Roche expands cobas 4800 System menu with HIV-1, HCV and HCV Genotyping Tests
System portfolio broadens to include high medical value virology assays

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the commercial availability of the cobas® HIV-1, HCV and HCV Genotyping (GT) assays in countries accepting the CE mark1. These new molecular diagnostic assays increase the available menu on the cobas® 4800 System, further improving efficiency and flexibility that allows laboratories to deliver results for rapid clinical decisions.

The new virology assays offer the latest generation of performance with dual target technology for HIV-1 and dual probe technology for HCV. All of the new virology assays can run simultaneously on the cobas 4800 System, with optimized sample processing volumes for streamlining workflow that increases flexibility for patient sample management. With these additions, the cobas 4800 System now has a menu of 12 high medical value IVD assays, making it the ideal solution for a highly efficient laboratory.

“With the addition of these assays to the cobas 4800 menu, more laboratories have access to advanced virology assays that provide reliable results for confident patient management,” said Roland Diggelmann, COO, Roche Diagnostics. “As the global market leader, we are also pleased to introduce cobas HCV genotype test which accurately identifies HCV genotypes and helps optimize treatment of hepatitis C patients.”

The assays launched today will be followed in the coming months by the cobas HBV Test, which will complete the portfolio of viral load monitoring and genotyping assays for the cobas 4800 System.

About the cobas 4800 System
The cobas 4800 System offers improved automation of nucleic acid purification, PCR (polymerase chain reaction) set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The system now has a comprehensive test menu including the cobas HIV-1 Test, cobas HCV Test,
cobas HCV Genotyping Test, cobas MRSA/SA Test, cobas HSV 1 and 2 Test, cobas C.diff Test, cobas CT/NG Test (chlamydia/gonorrhea), cobas HPV Test, cobas BRAF V600 Mutation Test, cobas EGFR Mutation Test, and the cobas KRAS Mutation Test.

For more information about the cobas 4800 System, please visit http://molecular.roche.com.

About the assays for the cobas 4800 System - assays for viral load monitoring and genotyping
The three new virology assays can run simultaneously on the cobas 4800 System with two different sample processing volumes for HIV-1 and HCV (200 μL and 400 μL) and only 400 μL for HCV GT streamlining workflow while increasing flexibility for patient sample management.

cobas HIV-1 is 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 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 (HCV) ribonucleic acid (RNA) with state-of-the-art sensitivity in order to confirm active HCV infection or assess a patient’s response to antiviral therapy.

cobas® HCV Genotyping is a highly accurate and sensitive real-time PCR-based test for the qualitative identification of HCV genotypes 1 to 6 and genotype 1 subtypes a and b in human plasma or serum from individuals with chronic HCV infection. Identification of the infecting genotype is required before a patient is prescribed antiviral therapy as response to treatment correlates to the HCV genotype.

About HIV-1
According to the World Health Organization (WHO), there were 35 million people living with HIV around the world in 2012. That same year 2.5 million people became newly infected with HIV worldwide. In the most impacted region of Sub-Saharan Africa, nearly 1 in every 20 adults are HIV-positive.
The transmission of HIV from an HIV-positive mother to her child during pregnancy, labor, delivery or breastfeeding is called vertical or mother-to-child transmission (MTCT). In the absence of any interventions, HIV transmission rates are between 15-45%.
Accurate diagnosis, highly active antiretroviral treatment (HAART) and viral load testing, a test to determine
the amount of circulating HIV, have contributed to a steady increase in life expectancy for HIV infected
people of 13 years.3

About Hepatitis C
According to the World Health Organization, HCV affects some 200 million people globally. Approximately
170 million people are chronic carriers of the hepatitis C virus, and most do not know they are infected. The
disease can ultimately result in cirrhosis, liver failure and hepatocellular carcinoma, which together are
responsible for hundreds of thousands of deaths each year.

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-
nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential
Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and
posted sales of 47.5 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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References

1 Local product availability may vary independently from CE Mark approval.