Aptima® HBV Quant Assay for Quantitation of Hepatitis B Viral Load Receives PMA Approval

Aptima assay portfolio rapidly expanding with the addition of tests to quantitate HIV-1, HCV and HBV now available on the fully automated Panther system

Marlborough, Massachusetts (January 25, 2018) – Hologic, Inc. (Nasdaq: HOLX) announced today that the United States Food and Drug Administration (FDA) has granted PMA approval for the Aptima® HBV Quant Assay for quantitation of hepatitis B viral load on the fully automated Panther® system.

The Aptima HBV Quant assay represents the newest addition to the Panther system's viral load menu, joining the previously approved Aptima HIV-1 Quant Assay (for human immunodeficiency virus) and Aptima HCV Quant Dx Assay (for hepatitis C virus). All three new assays use Hologic's proprietary real-time transcription-mediated amplification (TMA), which provides highly sensitive and specific performance. The HBV Quant assay reliably quantitates HBV DNA across all major genotypes A-H.

"This approval represents a milestone for Hologic's growing virology assay menu," said Tom West, president, Diagnostic Solutions division at Hologic. "We now have available on a single system the three major viral load assays that most laboratories are asked to run for patients."

These Aptima assays run on the Panther system, which provides full, sample-to-result automation and substantially reduces hands-on time with random and continuous access. With the Panther system, laboratorians can now run viral load assays for HIV-1, HCV and HBV in parallel, or even from a single patient sample.

The Aptima HBV Quant assay offers a unique, dual-target approach that delivers accurate quantitation over a broad linear range and tolerates potential mutations in the HBV genome. The Aptima HBV Quant assay's linear range is one of the broadest on the market (from 10 IU/mL to 1 billion IU/mL). This helps ensure precise quantitation even for samples with the high viremia often associated with chronic HBV infection.

The HBV assay joins a growing menu of tests available on the Panther system in the U.S. market. In addition to the three viral load assays, the Panther menu includes tests for sexually transmitted infections including chlamydia, gonorrhea, trichomonas, human papillomavirus (HPV), and herpes simplex virus (HSV).

"We hear repeatedly from clinical laboratory customers that menu consolidation is a top priority," said West. "Offering a robust virology and women's health menu on a single automated platform will enable them to reach their efficiency goals."

Hologic has a long-term legacy in the virology space, beginning two decades ago and spanning development of nucleic acid tests to screen the blood supply for HIV, HCV and HBV. This expertise was applied to the development of the viral load portfolio on the Panther system.

To learn more about the Aptima Quant assays available in the United States, please visit http://usaptimavirology.com.

In Europe, the Aptima HBV Quant assay is CE-IVD marked for viral load monitoring. In addition, both the Aptima HIV-1 Quant Dx assay and Aptima HCV Quant Dx assays are approved in Europe for both diagnosis and viral load monitoring.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's diagnostic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

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