
Hologic Expands its European Virology Portfolio with CE-IVD Certified Assay for HBV Viral Load



-- Aptima® HBV Quant Assay Joins Tests for HIV-1 and HCV on the Fully Automated Panther Instrument --

Hologic, Inc. has earned CE-IVD certification for its Aptima HBV Quant assay on the fully automated Panther® instrument, the Company has announced.

This assay expands the European virology menu available on the Panther system, which previously included the Aptima HIV-1 Quant Dx and Aptima HCV (hepatitis C virus) Quant Dx viral load assays.

“We are excited to now offer European customers three important viral load assays on our Panther system,” said Claus Egstrand, Hologic’s Group President, International. “Laboratories can now quantify HIV-1, HCV and HBV accurately while benefiting from random access and more walkaway freedom.”

The newest addition to the Panther system’s viral load menu quantitates HBV DNA across all major genotypes A-H. The assay offers the only 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.

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. This combination provides not only sensitive and precise amplification, but also sample-to-result automation. The Panther system’s growing assay menu also includes tests for chlamydia, gonorrhea, trichomoniasis, HPV and HPV genotyping.

The Aptima HBV Quant assay, Aptima HCV Quant Dx assay, and Aptima HIV-1 Quant Dx assay are not approved for use in the United States.

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