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## **Roche receives FDA clearance for U.S. launch of cobas 8000 modular analyzer series for high-volume laboratory testing**

***Flexible “Intelligent LabPower” system helps labs increase efficiency, lets them reconfigure modules for changing needs***

**INDIANAPOLIS** – Roche Diagnostics (SIX: RO, ROG; OTCQX: RHHBY) announced today it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the **cobas**<sup>®</sup>8000 modular analyzer series, a Serum Work Area solution designed for diagnostic laboratories with a workload of 3-15 million clinical chemistry / immunochemistry tests per year.

The **cobas** 8000 series is the newest member of the Roche **cobas** modular platform family, which combines clinical chemistry and immunochemistry testing. With a peak throughput of up to 9,800 tests per hour and up to 280 reagents onboard, it offers a variety of features to help high-volume labs deliver reliable test results with greater efficiency and throughput. The system also provides extensive modular flexibility so labs can configure tailored solutions to meet their individual needs.

With the introduction of the **cobas** 8000 modular analyzer series, Roche now offers a comprehensive portfolio of standardized integrated systems to meet the needs of all types and sizes of clinical laboratories: the stand-alone **cobas** 4000 analyzer series for low-volume labs; the **cobas** 6000 analyzer series for mid-volume labs; and the **cobas** 8000 modular analyzer series for high-volume labs.

“The **cobas** 8000 modular analyzer series delivers a new dimension in productivity, process innovation and consolidation for high-volume laboratories,” said Jack Phillips, president and CEO of Roche Diagnostics Corporation. “There are many innovative design elements that help reduce sample turnaround time, and the modular design gives labs the freedom to reconfigure their system on-site as they grow or their needs change.”

The **cobas** 8000 modular analyzer series features intelligent sample routing with fast transportation and return lines, independent processing lines within each module, and a modular sample buffer in each module for true random-access sampling. The series also uses the same operator interface and the standardized reagent cassette concept used on other **cobas** analyzer platforms. Tests run on the new platform give physicians important clinical information in a wide range of medical areas, such as cardiac and infectious diseases, bone disorders and cancer.

The first configuration of the system, which will be available September 20, includes two clinical chemistry analytical modules: the high-volume **cobas c** 701 module (up to 2000 tests/hour) and the mid-volume **cobas c** 502 module (up to 600 tests/hour). The system automatically manages samples to provide optimal throughput by allocating the most frequently requested assays to the high-volume module and less frequently requested assays to the mid-volume module.

Roche anticipates that the system’s immunochemistry module, the **cobas e** 602 analyzer, will be available in October 2010. (The **cobas e** 602 module is currently in development/for research use only. The product is not available in the U.S.). With the addition of this module, laboratories will be able to combine chemistry and immunochemistry modules to create 24 unique system configurations to match their specific testing needs.

### **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 2009, Roche had over 80,000 employees

worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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](http://www.roche.com) or [www.roche-diagnostics.us](http://www.roche-diagnostics.us).

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