RAPID, FULLY AUTOMATED DETECTION

IDYLLA™ SARS-COV-2 TEST

BIOCARTIS

INTRODUCING - IDYLLA™ SARS-COV-2 TEST

The Idylla™ SARS-CoV-2 Test is a fully 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.

SARS-CoV-2 genes
N and ORF1b[1]

90 minutes
assay turnaround time

< 2 minutes
hands-on time

Nasopharyngeal swab specimens collected in viral transport medium (200 µl VTM) pipetted directly into the cartridge

Fully automated nucleic acid testing including extraction, amplification and detection in a single-use cartridge

SHOWING EXCELLENT PERFORMANCE

CLINICAL PERFORMANCE

Negative Percent Agreement[2]
96.7%
Positive Percent Agreement[2]
100%

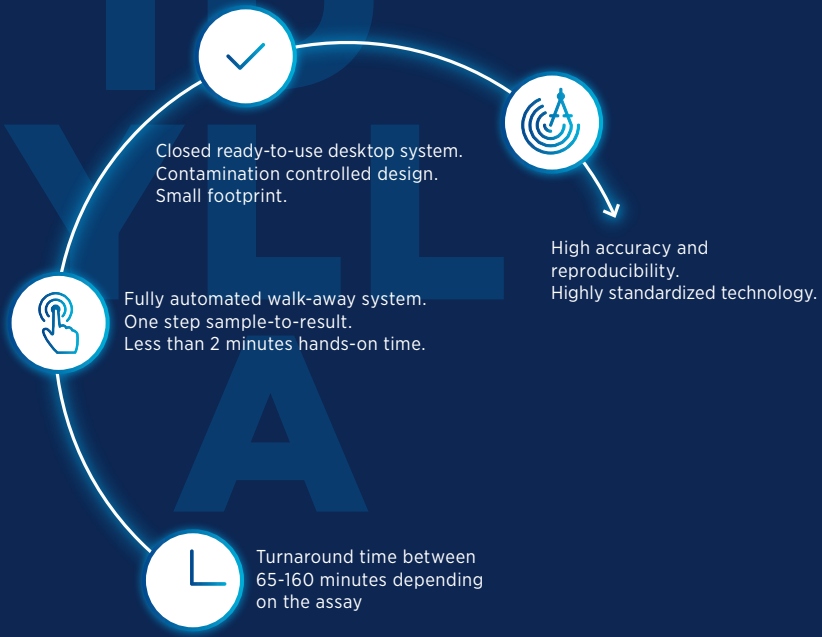
ANALYTICAL PERFORMANCE

Limit of Detection
500 copies/ml

(1) N1 is the primer pair used for the N gene, ORF1b is a subregion of gene ORF1ab.
(2) 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™ – MAKING MOLECULAR TESTING CONVENIENT AND SUITABLE FOR ANY LAB

Idylla™, a fully automated, one step sample-to-result PCR based molecular diagnostics system that can be used in any laboratory setting thanks to its compact, scalable design and outstanding ease of use.



IDYLLA™ - A REVOLUTIONARY WORKFLOW

Just add your sample. Idylla™ will take care of the rest. Our fully automated test enables detection of SARS-CoV-2 virus in about 90 minutes – from sample input to result reporting.

IDYLLA™, A REVOLUTIONARY SYSTEM FOR PCR BIOMARKER TESTING IN ONCOLOGY AND INFECTIOUS DISEASE

IDYLLA™ SYSTEM

- One step sample-to-result testing
- Unsurpassed ease of use
- Test results within 65-160 minutes
- Only 2 minutes hands-on time
- Generating actionable results with direct impact on treatment decisions

IDYLLA™ TEST MENU

Oncology: diagnostic tests for solid and liquid biopsies in colorectal cancer, lung cancer and melanoma

Infectious diseases: diagnostic tests for COVID-19[1] and sepsis[2]

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(1) The Idylla™ SARS-CoV-2 Test is a CE-marked IVD in Europe validated for the qualitative detection of SARS-CoV-2 RNA. The Idylla™ SARS-CoV-2 Test has been validated by Biocartis and is filed for Emergency Use Authorization with the FDA. The FDA's independent review of this validation is pending. The Idylla™ SARS-CoV-2 Test uses SuperScript™ III. The SuperScript™ III trademark is owned by Life Technologies Corporation. (2) SeptiCyte® RAPID is a CE-marked IVD, developed by Immunexpress Inc in collaboration with Biocartis. Biocartis has the exclusive distribution rights for the EU. The test is not available in all countries. Availability to be checked with local Biocartis representative.

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