# **HOLOGIC®**

### **NEWS RELEASE**

# Open Access™ Functionality Now Available on Hologic's New Panther Fusion® System

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# -New myAccess™ Software Allows Laboratory Developed Tests to Run Alongside Hologic's Commercially Available IVD Assays-

MARLBOROUGH, Mass., November 8, 2018 – Hologic, Inc. announced today the availability of Open Access™ functionality for its Panther Fusion® system. This enhanced functionality will allow CLIA-certified laboratories to develop laboratory developed tests (LDTs) to run on the fully automated Fusion platform. Laboratories will be able to run their LDTs simultaneously with commercially available IVD assays, and results will release automatically to laboratory information systems.

"We know that our diagnostic lab customers place a high value on flexibility, which is one of the reasons we launched Panther Fusion with polymerase chain reaction, commonly known as PCR, capability last year," said Tom West, president of the Diagnostic Solutions division at Hologic. "The current software introduction builds on that launch by providing tools that labs can use to design and use LDTs on a fully automated platform, as well as consolidate their LDTs with commercial assays to maximize productivity."

The Panther Fusion is available as a full system, or the Panther Fusion module 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 in addition to tests based on TMA (transcription-mediated amplification), the proprietary Hologic chemistry that powers the company's Aptima® brand.

The Open Access functionality is enabled by the new myAccess™ software, which is designed to help laboratories create protocols, analyze data, set thresholds, and interpret results.

The Panther Fusion system retains all the key benefits of the Panther platform, including full sample-to-result

automation, the ability to run multiple tests from a single sample, random and continuous access, continuous loading, and STAT capabilities.

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

# **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 customer or 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 customer or 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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### **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