

Pleasanton, CA

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Roche receives FDA approval for cobas p 630 pre-analytical solution for automated molecular testing platform

New instrument, software integrate automated primary tube handling with fully automated platform for sample preparation, amplification and detection

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the FDA approval of a new pre-analytical instrument that provides an integrated primary tube handling solution for its widely adopted automated molecular testing platform. The cobas p 630 Instrument, being introduced with new AMPLILINK 3.3 series software, unites primary tube handling with fully automated sample preparation, amplification and detection for molecular diagnostics on COBAS® AmpliPrep instruments and COBAS® TaqMan® analyzers.

"The complete system provides molecular laboratories with a flexible and integrated solution for automated pre-analytics and real-time PCR diagnostic testing," said Paul Brown, Ph.D., Head of Roche Molecular Diagnostics. "Combined with the latest version of our software, the cobas p 630 Instrument helps labs enhance their throughput for a broad menu of important molecular virology tests, including HIV, hepatitis B and hepatitis C."

The cobas p 630 Instrument is designed to protect the integrity of the primary patient tube and combines automated primary tube handling with full sample traceability, process surveillance and bi-directional connectivity. Together, these features help labs improve efficiency by effectively eliminating manual steps.

The cobas p 630 Instrument has a number of additional automation features that ensure full sample traceability while reducing hands-on labor time. The cobas p 630 Instrument received CE mark in October 2009 and is used throughout Europe, Africa, Asia and South America.

About AMPLILINK 3.3 series software

AMPLILINK Software, a Windows® operating system-based application, is designed to deliver maximum flexibility, efficiency and integrity to the laboratory's workflow – from sample input through results output. AMPLILINK 3.3 series software is an intuitive graphical user interface that manages the operation of the connected COBAS® instruments and analyzers. One AMPLILINK data station will connect one cobas p 630 Instrument to up to three

COBAS® AmpliPrep instruments and three analyzers (combination of COBAS® TaqMan® and COBAS® TaqMan® 48 analyzers), helping to maximize throughput capabilities and optimize laboratory efficiencies. The software's bi-directional connectivity gives labs the capability of having patient orders sent from their Laboratory Information System (LIS) to the cobas p 630 Instrument, tracking the patient sample from the time the order is entered through the LIS to reporting of the patient result.

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, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 billion Swiss francs. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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