



Blood Systems Research Institute

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Blood Systems Research Institute Partners with Hologic to Improve Efficiency and Precision of HIV Detection

Collaboration provides the UCSF-based amfAR Institute for HIV Cure Research with access to Hologic's clinical diagnostic instrument system, Panther, for more efficient and high-throughput testing of samples

SAN FRANCISCO, Calif. — July 21, 2017 — Blood Systems Research Institute (BSRI) today announced a collaboration to more precisely and efficiently measure the human immunodeficiency virus (HIV) latent reservoir in clinical samples using [the Panther® system](#) from Hologic, Inc. – a fully automated molecular diagnostics platform that provides test consolidation, random-access sample loading, and proven assay chemistry.

As part of this collaboration, BSRI will provide access to the Panther system to key thought leaders at the amfAR Institute for HIV Cure Research, an innovative collaborative enterprise focused on developing and validating new approaches in HIV research that could ultimately lead to a cure.

The amfAR Institute for HIV Cure Research brings together a team of HIV experts from BSRI, University of California, San Francisco (UCSF), the Gladstone Institutes, and other partners. This San Francisco-based team was the sole winner of amfAR's invitation-only \$20 million grant funding competition. The Institute is the cornerstone of amfAR's \$100 million cure research investment strategy and is focused on developing the scientific basis of a cure for HIV by the end of 2020. The BSRI team is led by Satish Pillai, Ph.D., Associate Investigator at BSRI and Michael P. Busch, M.D., Ph.D., Senior Vice President of Research and Director at BSRI.

Investigators at BSRI have begun using the Panther system to measure very low levels of HIV RNA in clinical material in an ultrasensitive and highly-precise manner, underscoring their cure research. Existing approaches to detect and quantify latent provirus in infected host cells, or low-level replicating HIV virus, are limited. Inaccuracies in quantification of target molecules, PCR inhibition, as well as vast differences between measurements in individual labs, make the identification of low-level replicating HIV exceedingly difficult, and the process can be long and arduous. The Aptima® HIV-1 Quant assay on the Panther system performs with excellent sensitivity and precision across a wide linear dynamic range, and can detect HIV-1 RNA concentrations as low as 12 copies/mL in a 0.5 mL plasma sample. This helps foster understanding of the latent reservoir further pushing us toward a cure. Testing on the Panther system allows simultaneous characterization of multiple replicate samples, 0.5 mL each in volume. This replicate testing and analysis can yield highly robust, quantitative data.

In addition to characterization of HIV expression in-vivo, BSRI researchers will analyze multiple human samples from treatment suppressed HIV-infected individuals, ex-vivo, testing the capacity of novel cure agents to induce viral replication in tissues and destroy infected cells.

“This is really helpful to study longitudinal samples of patients in latency reversal trials or other cure interventions,” said Dr. Michael Busch. “Utilizing the Panther system allows us to detect very minor blips of virus [that is supposedly latent].”

“Hologic is committed to improving public health,” said Tom West, president, Diagnostic Solutions division at Hologic. “We are excited that our technology was selected to support this research into a cure for HIV infection.”

Preliminary data from the collaboration will be presented at the 9th IAS Conference on HIV Science in Paris, France on July 24th.

About the Aptima HIV-1 Quant Assay

The Aptima HIV-1 Quant assay is an *in vitro* nucleic acid amplification test (NAAT) for the quantitation of human immunodeficiency virus type 1 (HIV-1) RNA in human plasma from HIV-1 infected individuals on the fully automated Panther system. The Aptima HIV-1 Quant assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/mL. One international unit is equivalent to 0.35 copies of HIV-1 RNA for the 3rd HIV-1 WHO International Standard (subtype B, NIBSC code: 10/152).

The Aptima HIV-1 Quant assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels.

This assay is not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.

Further details about the Aptima HIV-1 Quant assay may be found at www.hologic.com.

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About Blood Systems Research Institute

Blood Systems Research Institute (BSRI), San Francisco, is a non-profit organization and the research division of Blood Systems, the second largest blood banking organization in the United States. Established in 1959, BSRI is the leading program in the U.S., and perhaps the world, with respect to transfusion-transmitted infectious diseases, and is at the forefront of several other areas of transfusion medicine research. More than 70 scientists, investigators and staff support a diverse research portfolio encompassing immunology, virology, cellular therapeutics, epidemiology and health policy. BSRI is one of only four significant blood bank-sponsored research programs in the United States. For more information, visit www.bsrisf.org.

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