



Hologic Receives European Regulatory Approval for New Molecular Test to Confirm Hepatitis C Infection and Quantify Viral Load

CE-IVD Certification of Aptima® HCV Quant Dx Assay on Panther® System
Continues Company's Expansion into Virology Testing Market

Marlborough, Mass., 20 October, 2015 – Hologic (NASDAQ: HOLX) has earned CE-IVD certification for its Aptima® HCV (hepatitis C virus) Quant Dx assay on the fully automated Panther® system, the Company announced today.

The Aptima HCV Quant Dx assay is CE-IVD certified for both confirmation of active infection in patients with a positive HCV antibody result, and for viral load monitoring. The assay complements the previously certified Aptima HIV-1 Quant Dx assay, as well as an expansive menu of women's health assays that run on the Panther system in Europe.

"The Aptima HCV Quant Dx Assay on the Panther system brings unprecedented agility and automation to HCV nucleic acid amplification testing (NAAT)," said Claus Egstrand, Hologic's Group President, International. "Laboratories that use the assay on the Panther system can customize their workflow with random access and more walkaway freedom compared to other viral load platforms."

The Aptima HCV Quant Dx assay uses real-time transcription-mediated amplification (TMA) to test plasma or serum samples. The assay's robust design provides three levels of protection against mutations, and offers excellent performance across all major genotypes, with high sensitivity and precision across a wide linear range. The assay's limit of detection (LoD) is 4.3 IU/mL in plasma and 3.9 IU/mL in serum, and its lower limit of quantitation (LLoQ) is 10 IU/mL.

Other assays that can be run on the Panther system in Europe include the Aptima HIV-1 Quant Dx assay, as well as tests for chlamydia, gonorrhea, trichomoniasis and human papillomavirus (HPV).

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

About Hologic

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products. The Company's core business units focus on diagnostics, breast health, GYN surgical, and skeletal health. With a unified suite of technologies and a robust research and development program, Hologic is dedicated to The Science of Sure. For more information on Hologic, visit www.hologic.com.

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