NEWS RELEASE

Hologic Panther Platform and HIV-1 Quant Assay Used in “HIV Cure” Research

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-- Two published studies demonstrate automated detection of viral loads as low as one copy per milliliter

Marlborough, Massachusetts (October 7, 2020) – Two studies in the current issue of the Journal of Clinical Microbiology demonstrated the utility of Hologic’s Panther® platform and Aptima® HIV-1 Quant assay in research related to potentially curing HIV-infected individuals. Hologic scientists collaborated on the studies1,2 with researchers at Vitalant Research Institute, the University of California, San Francisco, the University of California, San Diego, and the University of Pittsburgh.

There is an intense international research effort to discover strategies to effectively cure HIV-infected individuals by eliminating the virus, so that they can discontinue medication permanently. To achieve this, scientists need a way to confirm that HIV has been eliminated.

“This is a promising field of research, but measuring very low levels of virus in patients’ blood has presented a major challenge,” said Andrew Worlock, Ph.D., senior director of R&D at Hologic. “We developed a way to take advantage of the flexibility of our Panther instrument and the high sensitivity of our Aptima HIV-1 Quant assay to measure single copy levels of virus in large volumes of plasma, and to do it quickly and inexpensively.” Methods used in the studies are for research use only, and are not for use in diagnostic procedures.

The Panther molecular diagnostics system is a fully automated, high-volume platform that can process approximately 1,000 tests in a 24-hour period. It is used in clinical diagnostic laboratories to run tests for sexually transmitted diseases and respiratory infections – including SARS-CoV-2/COVID-19 – and to monitor viral loads in HIV-, HCV- or HBV-infected individuals. The Aptima HIV-1 Quant assay is performed on a blood sample and will quantitate viral loads down to 30 copies/milliliter (ml).

In the new studies, the investigators described an approach in which samples were run in replicate, meaning multiple aliquots were run from the same tube loaded on the Panther system. The results of individual replicates were then combined to give the result for a sample. With this approach, the researchers demonstrated that they could detect HIV-1 RNA in all antiretroviral therapy-suppressed participants when 45 replicate 0.5 ml aliquots of plasma were tested. When nine replicates were tested, 100% of participants with an HIV concentration in the range of five copies/ml were positive, and 70% were positive with concentrations as low as one copy/ml.

"By running replicates of plasma samples on the automated Panther system, we succeeded in quantifying HIV viral loads in individuals well below the detection limits typically achieved with viral load assays used for clinical diagnosis and monitoring," said Michael Busch, Ph.D., from Vitalant Research Institute and UCSF, the senior author of one of the studies. "It really opens the door to automating quantitation of viral loads that were previously only detectable using highly laborious, ultrasensitive HIV RNA assays that required manual processes including ultracentrifugation of large volumes of plasma. This new approach should help lead to progress in evaluating

promising new interventions in the HIV cure research field."

About the Panther System

The Panther molecular diagnostics system is a best-in-class, fully automated, sample-to-result platform that can be used in low-, medium- or high-throughput laboratories. With a small footprint, adaptable workflow options and consolidated testing menu, it combines women's health, sexually transmitted infections and viral load testing, which can all be done simultaneously. More than 2,000 Panther systems have been installed in clinical diagnostic laboratories around the world.

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 Panther system and Aptima HIV-1 Quant assay. There can be no assurance these products will achieve the benefits described herein. 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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