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## **Roche announces the first FDA-approved CMV test for use in hematopoietic stem cell transplant recipients**

### ***New test standardizes CMV testing for both solid organ and hematopoietic stem cell transplant recipients***

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the United States Food and Drug Administration (FDA) approval of the first cytomegalovirus (CMV) test for use in hematopoietic stem cell transplant recipients. With this approval, the COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is available for monitoring CMV treatment in all types of transplant patients in the USA. The test was the first in vitro diagnostic test conforming to the WHO International Standard, making it possible for laboratories worldwide to obtain comparable results when testing for CMV and it is now the most commonly used in vitro diagnostic test for CMV solid organ transplant recipients in the USA.

“Cytomegalovirus is the most important viral infection in hematopoietic stem cell transplant patients,” said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “With this new FDA approval, hematopoietic stem cell transplant clinicians and patients have another tool to help fight CMV. As the world’s leading molecular virology testing company, Roche is proud to offer a WHO-standardized test to improve care for transplant recipients.”

Roche’s standardized real-time polymerase chain reaction (PCR)-based CMV test is designed for use on the automated COBAS® AmpliPrep/COBAS® TaqMan® System, an established platform for viral load monitoring of multiple infectious diseases.

#### **About the test**

The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is an in vitro nucleic acid amplification test for the quantitative measurement of cytomegalovirus (CMV) DNA. The test is intended for use as an aid in the management of solid-organ transplant and hematopoietic stem-cell transplant recipients who are undergoing anti-CMV therapy. In this population, serial DNA measurements can be used to assess virological response to antiviral treatment. The results from the test must be interpreted within the context of all relevant clinical and laboratory findings. The test is traceable to the first WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162) and reliably monitors cytomegalovirus (CMV) infections. The COBAS® AmpliPrep/COBAS®

TaqMan® CMV Test is not intended for use as a screening test for the presence of CMV DNA in blood or blood products.

### **About the COBAS® AmpliPrep/COBAS® TaqMan® System**

Roche's fully automated COBAS® AmpliPrep/COBAS TaqMan® System combines the COBAS® AmpliPrep Instrument for automated sample preparation and the COBAS® TaqMan® Analyzer or the smaller COBAS® TaqMan® 48 Analyzer for automated real-time PCR amplification and detection. The COBAS® AmpliPrep/COBAS® TaqMan® System has parallel processing with other key molecular diagnostics assays targeting medically relevant diseases (hepatitis B virus, hepatitis C virus, and human immunodeficiency virus). Roche's AmpErase enzyme is also included in each test and is designed to prevent cross-contamination of samples and labs.

### **About cytomegalovirus**

CMV is the most common and important 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 occur by reactivation of the virus 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 – 80% of all people in the US 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 Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

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. 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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. 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 seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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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