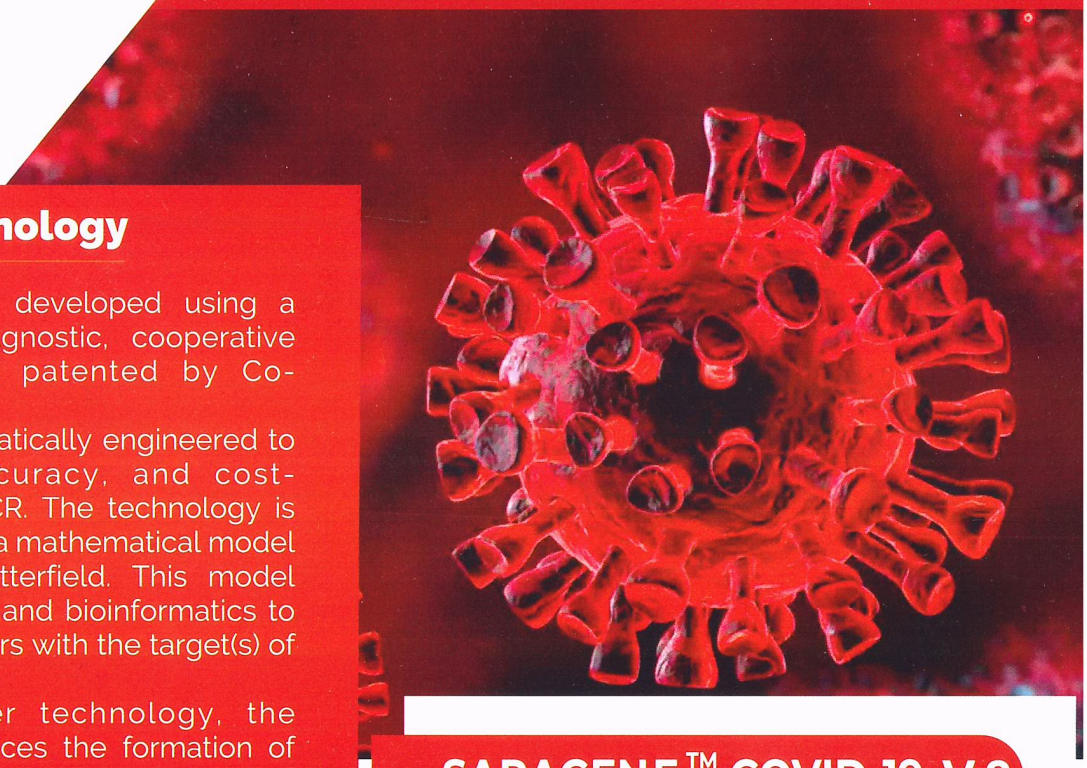
COSARA DIAGNOSTICS PVT. LTD

Joint venture between Synbiotics Ltd, India and Co-Diagnostics Inc., USA

SARAGENE™ COVID-19.V.2 Real-time PCR test



About Co-Dx™ Technology

The Coronavirus Kits were developed using a revolutionary molecular diagnostic, cooperative technology invented and patented by Co-Diagnostics, Inc.

Co-Dx technology is mathematically engineered to enhance the speed, accuracy, and cost-effectiveness of real-time PCR. The technology is based on cooperative theory, a mathematical model developed by Dr. Brent Satterfield. This model applies advanced algorithms and bioinformatics to optimize the design parameters with the target(s) of interest.

In comparison with other technology, the cooperative technology reduces the formation of primer-dimmers and increases specificity and sensitivity. For more information visit www.codiagnostics.com.

About the Kit

The SaragenеTM Coronavirus Disease Real-Time PCR Kit is available for qualitative screening of RdRp and E genes associated with infection of severe acute respiratory syndrome coronavirus type 2 (SARs-CoV-2 or COVID-19). The assay uses cooperative technology designed by CoDiagnostics, Inc (Utah, USA). The Coronavirus Disease Kits is intended to be used in molecular biology applications to detect the presence or absence of the SARs-CoV-2 virus from nasopharyngeal swab, oral swab, tracheal aspirates, sputum, bronchial lavage, or saliva. The assay is a singlestep reverse transcriptase real-time polymerase chain reaction that detects the presence of the virus through fluorescence of amplified virus. RNA extraction and real-time PCR is required to perform this test.

RNA Extraction	Assay Set-Up & Run Time	Analysis & Report
< 45 min	90 –120min	<10 min

SARAGENE™ COVID-19 .V.2

- Compatible with multiple sample types
- Contains a simple and streamlined workflow
- Includes internal control to verify sample quality
- Includes a positive control to verify master mix quality
- Produces results that are easy to interpret
- Compatible with multiple platforms & sample extraction techniques

Results within Three Hours

The Coronavirus Kits are compatible with most real-time PCR instrumentation containing green, yellow, and orange detectors. Each test can be completed from sample to report within three hours with the ability to automate any process for high throughput applications.

IVD | ICMR Approved

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Sensitive, Fast and Affordable Molecular Diagnostics

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About

SARAGENE™ COVID-19.V.2

Product Performance Characteristics

Intended Use	Qualitative real time RT-PCR test for detection of SARs-CoV-2 RdRp and E genes
Sample Type	Lower respiratory tract fluids (bronchoalveolar lavage - BAL, tracheal aspirate, and sputum), and upper respiratory tract fluids (Nasopharyngeal and oropharyngeal swabs).
User	Laboratory technician trained in molecular diagnostics procedures
Min. Sample for Extraction Inpute and Elution	200uL sample and 60uL elution
	SARAGENE™ COVID-19.V.2
Limit of Detection (copies/ uL)	3.73 copies/uL (*RdRp gene*) / 5.04 copies.uL (*E* gene)
Sensitivity	98.7%
Specificity	98.8%
Clinical Matrix used for analytical verification	Lower respiratory tract fluid (Bronchoalveolar Lavage (BAL) and sputum), upper respiratory tract fluid (Naso-pharyngeal fluid), and serum
Analytical Specificity (wet-test or in silico analysis)	**DOES NOT** cross-react with the following microorganisms: SARS-CoV, MERS-CoV, Human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1), Adeno-virus, Influenza A H3N2, Novel Influenza A H1N1, Influenza B, Influenza C, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Respiratory syncytial virus (subtype A), Respiratory syncytial virus (subtype B), Parechovirus, *Candida albicans, Corynebacterium diphtheriae,* Legionella non-pneumophila, *Bacillus anthracis, Moraxella catarrhalis, Neisseria elongata, Neisseria meningitides, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus salivarius,* Leptospirosis, *Chlamydia psittaci, Coxiella burnetii (Q-Fever), Staphylococcus epidermidis,* Enterovirus, **Rhinovirus**, *Haemophilus Influenzae, Mycobacterium tuberculosis, Bordetella parapertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, and Legionella pneumophila*
Time to detection	63-90 minutes, depending on the machine used
Thermal cycler compatibility	Green (FAM), Yellow (Cal Fluor 560), and Orange (Cal Fluor 610) channels
Thermal Cycler Compatibility tested with CoDx Box Real-Time PCR System, Magnetic Induction Cycler qPCR System (BioMolecular Systems), CFX96/384 (Bio-Rad), 7500/ QuantStudio5 (ThermoFisher).	

COVID -19 Kits

Materials Included:

- Ready-to-use Master Mix with Internal Control
- Positive Control
- Nuclease Free Water

Materials Needed to Run Kit (not included):

- Real-time PCR System and Software
- Optical PCR plates/tubes and caps/film
- Pipettes and tips

Product Name	Pack Size
SARAGENE™ COVID-19.V.2 Test Kit	100 Rx
SARAGENE™ COVID-19.V.2 Test Kit	250 Rx

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