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Panther Fusion® Flu A/B/RSV Assay Now FDA Cleared on Hologic's New Panther Fusion® System

- New Panther Fusion Module Expands System's Molecular Testing Capabilities, Increases Efficiency and Flexibility for the Laboratory

MARLBOROUGH, Mass., Oct. 5, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its Panther Fusion® Flu A/B/RSV assay running on the new Panther Fusion® system.

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 adds the capacity to run PCR (polymerase chain reaction) assays in addition to tests based on TMA (transcription-mediated amplification), the proprietary Hologic chemistry that powers the Company's Aptima® brand.

"Consolidating testing remains a key focus of our clinical laboratory customers," said Tom West, president of the Diagnostic Solutions Division at Hologic. "Offering multiple chemistries on a single platform expands menu while allowing labs to further consolidate testing and meet efficiency goals."

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 access sample processing, continuous loading, and STAT capabilities. Additional benefits include a higher throughput of up to 335 Panther Fusion tests in eight hours, or up to 500 Fusion and Aptima tests.

In addition to the current clearance of the Panther Fusion® Flu A/B/RSV assay, two additional respiratory panels, the Panther Fusion Paraflu assay and the Panther Fusion AdV/hMPV/RV (adenovirus/human metapneumovirus/rhinovirus) assay, are under review by the FDA. These assays are not currently available for sale in the United States.

Once all three Panther Fusion respiratory assays are cleared, they will offer a modular approach to testing via the ability to run one, two or all three assays from a single patient specimen. The Panther Fusion assays also utilize ready-to-use reagents, which offer up to 60-day on-board stability.

"We have heard from customers that many panels currently on the market are too large, requiring them to run up to 20 or more targets when perhaps a physician has only requested three or four," said West. "Not only is this time-consuming for the lab, it is also not cost-effective. By offering three smaller panels focused on the tests most frequently requested, we will offer labs maximum flexibility to design test runs to meet specific needs."

"Hologic has long-standing expertise in flu extending back to the introduction of ProFlu+, the first FDA-cleared Flu A/B/RSV assay on the market in 2008," said West. "This expertise has translated to the development of a test with excellent performance, and that test is now available on our integrated platform, which fully automates all aspects of testing, from sample to result."

The Panther Fusion system substantially reduces hands-on time for laboratories by providing random and continuous access with rapid turnaround time. The new Panther Fusion PCR-based assays, combined with select Aptima TMA assays, make the Panther Fusion system the only instrument worldwide that combines TMA, real-time TMA, and real-time PCR with full sample-to-result automation.

The Panther Fusion system and Panther Fusion Flu A/B/RSV, Paraflu, and AdV/hMPV/RV assays have also been CE-marked for diagnostic use and are commercially available in Europe.

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 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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