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Roche receives FDA approval for acute hepatitis B test

Elecsys Anti-HBc IgM assay completes acute hepatitis test panel on cobas e 601 analyzer

INDIANAPOLIS—Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) granted Premarket Approval (PMA) for its IgM antibody to hepatitis B core antigen (Anti-HBc IgM) assay for use on the **cobas e 601** analyzer, the immunoassay module of the **cobas**[®] 6000 analyzer series for mid-volume laboratories. The test represents the final component of the acute panel within the hepatitis test menu for the cobas 6000 series.

The Anti-HBc IgM assay is used for 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 an acute or recent hepatitis B virus (HBV) infection.* The assay is intended for use with Roche's electrochemiluminescence (ECL) technology, a highly sensitive light detection system that provides excellent low-end sensitivity and broad dynamic measuring ranges.

With this approval, Roche now offers a full selection of hepatitis tests in its immunoassay portfolio: HBsAg, HBsAg Confirmatory, Anti-HBs, Anti-HCV, Anti-HAV, Anti-HAV IgM, Anti-HBc IgM (approved for cobas e 601 analyzer) and Anti-HBc (approved for MODULAR ANALYTICS E170 analyzer). The combination of full hepatitis menu with the lowest assay duration on the market, the broadest integrated menu and ECL technology allows the Roche total solution to inspire confidence in the laboratory environment. The Anti-HBc IgM assay is also pending FDA approval for use on Roche's **cobas e 411** and **MODULAR ANALYTICS E170** analyzers. Roche's current analyzer portfolio offers labs short assay duration (9 to 27 minutes) and the broadest test menu available on an integrated platform.

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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