



NEWS RELEASE

# Hologic Announces Two New Respiratory Assays for the Detection of COVID-19, Flu A, Flu B and RSV

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--New assays for the Panther Fusion and Novodiag Systems further build on Hologic's leading molecular scalable solutions offering to European customers--

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that it is now offering its Panther Fusion® SARS-CoV-2/Flu A/B/RSV assay and its Novodiag® RESP-4 molecular diagnostic test for sale in the European Union in time for the northern hemisphere's respiratory viral season. Both assays detect and differentiate four of the most prevalent respiratory viruses that can present with similar clinical symptoms: severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A (Flu A), influenza B (Flu B) and respiratory syncytial virus (RSV).

The Panther Fusion SARS-CoV-2/Flu A/B/RSV assay is a high-performance cartridge-based assay that runs on the fully automated high-throughput Panther Fusion system. The test uses nasopharyngeal swab samples.

The Novodiag RESP-4 assay runs on the Novodiag system, the fully automated molecular diagnostic solution that delivers on-demand testing for infectious disease and antimicrobial resistance. This test also uses nasopharyngeal swab samples and includes an embedded cellularity control to ensure that the sample was correctly taken.

Both products are compliant with the European In Vitro Diagnostic Medical Device Directive (IVDD) 98/79/EC, and transition provisions for such devices included in the IVD Regulation (EU) 2017/746.

"As we move into the next phase of COVID, it is important that we evolve our assays to support our customers with tests that enable them to differentiate between the multiple respiratory pathogens as easily as possible. The ability to accurately differentiate between respiratory viruses with similar symptoms is essential if physicians are to ensure



optimized care for each patient,” said Jan Verstreken, Group President International. “Together, these two assays further build our international offering of molecular diagnostic scalable solutions that meet the growing needs of a broad range of customers, from single-patient rapid testing to population-level screening.”

He continued, “The RESP-4 assay, developed and manufactured in Espoo, Finland is the first new Novodiag assay to be launched since Hologic’s acquisition of Mobidiag in June 2021. The Panther Fusion SARS-CoV-2/Flu A/B/RSV assay was developed and will be manufactured at our facility in San Diego, CA. It adds to our quickly growing menu of Panther Fusion assays, including the Panther Fusion EBV and BKV assays designed and manufactured at our recently acquired facility in Liège, Belgium.”

The launch of the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay adds to the respiratory portfolio for the Panther Fusion system, which currently includes the Panther Fusion Flu A/B/RSV assay, the Panther Fusion Paraflu (Parainfluenza 1/2/3/4) assay, the Panther Fusion AdV/hMPV/RV (adenovirus/human metapneumovirus/rhinovirus) and the Panther Fusion Bordetella assay.

The launch of the Novodiag RESP-4 assay further expands the Novodiag assay menu, which currently includes diagnostic assays for gastrointestinal infections, hospital acquired infections, antimicrobial resistance and respiratory infections.

For more information visit [www.hologic.com](http://www.hologic.com).

## About the Panther and Panther Fusion Systems

The Panther molecular diagnostics system is a best-in-class, fully automated, sample-to-result platform that can be used in low-, medium- or high-throughput laboratories. With a small footprint, adaptable workflow options and consolidated testing menu, it combines women’s health, sexually transmitted infection and viral load testing, which can all be done simultaneously. The Panther Fusion system provides an expanded in vitro diagnostics menu, as well as Open Access™ functionality to run laboratory developed tests.

## About the Novodiag System

The Novodiag system combines real-time PCR and microarray capabilities that enable multiple pathogens to be identified in a single sample, providing a simple and fast way to pinpoint patients most at risk with targeted and syndromic on-demand testing. It delivers clinically relevant results in central labs or tertiary settings and its rapid ‘sample-in, result-out’ system allows for the fully automated detection of novel coronavirus in approximately one hour. It can be used as the main molecular platform for emergency, decentralised, and out-of-hours testing, or in association with the Panther® System.

## About Hologic, Inc.

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](http://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 that 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 publicly release 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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