HOLOGIC®

SARS-CoV-2 Assays*

- Fully automated, high-throughput assays for the detection of the SARS-CoV-2 virus.

Accurate and fully automated testing is critical in the fight against the coronavirus disease (COVID-19) – and key to quickly identifying who's infected and subsequently helping alleviate the spread of this novel virus.

Challenges Facing Labs

Unanticipated surge of testing demand, underscoring the need for high-throughput automation.[1]

Urgency to process a large number of samples rapidly.[2]

Uncertainty around future and continued SARS-CoV-2 and other respiratory virus testing needs.[3]

The power to choose. The potential to grow. The flexibility and scalability of the Panther® system provides accessibility to three molecular SARS-CoV-2 assays allowing labs to:

- Meet the urgent need for high-throughput and fully-automated testing.[3]
- Detect the SARS-CoV-2 virus to guide patient management and mitigate the spread of infection.[4-6]
- Detect and differentiate SARS-CoV-2 and Influenzas A & B during respiratory season.

Test more patients for COVID-19 in less time on the Panther® and Panther Fusion® systems. These high-throughput, highly sensitive tests now available for use under Health Canada's emergency use authorization (EUA).[4-6]

- Significantly increase testing capacity by running more than 1000 tests in 24 hours.†
- Boost efficiency and increase clinical insight by running other respiratory viral assays from the same sample.
- Easy-to-interpret test results available in about 3 hours.
- Maximize throughput by running infectious disease, women's health and virology assays on a single fully automated platform.

Aptima® | Panther Fusion®

Three Assays Delivering the Performance and Flexibility You Need

Aptima SARS-CoV-2 Assay on the Panther System[4]

Aptima® SARS-CoV-2 Assay

For the qualitative detection of SARS-CoV-2 from individuals meeting COVID-19 clinical and/or epidemiological criteria as well as individuals without symptoms or other reasons to suspect COVID-19 infection.

Applicable specimen types include:

- Nasopharyngeal (NP), nasal, mid-turbinate nasal and oropharyngeal (OP) swab specimens collected in UTM/VTM, saline, Liquid Amies or STM
- Nasopharyngeal wash/aspirate or nasal aspirates
- Pooled samples containing up to 5 individual upper respiratory swab specimens (i.e. nasopharyngeal, nasal, mid-turbinate, or oropharyngeal swabs)

Aptima SARS-CoV-2/Flu Assay on the Panther System[5]

Aptima® SARS-CoV-2/Flu Assay

For the qualitative detection and differentiation of SARS-CoV-2, influenza A virus and influenza B virus from individuals suspected of respiratory viral infection consistent with COVID-19.

Applicable specimen types include:

- Nasopharyngeal (NP) and nasal swab specimens collected in UTM/VTM, saline or STM

Panther Fusion SARS-CoV-2 Assay on the Panther System[6]

PANTHER FUSION® SARS-CoV-2 Assay

For the qualitative detection of SARS-CoV-2 from individuals meeting COVID-19 clinical and/or epidemiological criteria as well as individuals without symptoms or other reasons to suspect COVID-19 infection.

Applicable specimen types include:

- Nasopharyngeal (NP), nasal, mid-turbinate nasal and oropharyngeal (OP) swab specimens collected in UTM/VTM, saline, Liquid Amies or STM
- Nasopharyngeal wash/aspirate or nasal aspirates and lower respiratory tract (LRT) specimens (such as bronchoalveolar lavage)

* The Aptima® SARS-CoV-2, Aptima® SARS-CoV-2/Flu and Panther Fusion® SARS-CoV-2 assays have not been Health Canada cleared or approved; These tests have been authorized by Health Canada under an EUA for use by authorized laboratories; The Aptima and Panther Fusion SARS-CoV-2 assays have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; The Aptima SARS-CoV-2/Flu assay has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus, influenza B virus, and not for any other viruses or pathogens. The Aptima SARS-CoV-2, Panther Fusion SARS-CoV-2, and Aptima SARS-CoV-2/Flu assays are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

† Number of actual test results per day may vary based on individual lab practices and workflows.

References: 1. Cohen J. 'We're behind the curve': U.S. hospitals confront the challenges of large-scale coronavirus testing. Science. Published March 11, 2020. Accessed November 10, 2020. https://www.science.org/content/article/were-behind-curve-us-hospitals-confront-challenges-large-scale-coronavirus-testing **2.** Johnson M. In Coronavirus Assay Validation for Emergency Use, Labs Encounter Multiple Pain Points. GenomeWeb. Published March 11, 2020. Accessed November 10, 2020. https://www.360dx.com/pcr/coronavirus-assay-validation-emergency-use-labs-encounter-multiple-pain-points#.X6qnV2hKg2w **3.** HHS Supports Development of First High-Throughput COVID-19 Diagnostic Test [press release]. Washington, D.C. U.S. Department of Health & Human Services. March 10, 2020. **4.** Aptima SARS-CoV-2 assay. Canadian package insert AW-21677-001_005_01. Hologic, Inc; 2020. **5.** Aptima SARS-CoV-2/Flu assay. Canadian package insert AW-22604-001_002_01. Hologic, Inc; 2020. **6.** Panther Fusion SARS-CoV-2 assay. Canadian package insert AW-21388-001_004_01. Hologic, Inc; 2020.