Roche launches new fully automated molecular diagnostic systems offering the fastest time to results with the highest testing capacity

The cobas 6800/8800 Systems offer advanced performance with next generation donor screening assays

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the commercial availability of the cobas 6800/8800 Systems, two integrated and fully automated molecular testing systems for blood and plasma donor screening in markets accepting the CE mark. The cobas 6800/8800 Systems offer the fastest time to results with the highest throughput available, along with the longest walk-away time, enabling laboratory staff to drive increased workflow efficiencies, while adapting to their ever-changing testing demands.

“The integrated and fully automated design of the new cobas 6800/8800 Systems will allow labs to generate a high volume of results faster, with fewer manual steps, thus improving laboratory operations,” said Harry Bos, Ph.D. MBA, Director of Diagnostics, Sanquin Blood Supply, Amsterdam, The Netherlands. “These systems will help ensure a safe blood supply as the dynamics of the blood screening industry continue to rapidly change.”

“The cobas 6800/8800 Systems represent a new class of molecular diagnostic instruments,” said Roland Diggelmann, COO of Roche Diagnostics. “Over the last several years, we have collaborated with top industry leaders and several hundred customers to design a platform that truly meets the evolving needs of the molecular diagnostics laboratory. These systems will set new industry standards with technical innovation for throughput, speed-of-results, automation and flexibility that have not been seen before in a molecular diagnostic system. We are proud of the benefits they will bring to people and the healthcare environment.”

The portfolio launched today includes the cobas 6800 and 8800 Systems, the cobas p 680 instrument to support the creation of donor sample pools, and three next-generation assays for donor screening: cobas MPX, cobas WNV and cobas HEV. In Q4, a next-generation cobas DPX test will be released to complete the donor screening menu. The systems menu will continue to expand beyond blood donor screening, including multiple tests for viral load monitoring. The cobas 6800/8800 Systems are now available in all markets accepting the CE mark in Europe, Latin America, Middle East, Africa and Asia. The Systems are not
currently available in the United States.

**About cobas 6800/8800 Systems**

The cobas 6800 and 8800 Systems are fully automated solutions designed for donor screening, viral load monitoring, women’s health and microbiology testing. They are available in medium and high throughput models. 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 flexibility to increase overall workflow efficiencies.

Each system provides results for the first 96 tests in less than 3.5 hours, with the cobas 6800 System delivering up to 384 results in an eight hour shift, and the cobas 8800 System generating up to 960 results in the same amount of time. Both systems also allow for simultaneous processing of multiple assays and are designed to enable up to eight hours (cobas 6800) and four hours (cobas 8800) of “walk-away” time* with minimal user interaction.

**About the Launch Assays**

cobas MPX, WNV and HEV are nucleic acid tests for the detection of blood-borne viruses in donors of blood and blood components and other living donors.

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 the Assays in Development***

cobas DPX is a real-time duplex test designed to quantify parvovirus B19 (B19V) DNA with a broad linear range and detect HAV RNA in a single test. It provides complete coverage of B19V and HAV genotypes.
**Assays for viral load monitoring**

**cobas HIV-1** is a quantitative real-time PCR test with an integrated dual target approach, focusing on two unique regions of the HIV-1 genome, gag and LTR, that are not subject to selective drug pressure.

**cobas HBV** is a quantitative real-time PCR test designed to offer broad coverage of all known HBV genotypes (A-H), including pre-core mutations with high sensitivity.

**cobas HCV** is a quantitative real-time PCR test that uses a dual-probe technique designed to accurately detect and quantify HCV genotypes 1-6 while maintaining high sensitivity.

**cobas CMV** is a quantitative real-time PCR test designed to reliably monitor patients receiving antiviral therapy and is traceable to the first WHO International Standard for Human CMV.

**Assays for other indications**

**cobas CT/NG** is a qualitative real-time PCR test designed to accurately test CT and NG in a single sample.

**cobas HPV** is a qualitative *in vitro* test designed to detect HPV DNA in human specimens, simultaneously providing results on high-risk genotypes while providing individual results on the highest risk genotypes (HPV 16 and 18).

**cobas MTB/MAI** is a qualitative real-time PCR test designed to detect mycobacteria including MTB and resistant organisms.

**cobas HIV Qual** is a qualitative *in vitro* diagnostic, total nucleic acid amplification test for the detection of HIV-1 DNA and RNA in human EDTA plasma or dried blood spots (DBS).

For more information about the systems, please visit [www.cobas68008800.com](http://www.cobas68008800.com).

**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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* May vary based on workflow demands
** For use on the cobas 6800/8800 Systems
*** Currently in development