

CE-IVD Marked

 Allplex™

SARS-CoV-2 Assay

Detection and identification of 4 target genes for SARS-CoV-2
using multiplex real-time PCR

N gene / S gene / RdRP gene / E gene

World's 1st technology

Individual Ct value of multiple analytes in a single channel



HIGH SENSITIVITY & SPECIFICITY

Multiplex real-time PCR with high sensitivity and specificity by
Seegene's innovative proprietary technologies

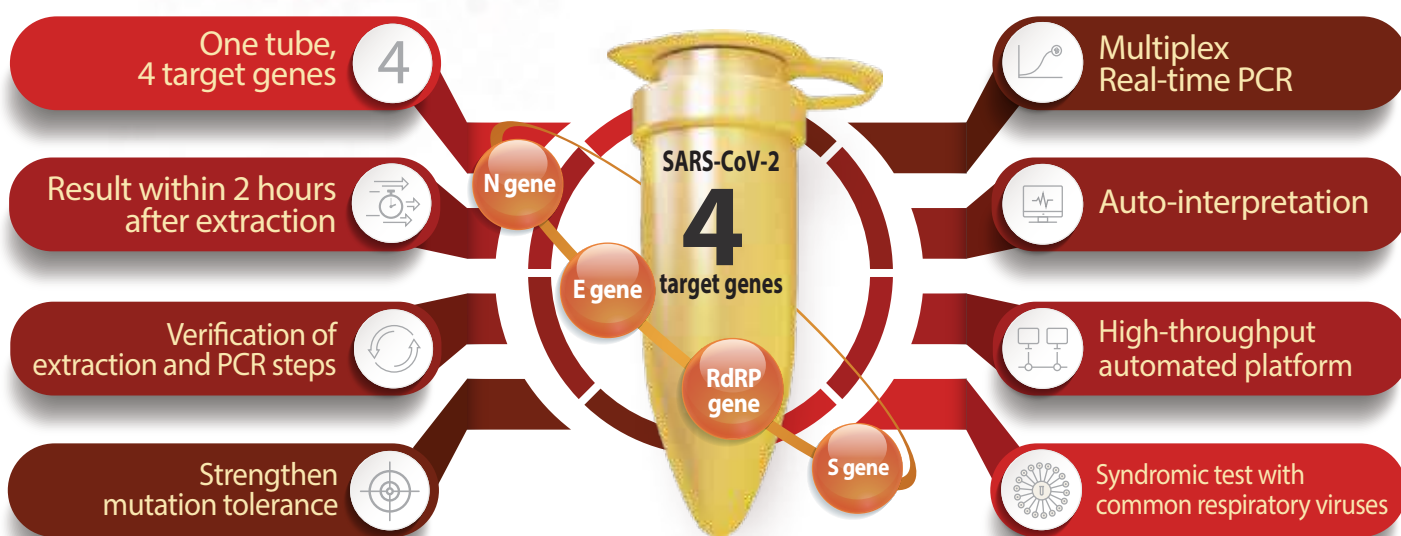
 Seegene



Allplex™ SARS-CoV-2 Assay

Detection and identification of 4 target genes for SARS-CoV-2 using multiplex real-time PCR

Allplex™ SARS-CoV-2 Assay is a multiplex real-time PCR assay to detect 4 target genes of SARS-CoV-2, a virus causing COVID-19 in a single tube. The assay is designed to detect RdRP, S and N genes specific for SARS-CoV-2, and E gene for all of *Sarbecovirus* including SARS-CoV-2. It can be applied on Seegene's automated system that enables high throughput testing.



Analytes

- N gene
- S gene
- RdRP gene
- E gene
- Internal Control (IC)

* S gene and RdRP gene are both detected in 1 signal.

Specimens

- Nasopharyngeal aspirate
- Nasopharyngeal swab*
- Bronchoalveolar lavage
- Oropharyngeal (throat) swab*
- Sputum
- Combo swab
- Saliva*

* Validated with extraction-free method

Compatible Instrumentation (CE-IVD Marked)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> - Automated Extraction & PCR Setup
Seegene NIMBUS
Seegene STARlet - Real-time PCR
CFX96™ Dx
Applied Biosystems™ 7500 | <ul style="list-style-type: none"> - Automated Extraction
NucliSENS® easyMAG®
SEEPREP32™
Maelstrom™ 9600
MagNA Pure 96
KingFisher™ Flex |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Syndromic test for detecting SARS-CoV-2 and common respiratory viruses

Allplex™ SARS-CoV-2 Assay enables a combination test with Allplex™ RV Essential Assay, including influenza A and B, metapneumovirus, parainfluenza virus 1/2/3/4, adenovirus A/B/C/D/E, rhinovirus A/B/C and respiratory syncytial virus A/B, to provide more insights for diagnosis of symptomatic patients.

Key Features and Benefits

High Accuracy

- Detecting 4 target genes of SARS-CoV-2 to complement genetic variation
- Targeting the conserved region in SARS-CoV-2 with low mutation frequencies

High Sensitivity and Specificity

- Limit of detection (LoD): 50 copies per reaction
- No cross-reactivity confirmed with 54 respiratory pathogens including SARS, MERS and SARS-related viruses

Test Quality Control

- Entire process verification from extraction to PCR using a whole process control
- Validation of the quality of the SARS-CoV-2 test with reference materials

High-Throughput Test

- High throughput test with Seegene's automated platform
- Results within 2 hours after nucleic acid extraction

Streamlined Automated System



Automated extraction & PCR setup
Seegene STARlet or NIMBUS

Real-time PCR
CFX96™ Dx

Automated interpretation
Seegene Viewer



- ✓ Variant trend monitoring
- ✓ Visual analytics of associated variants
- ✓ In-depth variant analysis



Web-based statistical data analysis
SG STATS

Convenient Data Interpretation by Seegene Viewer

The example of the positive result for E gene, RdRP/S gene and N gene of SARS-CoV-2



The result represents the positive result for E gene of *Sarbecovirus*, RdRP/S gene and N gene of SARS-CoV-2 in FAM, Cal Red 610 and Quasar 670 channel, respectively.

Seegene Viewer

Automated Interpretation S/W

Optimal software for simultaneous multiplex test data analysis

- a. Interface specialized for multiplex testing
- b. Interlocked with LIS
- c. Patient information input via barcode scanning system or LIS

Kick your Real-time PCR up a notch !

With Seegene's core technologies and proprietary know-hows, enhance your MDx products with incomparable performance and usability.



Oligo Design

Oligo design technology for high multiplex PCR: SG-Insilico™

Enables rapid designing of high multiplex oligos using Seegene-developed algorithms and confidential variables



Amplification

Highly specific amplification technology for high multiplex PCR: DPO™

Allows the implementation of high multiplex diagnostics with unparalleled specificity using Seegene's unique primer structure



Target Detection

High multiplex target detection technology: TOCE™

Achieves accurate target signals by independently controlling multiple target signals for primer and probe annealing temperatures



Quantitative Detection

High multiplex target detection & quantification technology: MuDT™

Broadens capacity for high multiplex target detection & quantification by enabling analysis of multiple Ct values in a single detection channel



Interpretation

High multiplex signal processing technology: DSP™

Enables accurate reporting of target's positive or negative results through Seegene's proprietary signal processing algorithms

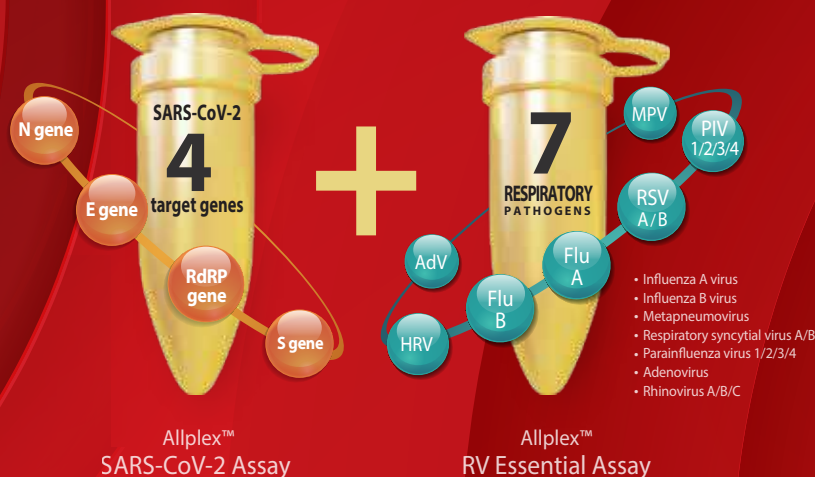
Ordering Information

Product	Volume	Cat. No.
Allplex™ SARS-CoV-2 Assay	50 rxns	RV10247Y
	100 rxns*	RV10248X
Allplex™ RV Essential Assay	50 rxns	RV9750Y
	100 rxns*	RV9750X
Instrument		Cat. No.
CFX96™ Dx (2 modules)		1845097-IVD & 1841000-IVD
Seegene NIMBUS		65415-03
Seegene STARlet		67930-03
SEEPREP32™		SG71100
Maelstrom™ 9600		M9600
STARMag 96 X 4 Universal Cartridge kit*		744300-4UC384
STARMag 96 x 4 Viral DNA/RNA 200 C kit*		EX00013C
STARMag 96 ProPrep (Plate type)**		EX00009P
STARMag 96 ProPrep (Tube type)**		EX00009T
STARMag 96 ProPrep C (Plate type)**		EX00017P
STARMag 96 ProPrep C (Tube type)**		EX00017T
TANBEAD® Nucleic Acid Extraction kit***		W665566
OptiPure Viral Auto Tube		W665A46
OptiPure Viral Auto Plate		W665A10

* For use with Seegene NIMBUS and Seegene STARlet only. ** For use with SEEPREP32™
*** For use with Maelstrom™ 9600

Not Available for Sale in the United States

Complete solution for respiratory infection management



• Syndromic test

The co-testing with Allplex™ SARS-CoV-2 Assay and Allplex™ RV Essential Assay helps clinicians make better decision for patient care and treatment especially during and/or after the outbreaks of certain viruses.

• Flexible multiplex test

from single targeted SARS-CoV-2 test to combination targeted test of other common respiratory viruses on one integrated platform

• Maximized efficiency

with convenient workflow and automated data interpretation



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