NEWS RELEASE

Aptima® HIV-1 Quant Dx Assay Awarded WHO Prequalification for Dried Blood Spot Samples

9/14/2020

MARLBOROUGH, Mass., September 14, 2020 /Businesswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that its CE-marked Aptima® HIV-1 Quant Dx assay has been awarded World Health Organization (WHO) prequalification for testing of dried blood spot (DBS) samples.

The Aptima® HIV-1 Quant Dx assay can be used with DBS samples to monitor viral load and disease progression among HIV-1 infected individuals, and to aid in the diagnosis of HIV-1 infected infants under 18 months. It is the first and only dual-claim assay for both viral load and early infant diagnosis (EID).

DBS sampling improves access to HIV diagnostic testing and care, particularly among HIV-infected populations living in remote areas. DBS samples are more stable and easily transportable compared to liquid whole blood or plasma samples. A finger stick or heel prick produces an adequate sample that is dried on a specially designed card. The DBS samples do not require refrigeration and when stored properly can withstand extreme conditions, including excess heat and humidity.

This additional approval is notable for the African market, where DBS is the primary sample type in several countries, and is expected to enable countries to expand their use of the Aptima® HIV-1 Quant Dx assay, the leading assay under Hologic's Global Access Initiative (GAI). The GAI launched in 2018 and offers customers a single, all-inclusive pricing structure with no upfront cost or capital expenditure. Qualified products include molecular assays for HIV, Hepatitis B and C, and human papillomavirus (HPV), as well as the ThinPrep® Pap test for cervical cancer screening.

"With 25 million people infected with HIV in sub-Saharan Africa, there continues to be an urgent need for access to cost-effective and quality diagnostic testing," said Joao Malagueira, vice president, Europe South, Middle East

and Africa. “The ability to test DBS samples underlines Hologic’s commitment to promote simple, scalable and sustainable solutions for countries that need it most. The new product extension will ultimately enhance patient care and allow for partner governments to mitigate the burden of disease and respond to broader health needs.”

Despite substantial progress toward the UNAIDS 95-95-95 **targets**, there continue to be gaps across the HIV testing and treatment cascade, with 15.7 million people living with HIV who have an unsuppressed viral load globally1. In addition, children and infants continue to be affected by the epidemic. In 2019, only 60% of infants born to pregnant women living with HIV received the recommended HIV test within two months of birth2. About 86% of the estimated 160,000 children newly infected with HIV in 2018 were in sub-Saharan Africa.3

The DBS sample type is the second approval Hologic has received from the WHO, following prequalification of the Aptima® HIV-1 Quant Dx assay for in vitro diagnostic use with plasma samples in December 2017.

About Hologic’s Global Access Initiative

The Hologic Global Access Initiative is a partnership with the Clinton Health Access Initiative, Inc. (CHAI) and MedAccess (backed by the UK government) to mitigate the burden of viral diseases in areas with high prevalence by providing greater access to testing using the Panther® system. Together with these organizations, Hologic delivers a pricing structure that allows eligible countries to procure testing with an all-inclusive* ceiling price of $12 per patient test, with no requirement for capital expenditure. The test result price is inclusive of all necessary reagents and consumables, instrument placement, service and maintenance, freight and logistics, and replacement tests.†

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

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* Testing services do not include ancillary costs, for example those associated with sample collection, sample transport, laboratory staff time, laboratory infrastructure, generic lab supplies (e.g., primary collection tubes, disposable gloves, bleach, bleach bottles, bleach enhancer, waste bottles), inventory management, or general administration and overhead costs.

† Replacement tests for one set of controls and calibrators per kit and documented instrument errors.

References:

https://aids2020.unaids.org/chapter/chapter-2-2020-commitments/the-hiv-test-and-treat-cascade. Accessed August 27, 2020.
https://data.unicef.org/wp-content/uploads/2019/07/HIV_Early_Infant_Diagnosis_July2020.xlsx. Accessed August 27, 2020.
https://www.who.int/gho/hiv/epidemic_response/PMTCT/en/. Accessed August 27, 2020.