SARS-CoV-2 CE IVD Rx only

TECHNICAL SHEET IDYLLA™ SARS-CoV-2 TEST

The **Idylla™ SARS-CoV-2 Test** is an automated rRT-PCR test intended for the qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Results are obtained using 200 µl of viral transport media (VTM) in approximately 90 minutes with less than 2 minutes hands-on time.

This test is performed on the Idylla™ platform that performs fully automated nucleic acid testing including extraction, amplification, and detection in a single-use cartridge.

FEATURES

Targets	
Targets	SARS-CoV-2 genes[i] N and ORF1b
Sample Processing Control	
Sample control	Exogenous RNA control, MS2 bacteriophage, is detected in each PCR chamber allowing control of all processing steps including extraction, rRT-PCR amplification, and detection.
Specimen requirements	
Sample type	Nasopharyngeal swab specimens collected in VTM. A volume of 200 µl VTM is to be pipetted directly into the cartridge.
Viral Transport Medium (VTM)	
Recommended VTMs	• Copan Universal Transport Medium (Copan Diagnostics, Inc. Cat. # 330C) • BD UVT Transport System (BD Cat. #220220) • Equivalent VTMs[ii]: A VTM composed of similar components and concentrations
Total turnaround time	
Time	90 minutes
Hands-on time	
Time	< 2 minutes

[i] N1 is the primer pair used for the N gene, ORF1b is a subregion of gene ORF1ab.

[ii] Compatible VTMs: Buffers containing PBS (Phosphate Buffered Saline) could interfere with test results and are not recommended for use with this test.

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Result reporting

Report	The Test result output is qualitative and offers the following possible results: • SARS-CoV-2 POSITIVE • SARS-CoV-2 NEGATIVE • INVALID

A quality statement about validity of the control is also provided on the report.

Performance

Clinical performance[i]	Negative Percent Agreement (NPA) Positive Percent Agreement (PPA)	96.7% 100%
Limit of Detection	500 copies/ml	

[i] Performance was evaluated using 60 retrospective (30 positive, 30 negative) nasopharyngeal specimens in viral transport medium obtained from patients with signs and symptoms of upper respiratory distress. Comparator method was FDA EUA Approved molecular rRT-PCR SARS-CoV-2 Test: Luminex NxTAG®CoV Extended Panel Assay.

IDYLLA™ PUBLICATIONS

Check our website: **https://www.biocartis.com/publications/articles-posters?cat=19** and subscribe to receive our newest publications.

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