HOLOGIC

SARS-CoV-2 Assays

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

Accurate and fully automated testing is critical in the fight against the threat of SARS-CoV-2 and key to quickly identifying who's infected and subsequently helping alleviate the spread of this novel virus.

Challenges facing laboratories

Huge sample demand, underscoring the need for high-throughput molecular automation.[1]

Requirement to deliver rapid results to patients and clinicians.[2]

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

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

- Meet the urgent need for high-throughput and fully-automated testing delivering more than 1000 test results in 24 hours.*[3]
- Detect SARS-CoV-2 to guide patient management and mitigate the spread of infection.[4-5]
- Detect and differentiate SARS-CoV-2 and influenzas A & B during respiratory season.

Supporting laboratories during the global pandemic

The Aptima® SARS-CoV-2 and Aptima SARS-CoV-2/Flu assays are designed for the Hologic Panther system. The assays can be run alongside current infectious disease, women's health and virology assays enabling laboratories to unlock the free capacity on their existing Panther systems.

Aptima®

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, nasal and oropharyngeal swab specimens collected in UTM/VTM, saline, Liquid Amies or Aptima Specimen Transport Medium
- Saliva specimens in Minimum Essential Medium
- Pooled samples containing up to 5 individual saliva samples or upper respiratory swab specimens

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 and nasal swab specimens collected in UTM/VTM, saline or Aptima Specimen Transport Medium

Assay product description	Catalogue number	Kit quantity	Additional notes
Aptima SARS-CoV-2 assay kit	PRD-06419	250 tests	Assay reagent kit only
Aptima SARS-CoV-2 assay controls kit	PRD-06420	5 sets	Order separately as needed

Assay product description	Catalogue number	Kit quantity	Additional notes
Aptima SARS-CoV-2/Flu assay kit	PRD-06815	250 tests	Assay reagent kit only
Aptima SARS-CoV-2/Flu assay controls kit	PRD-06816	5 sets	Order separately as needed

Additional respiratory assays for the qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus, adenovirus, human metapneumovirus, rhinovirus, parainfluenza and Bordetella are available on the Panther Fusion®, please refer to the Panther Fusion catalogue. Please note that a Panther Fusion module will be required to run these assays.

* 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.sciencemag.org/news/2020/03/were-bhind-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 9, 2020. **4.** Aptima SARS-CoV-2 assay. Package insert AW-22752-004. Hologic, Inc; 2021. **5.** Aptima SARS-CoV-2/Flu Package Insert AW-22365-003. Hologic, Inc; 2021.

CE EC REP **Hologic BV, Da Vincilaan 5, 1930 Zaventem, Belgium.**

Diagnostic Solutions | Hologic.com | euinfo@hologic.com