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 samples underscoring the need for automation.[1]

Extreme urgency to establish diagnostic capabilities.[2]

Uncertainty around future and continued pandemic testing needs.[3]

The power to choose. The potential to grow. The flexibility and scalability of the Panther system provides accessibility to two molecular diagnostic tests that quickly detects SARS-CoV-2 allowing labs to:

- Meet the urgent need for high-throughput and automated testing.[3]
- Detect the virus to guide patient management and mitigate the spread of infection.[4-6]
- Prepare to respond to the evolving needs of the COVID-19 global health crisis.

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 the FDA's emergency use authorization (EUA).[4-6]

- Significantly increase testing capacity by running greater 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®

Two Assays Delivering the Performance You Expect[5,6]

- The Aptima® and Panther Fusion® assays are intended for the qualitative detection of RNA from SARS-CoV-2 from individuals meeting COVID-19 clinical and/or epidemiological criteria.
- Both assays target two specific regions of the ORF1ab gene in the SARS-CoV-2 virus.

Performance Relative to Expected Results[5,6]

Aptima® SARS-CoV-2 Assay on the Panther System[6*†]

	Contrived Specimen Expected Result	
	Positive	**Negative**
Positive	50	1
Negative	0	54

Positive Percent Agreement: 100% (92.9%-100%) Negative Percent Agreement: 98.2% (90.4%-99.7%) Overall Agreement: 99.0% (94.8%-99.8%)

PANTHER FUSION® SARS-CoV-2 Assay on the Panther Fusion System[5*†]

	Contrived Specimen Expected Result	
	Positive	**Negative**
Positive	70	0
Negative	0	108

Positive Percent Agreement: 100% (94.8%-100%) Negative Percent Agreement: 100% (96.6%-100%) Overall Agreement: 100% (97.9%-100%)

Sample Collection Types[5,6]

For use with nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, Nasopharyngeal wash/aspirate or nasal aspirates can be processed with the Aptima SARS-CoV-2 assay. Additionally, the Panther Fusion assay has been verified for use with lower respiratory tract specimens.

Swabs may be used with:

- ✓ BD Universal Viral Transport System
- ✓ COPAN Universal Transport Medium
- ✓ Remel MicroTest M4, M4RT, M5 or M6 formulations
- ✓ Saline
- ✓ Liquid Amies
- ✓ Aptima® Multitest Swab Specimen Collection Kit[¶]

* The Aptima® and Panther Fusion® SARS-CoV-2 assays:
- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is 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.

† The Panther Fusion SARS-CoV-2 assay is available for EUA use in the United States, Australia, New Zealand and Canada. EUA does not apply to the European Union. The Aptima SARS-CoV-2 assay is available for EUA use in the United States.
‡ Number of actual test results per day may vary based on individual lab practices and workflows.
¶ For oropharyngeal sample type.

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 March 18, 2020. https://www.sciencemag.org/news/2020/03/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 March 18, 2020. https://www.genomeweb.com/pcr/coronavirus-assay-validation-emergency-use-labs-encounter-multi¬ple-pain-points#.XnKtofZFzRM. **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 9, 2020. **4.** CDC. Coronavirus Disease 2019 (COVID-19): If You Are Sick. Last reviewed March 13, 2020. Accessed March 15, 2020. https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html **5.** Panther Fusion SARS-CoV-2 assay [package insert]. AW-21159-001. San Diego, CA: Hologic, Inc; 2020. **6.** Aptima SARS-CoV-2 Assay (Panther System) [package insert]. AW-21490-001 Rev. 002. San Diego, CA: Hologic, Inc; 2020.