas 6800/8800 Systems**

The cobas 6800 and cobas 8800 Systems are fully integrated, automated solutions that set the standard for routine molecular testing in the areas of donor screening, viral load monitoring, women's health and microbiology. Based on Nobel-prize winning PCR technology, the systems are designed to deliver full automation, increased throughput and faster turnaround time, providing users with greater 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 eight-hour shift. Both make 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 walk-away time with minimal user interaction.

For more information about the systems, please visit <http://molecular.roche.com>.

## **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 personalised 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 to improve patient access to medical innovations by working with all relevant stakeholders. Twenty-nine 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 recognised 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](http://www.roche.com).

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