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Hologic's New Panther Fusion® System, Flu and Respiratory Assays Now CE Marked in Europe



New Panther Fusion® Module Expands Molecular Testing Capabilities, Increases Productivity and Flexibility for the Laboratory

Hologic, Inc. has obtained a CE mark in Europe for its new Panther Fusion system and Panther Fusion assays for flu and respiratory testing, the Company has announced. The Fusion module system offers laboratories the ability to extend the testing capabilities of the existing Panther system.

The Panther Fusion module is an in-lab upgrade to the Panther® instrument. This addition adds the flexibility of PCR (polymerase chain reaction) to the proven performance of TMA (transcription-mediated amplification), which is used by the Panther system. Offering labs multiple chemistries on a single platform enables further consolidation of their lab testing portfolio. The Panther Fusion system retains all the key benefits of the Panther platform, including fully automated sample-to-result automation, 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. Flexibility is also improved with the addition of Open Access functionality to run laboratory-developed tests and protocols. This new capability allows laboratories to concentrate on developing assays, while the Panther Fusion system automates workflow and reduces overall hands-on-time.

"The Panther Fusion system, the latest innovation from our Diagnostics division, creates an integrated workflow that provides our customers with enhanced flexibility and increased efficiency," said João Malagueira, VP Sales Diagnostics, EMEA. "The addition of the flu and respiratory assays to the broad menu of Aptima tests already available for the Panther instrument further extends the range of diagnostics tests that laboratories can run on one Hologic system. Hologic's flu and respiratory assays enable customers to run only the targets requested for a patient, allowing for personalized testing and helping them control costs within their laboratories."

The Panther Fusion respiratory panel assays include the Panther Fusion Flu A/B/RSV, Panther Fusion Paraflu, and Panther Fusion AdV/hMPV/RV tests. The Panther Fusion respiratory assays offer a modular approach to syndromic testing via the ability to run one, two or all three assays from a single

patient specimen depending on the needs of a given patient.

The new Panther Fusion PCR assays, combined with the 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 assays have not been cleared for marketing by the U.S. Food and Drug Administration, and are not available for diagnostic use in the United States

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