

German Lab Demonstrates Feasibility to Detect SARS-Coronavirus-2 (SARS-CoV-2) Using Hologic's Panther Fusion® System

3/5/2020

– Laboratory Developed Test Uses Panther Open Access™ Functionality–

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- A molecular assay for detecting the novel coronavirus SARS-CoV-2 (previously 2019-nCoV) on the automated Panther Fusion® system has been developed by investigators at Hannover Medical School in Germany, Hologic (Nasdaq: HOLX) announced today. The preclinical assay is described **online** in the Journal of Clinical Virology.¹

The Open Access™ functionality on the Panther Fusion® system allows accredited medical laboratories to design and validate laboratory developed tests (LDTs) to run on the fully automated, high-throughput platform. Laboratories can run their LDTs simultaneously with commercially available CE-IVD assays in a random access model, without waiting to batch tests.

"Rapid diagnosis is critical to combatting the spread of pandemics, and the Panther Fusion system is well suited to this purpose," said Albert Heim, M.D, head of molecular diagnostics at Hannover Medical School. "Using inactivated virus from cell cultures and commercially available control materials, we adapted two recently published PCR protocols² to run on the Panther Fusion system. Our next step will be to validate our assay on clinical samples."

The emerging SARS-coronavirus-2 (SARS-CoV-2) can cause severe respiratory tract infections (COVID-19) and has been declared a public health emergency by the WHO.^{3,4}

"It's extremely gratifying to see our instrument system being used to quickly develop a response to an urgent public health threat," said Kevin Thornal, president of the Diagnostic Solutions division at Hologic. "We specifically

designed Panther Fusion and Open Access functionality to give diagnostic lab customers maximum flexibility, both for their day-to-day needs and to respond quickly to emerging threats.”

Users of Open Access are required to follow all applicable local requirements for their laboratory and users in developing and validating their own LDTs on the Panther Fusion system.

The Panther system launched in Europe in 2010 and in the U.S. in 2012. The Panther Fusion module, which was launched in Europe in 2016, can be attached to existing Panther systems in the field to extend testing capabilities. Specifically, the Panther Fusion module adds the capacity to run PCR assays and the Open Access functionality allows labs to develop LDTs using the platform.

The assay described in this press release has not received CE-IVD certification in Europe or clearance from the Food and Drug Administration (FDA) in the United States.

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 receive regulatory clearance in the United States or Europe, detect the SARS-coronavirus-2 effectively, meet potential demand, or 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.

Hologic, Panther, Panther Fusion, and Open Access are trademarks and/or registered trademarks of Hologic, Inc. in the United States and/or other countries.

References:

1. <https://www.sciencedirect.com/science/article/pii/S1386653220300470?viewFullText=true>. Accessed March 4, 2020.

2. V M Corman, O Landt, M Kaiser, R Molenkamp, A Meijer, D K Chu, T Bleicker, S Brunink, J Schneider, M L Schmidt, D G Mulders, B LHaagmans, B van der Veer, S van den Brink, L Wijsman, G Goderski, J L Romette, J Ellis, M Zambon, M Peiris, H Goossens, C Reusken, M P Koopmans, and C Drosten. 2020. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill, 25. DOI: 10.2807/1560-7917.ES.2020.25.3.2000045.
 3. N Zhu, D Zhang, W Wang, X Li, B Yang, J Song, et al. A Novel Coronavirus from Patients with Pneumonia in China. 2020. N Engl J Med. 382:727-733. DOI: 10.1056/NEJMoa2001017.
 4. T Ganzenmueller, R Kaiser, C Baier, M Wehrhane, B Hilfrich, J Witthuhn, et al. Comparison of the performance of the Panther Fusion respiratory virus panel to R-Gene and laboratory developed tests for diagnostic and hygiene screening specimens from the upper and lower respiratory tract. J Med Microbiol. (2020) In press. DOI 10.1099/jmm.0.001133.
- SOURCE: Hologic, Inc.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20200304005866/en/>

Investor Contact:

Michael Watts

+1 858.410.8588

michael.watts@hologic.com

Media Contact:

Jane Mazur

+1 508.263.8764 (direct)

+1 585.355.5978 (mobile)

jane.mazur@hologic.com

Source: Hologic, Inc.