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DIAGNOSTICS
PVT. LTD

SARAGENE™ COVID-19 IVD

Real-time PCR test

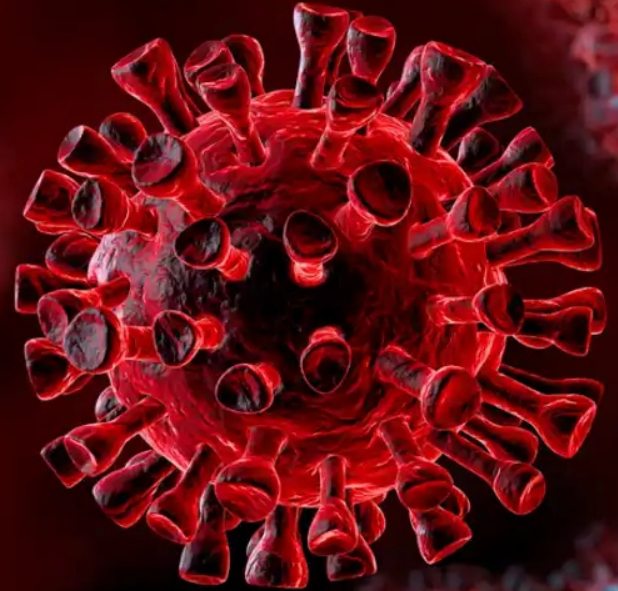
About SARAGENE™ COVID-19 Real-time PCR test

The SARAGENE™ Coronavirus Disease 2019 (COVID-19) test kit is an in vitro diagnostic test that uses patented CoPrimer™ technology for the qualitative detection of RNA from SARS-CoV-2 coronavirus (COVID-19) from lower respiratory tract specimens (e.g. bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory tract specimens (e.g. nasopharyngeal fluids, nasal swab), and serum from patients who meet the clinical criteria (e.g. signs and symptoms) for coronavirus disease 2019 (COVID-19) as established by WHO (WHO, 2020) and the US CDC (CDC, 2020) (e.g. fever, cough, shortness of breath, travel history to endemic areas).

The test kit has been tested with the QIAamp® Viral RNA Mini Extraction Kit (Qiagen) on the CoDx Box thermocycler (Bio Molecular Systems), and the Eco 48 Real Time PCR (PCRmax).

CDC. (2020, Feb 13). Coronavirus Disease 2019 (COVID-19): Evaluating and Reporting Persons Under Investigation (PUI). Retrieved Feb 19, 2020, from Centers for Disease Prevention and Control: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>

WHO. (2020). Coronavirus disease (COVID-19) technical guidance: Surveillance and case definitions. Retrieved Feb 19, 2020, from World Health organization: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/surveillance-and-case-definitions>



SARAGENE™ COVID-19

- **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**

IVD



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Sensitive, Rapid and Affordable Molecular Diagnostics
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About SARAGENE™ COVID-19

Product Performance Characteristics

Intended Use	Qualitative real time RT-PCR test for detection of gene <i>RdRp</i> of SARS-CoV-2 (COVID-19).
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
SARAGENE™ COVID-19	
Limit of Detection (copies/ml)	4290
Sensitivity†	100.00%
Specificity†	100.00%
Clinical Matrix used for analytical verification	Lower respiratory tract fluid (Bronchoalveolar Lavage (BAL) and sputum), upper respiratory tract fluid (Nasopharyngeal 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), Adenovirus, 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, <i>Candida albicans</i> , <i>Corynebacterium diphtheriae</i> , <i>Legionella non-pneumophila</i> , <i>Bacillus anthracis</i> , <i>Moraxella catarrhalis</i> , <i>Neisseria elongata</i> , <i>Neisseria meningitidis</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus salivarius</i> , <i>Leptospirosis</i> , <i>Chlamydia psittaci</i> , <i>Coxiella burnetii</i> (Q-Fever), <i>Staphylococcus epidermidis</i> , Enterovirus, Rhinovirus , <i>Haemophilus Influenzae</i> , <i>Mycobacterium tuberculosis</i> , <i>Bordetella parapertussis</i> , <i>Mycoplasma pneumoniae</i> , <i>Chlamydia pneumoniae</i> , and <i>Legionella pneumophila</i>
Time to detection	63-90 minutes, depending on the machine used
Extraction System	QIAamp Viral RNA Mini kit (QIAGEN)
Thermal cycler compatibility	CoDx Box (Bio Molecular Systems) Eco 48 (PCRmax) 2 channels: FAM and CF610 (ROX)

†Calculations are based on 360 replicates of contrived samples using synthetic SARS-CoV-2 RNA template.

Each SARAGENE™ Coronavirus Disease 2019 (COVID-19) kit includes:

- 1x500 µl (100rxns) or 1x1250 µl (250rxns) SARAGENE™ COVID-19 Master Mix
- 1x500 µl (100rxns) or 1x1250 µl (250rxns) SARAGENE™ COVID-19 Positive Control
- 1x500 µl (100rxns) or 1x1250 µl (250rxns) Nuclease Free Water

Product Name	Product ID
Co-DX Box™ Thermocycler	Request Quote
SARAGENE™ Coronavirus Disease 2019 (COVID-19) IVD kit 100 rxns	COVID-K-100I
SARAGENE™ Coronavirus Disease 2019 (COVID-19) IVD kit 250 rxns	COVID-K-250I

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