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## **Roche submits total Vitamin D assay to FDA for clearance on cobas immunoassay and Elecsys analyzers**

*Elecsys total vitamin D assay would help labs address growing demand and enhance efficiency by integrating test into existing workflow*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has filed a 510(k) submission to the U.S. Food and Drug Administration (FDA) for a fully automated, total vitamin D assay (25-hydroxyvitamin D) for use on Roche's full portfolio of laboratory analyzers.\* The Elecsys® vitamin D test can be combined with routine testing on existing Roche immunoassay analyzers and integrated chemistry/immunoassay systems, enabling labs to address the growing demand for vitamin D testing while maximizing their productivity.

"The demand for vitamin D testing is increasing rapidly as global deficiency rates rise and studies show a link between insufficiency and disease states," said Randy Pritchard, vice president of marketing at Roche Diagnostics Corporation. "This new test will give healthcare providers confidence in their patient results and, at the same time, enable labs to integrate vitamin D testing into their existing workflow, to save time and maintain 'lean' operations. Roche currently offers the largest menu available on integrated systems, and the submission of the Vitamin D assay demonstrates our continued commitment to the development of assays that can help improve patient care."

According to the National Institutes of Health Office of Dietary Supplements, the serum concentration of 25(OH)D is the best indicator of vitamin D status. It reflects vitamin D produced cutaneously (D3) and obtained from food and supplements (D2 and D3). The ability of an assay to detect both D2 and D3 forms (total vitamin D) is important for physicians who have patients taking vitamin supplements.

The assay is designed for use on all Roche immunoassay systems for low-, mid- and high-volume

testing environments, including the Elecsys 2010, **cobas e 411**, **cobas e 601**, **cobas e 602** and **MODULAR ANALYTICS E170** analyzers. The FDA has a 90-day period after the 510(k) submission for substantive review of the application.

### **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 2010, Roche had over 80,000 employees worldwide and invested over 9 billion Swiss francs in R&D. 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](http://www.roche.com) or [www.roche-diagnostics.us](http://www.roche-diagnostics.us).

\* This product is not cleared or available for use in the U.S. A 510(k) submission is pending.

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