



NEWS RELEASE

Hologic Announces European CE Mark for Molecular Assays for Use with Transplant Patients

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-- New quantitative assays for Epstein-Barr Virus and BK Virus expand Hologic's Panther Fusion transplant pathogen monitoring menu --

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced it has received CE marking for two new molecular assays, Panther Fusion EBV Quant Assay and Panther Fusion BKV Quant Assay, expanding its transplant pathogen monitoring menu on the Panther Fusion system. The assays quantify the viral load of the respective viruses and are intended to aid the diagnosis and management of solid organ transplant patients and hematopoietic stem cell transplant patients.

The assays are in vitro nucleic acid amplification tests (NAAT) that are run on the fully automated Panther Fusion system using real-time Polymerase Chain Reaction (PCR) technology. The Panther Fusion EBV Quant is validated for use with whole blood and plasma samples. The Panther Fusion BKV Quant is validated for use with human plasma and urine samples. Plasma, whole blood and urine specimens are important biomarkers when using quantitative NAATs for diagnosis and management of transplant patients. It is crucial that viral levels are accurately quantitated in transplant recipients to guide treatment decisions and monitor response to therapy.^{1,2}

"Immunocompromised patients are vulnerable to a range of infections. As both the Epstein-Barr virus (EBV) and the BK virus (BKV) are extremely common and mainly asymptomatic, it is important that healthcare providers can quantitate and monitor for their presence," said Jan Verstreken, Group President, International at Hologic. "These assays, along with our Aptima CMV Quant assay that we launched in Europe last year, provide our laboratory partners with the tools they need to accurately assess transplant patient samples quickly and confidently."

"These two assays represent two firsts for us. They are the first quantitative assays developed for the Panther



Fusion system, further expanding our existing portfolio of diagnostic and viral load tests. They are also the first Panther Fusion assays developed in our R&D facility in Liege, Belgium, which we acquired last year,” concluded Verstreken.

For more information on the Aptima and Panther Fusion assays, visit www.hologic.com.

About Epstein-Barr Virus

EBV is a ubiquitous virus that belongs to the herpesvirus family. It is estimated that 90% of the population worldwide is infected with EBV.³ In immunocompromised people such as transplant patients, it is a significant cause of morbidity and mortality.

About BK Virus

BKV is a highly prevalent human polyomavirus that belongs to the papoviridae family. Primary exposure to BKV occurs in childhood, resulting in 80-90% of adults having developed antibodies against BKV. The majority of BKV infections are asymptomatic, with the virus remaining latent in the urinary tract.⁴ Viral reactivation occurs in immunocompromised individuals, frequently in renal transplant and hematopoietic stem cell transplant patients, and is associated with nephropathy, ureteral stenosis and late onset haemorrhagic cystitis.⁵

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.

Hologic 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 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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Source: Hologic, Inc.

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