

CE-IVD Marked

 Allplex™

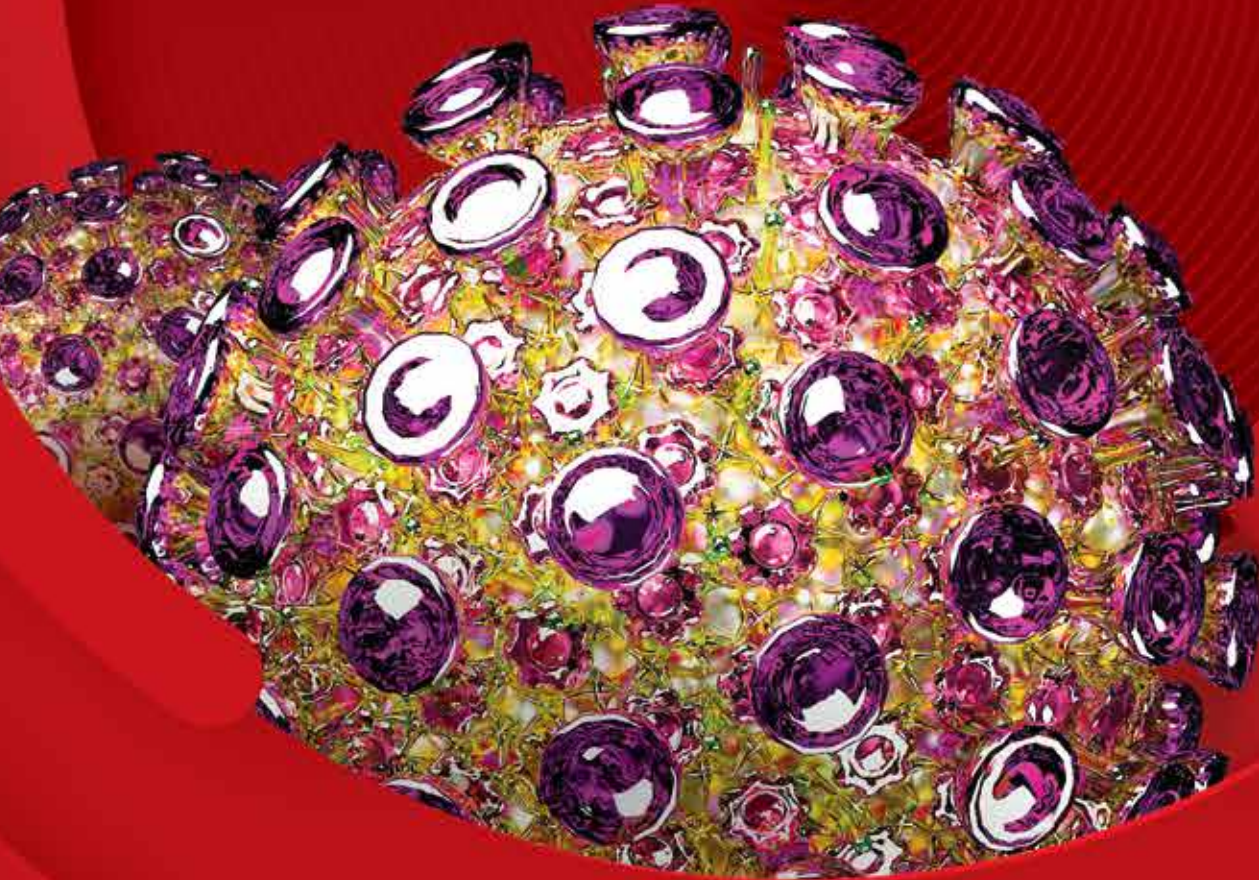
# SARS-CoV-2 Assay

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 analyte in a single channel



**HIGH SENSITIVITY & SPECIFICITY**

Multiplex real-time PCR with high sensitivity and specificity by utilization of DPO™ and TOCE™ technologies

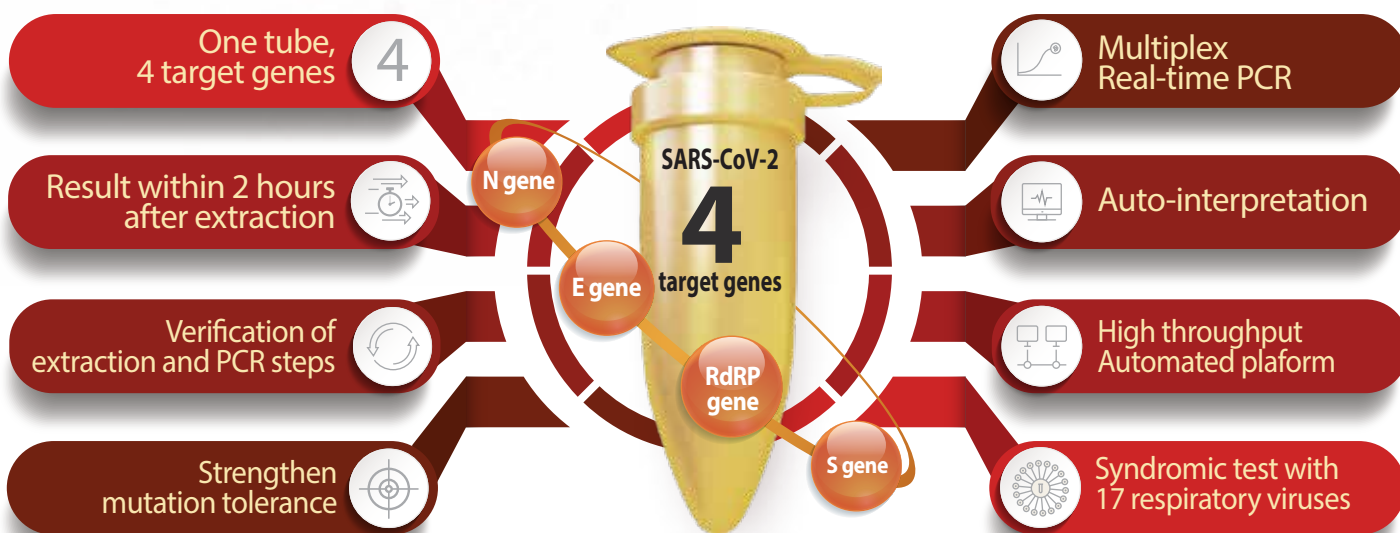
 **Seegene**



# 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 detected in 1 signal.

## Specimens

- Nasopharyngeal swab
- Nasopharyngeal aspirate
- Throat swab
- Bronchoalveolar lavage
- Sputum

## Compatible Instrumentation (CE-IVD Marked)

- |   |   |  |
|---|---|--|
| - Automated Extraction & PCR Setup<br>Seegene NIMBUS<br>Seegene STARlet | - Automated Extraction<br>NucliSENS® easyMAG®<br>SEEPREP32™ | - Real-time PCR<br>CFX96™ Dx<br>Applied Biosystems™ 7500 |
|---|---|--|

*Syndromic test for detecting SARS-CoV-2 and 17 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

### 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

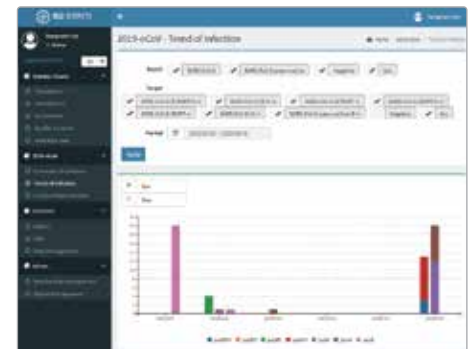
## Seegene's automated platform



### SG STATS

#### Web-based statistical data analysis platform

Provides frequency of 4 different target genes of SARS-CoV-2



## Result of Allplex™ SARS-CoV-2 Assay



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.

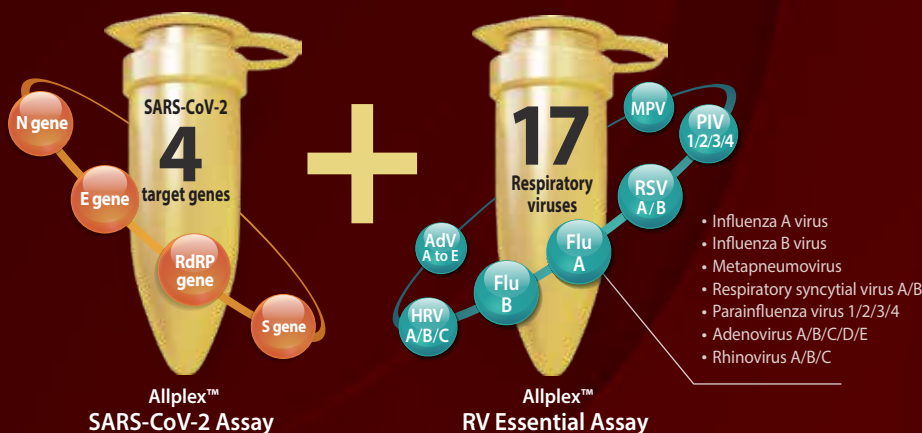
### Seegene Viewer

#### Automated interpretation S/W

Optimal software for simultaneous multiplex test data analysis

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

# 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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## Ordering Information

Category	Product	Package 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	Type	Cat. No.
CFX96™ Dx	Real-time PCR _ Optical Reaction Module	1845097-IVD
	Real-time PCR _ Thermal Cycler	1841000-IVD
Seegene NIMBUS	Automated extraction & PCR Setup	65415-03
Seegene STARlet	Automated extraction & PCR Setup	67930-03
SEEPREP32™	Automated extraction	SG71100
STARMag 96 X 4 Universal Cartridge kit*	Nucleic acids extraction reagent	744300.4UC384
STARMag 96 X 4 Universal plus Cartridge kit*	Nucleic acids extraction reagent	EX00006C
STARMag 96 ProPrep**	Nucleic acids extraction reagent	EX00009P
		EX00009T
STARMag 96 ProPrep plus**	Nucleic acids extraction reagent	EX00010P
		EX00010T

\* For use with Seegene NIMBUS and Seegene STARlet only, \*\* For use with SEEPREP32™