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Roche submits acute hepatitis B test to FDA for premarket approval

Elecsys Anti-HBc IgM assay would complete acute hepatitis test panel on Roche analyzers

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has submitted a Premarket Approval Application (PMA) to the U.S. Food and Drug Administration (FDA) for the Elecsys Anti-HBc IgM assay for use on the **cobas e 411**, **cobas e 601** and **MODULAR ANALYTICS E170** analyzers. The hepatitis B test represents the final component of the acute panel within the hepatitis menu on Roche's family of immunoassay analyzers.

The PMA submission is for use of the assay in the in-vitro qualitative determination of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum or plasma. The presence of anti-HBc IgM, in conjunction with other laboratory results and clinical information, is indicative of acute or recent hepatitis B virus (HBV) infection.* The assay is intended to be used with Roche's electrochemiluminescence (ECL) immunoassay technology.

Roche currently has seven other immunoassay tests available on its hepatitis menu: HBsAg, HBsAg Confirmatory, Anti-HBs, Anti-HCV, Anti-HAV, Anti-HAV IgM and Anti-HBc.

The FDA has 45 days after the PMA is received to notify Roche whether the application has been filed. If the PMA is accepted for filing, the FDA has a 180-day period 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 or www.roche-diagnostics.us.

* The Elecsys Anti-HBc IgM immunoassay's performance has not been established for the monitoring of HBV disease or therapy.

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