Seegene

Why Screening and Identification of SARS-CoV-2 and Variants?

Concerns about the impact of the SARS-CoV-2 variants

While the world continues to fight with the SARS-CoV-2 crisis, the virus has evolved, and many new variants have emerged around the world in the past few months. And these SARS-CoV-2 variants have raised great concerns about the effect on infectivity, disease severity, and vaccine efficacy.

Therefore, **US-CDC (Centers for Disease Control and Prevention) classified the most reported SARS-CoV-2 variants for the surveillance.**[1)]

Monitor — Variant of Interest | **Variant of Conern** | Variant of High Consequence (no report) — Serious

Variant of Concern (VOC)

* Seegene products' targets

Pango lineage	First reported	Key mutations (S proteins)
B.1.1.7	United Kingdom	**HV69/70 del, Y144 del, N501Y, P681H,** A570D, D614G
P.1	Japan/Brazil	**K417T, E484K, N501Y,** D614G
B.1.351	South Africa	**K417N, E484K, N501Y,** D614G
B.1.427, B.1.429	US-Califonia	S13I, **W152C, L452R,** D614G

What are classified as VOC?

Variants that reported

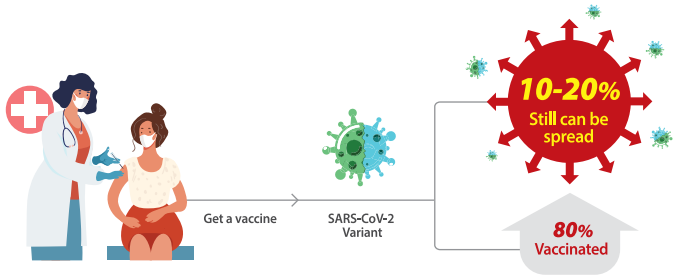
- ↑ Transmissibility
- ↑ Illness severity (Hospitalization or death)
- ↓ Effectiveness of treatments or vaccines
- ↓ Neutralization by antibodies
- Diagnostic failure

Detection of SARS-CoV-2 variants is necessary for continuous surveillance

In particular, there are many reports that these SARS-CoV-2 variants can affect the vaccine efficacy and still require accurate testing, contrary to expectations that we will be all free after vaccination.[2)]

Efficacy of COVID-19 vaccine

Manufacture	SARS-CoV-2	Variants of SARS-CoV-2	
		B.1.1.7	B.1.351
O / A (Viral)	82.4%	Decreased (74.6%)	Unknown
N (Protein)	95.6%	Decreased (85.6%)	Decreased (60%)
J & J (Viral)	72%	Unknown	Decreased (57%)



Seegene SARS-CoV-2 Variants Products

Full Screening of SARS-CoV-2 and Variants

- SARS-CoV-2 Master Assay

Identification of Variants of Concerns

- SARS-CoV-2 Variants Ⅰ Assay
- SARS-CoV-2 Variants Ⅱ Assay*

*Upcoming

"Seegene's multiplex real-time PCR assays are able to screen and/or identify the most reported and concerned SARS-CoV-2 variants at once."

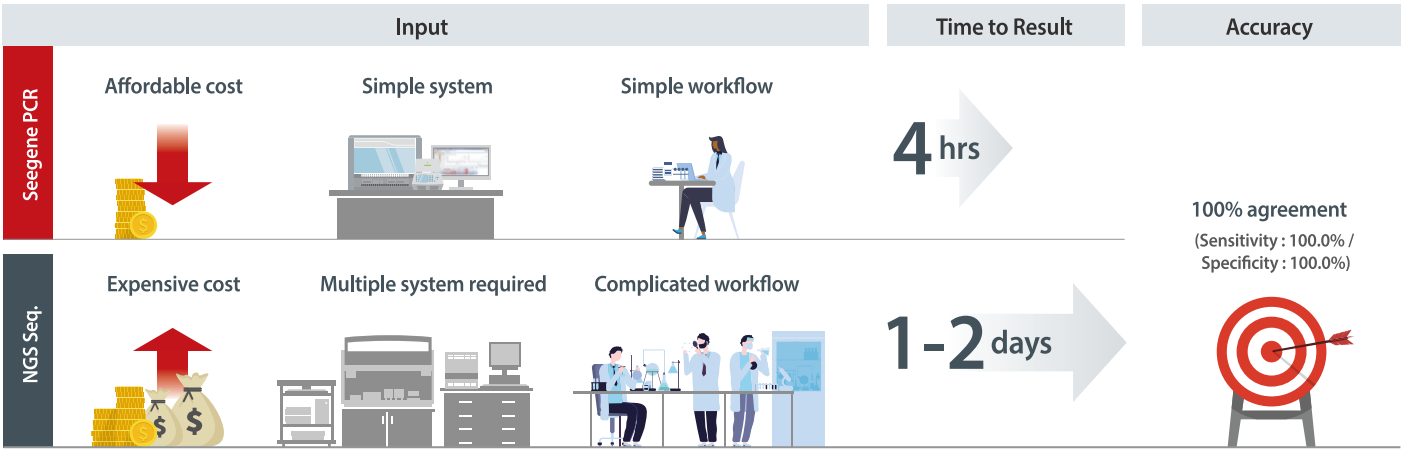
Why Seegene?

Seegene Provides the Best Solution for SARS-CoV-2 and Variants

Full Screening and/or Identification of SARS-CoV-2 and Variants with 1 tube

Seegene PCR products	VS	Other PCR products
1st Screening Potential Infected People Detection and Discrimination of SARS-CoV-2 and/or the variants infections SARS-CoV-2 Variants		Potential Infected People **1st Screening** Positive Detection of SARS-CoV-2 infections, No information on variants infections
2nd Identification ID test ONLY for **whom detected as variants infection** Variants **1 Tube** Identification of all three most reported mutations		Positive Variants **2nd Identification** ID test for all positive patients **Multi Tubes** Discrimination and identification of each SARS-CoV-2 variant

Strengths to variants detecting vs Sequencing[3) 4)]



Most efficient method of detecting SARS-CoV-2 and variants[5) 6)]

Seegene PCR	Detection Method for SARS-CoV-2	Rapid Test
O	Gold Standard	X
O	Variants Discrimination	X
High	Accuracy	Mid to low
Up to 94 Samples (96 plate)	Throughtput	Only 1 Sample (Cartridge)
4 hrs	TAT	< 1 hr

Seegene's Complete Variant Surveillance Solution

Seegene

Full Screening of SARS-CoV-2 and Variants at Once

CE-IVD Marked

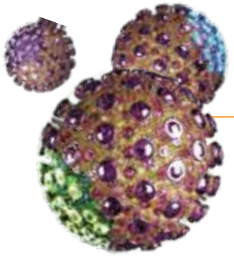
- E gene
- RdRP/S gene
- N gene
- HV69/70 deletion
- Y144 deletion
- E484K
- N501Y
- P681H

Allplex™ SARS-CoV-2 Master Assay

Screening of four SARS-CoV-2 targets and five notable mutations in S gene in one signal

Identification of the Most Concerned SARS-CoV-2 Variants

CE-IVD Marked



- RdRP gene
- HV69/70 deletion
- E484K
- N501Y

Allplex™ SARS-CoV-2 Variants I Assay

CE-IVD In progress

- W152C
- K417N
- K417T
- L452R

Allplex™ SARS-CoV-2 Variants II Assay*

Identification of multiple spike mutations in S gene that have reported spreads across borders

Specimens : - Nasopharyngeal swab - Nasopharyngeal aspirate - Sputum - Bronchoalveolar lavage - Oropharyngeal swab - Saliva

*Upcoming

Variants surveillance
Implements variants surveillance for efficient infection control

Multiplex real-time PCR
Detects and identifies simultaneously using multiplex real-time PCR

Individual Ct value
Provides individual Ct value of multiple targets

Whole process verification
Verifies whole process including validation of correct sampling with an endogenous internal control

Automated platform
Runs on a streamlined automated platform for high-throughput testing

Reliable test result
Provides reliable test result by minimizing false-negative results

Seegene's All-in-One Automated Platform

Automated extraction & PCR setup	Real-time PCR	Automated interpretation	Web-based statistical data analysis
Seegene STARlet or NIMBUS	CFX96™ Dx	Seegene Viewer	SG STATS

Kick your Real-time PCR up a notch !

With Seegene's core proprietary technology and expertise, 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 Master Assay	100 rxns*	RV10284X
	50 rxns	RV10285Y
Allplex™ SARS-CoV-2 Variants I Assay	100 rxns*	RV10286X
	50 rxns	RV10287Y
Allplex™ SARS-CoV-2 Variants II Assay	100 rxns*	RV10305X
	50 rxns	RV10306Y

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*	744300.4.UC384
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***	
OptiPure Viral Auto Tube	W665566
OptiPure Viral Bulk Plate	W665A10
SGRespi™ Pure (Plate type)***	EX00023P
SGRespi™ Pure (Plate type)***	EX00024P
SGRespi™ Pure (Tube type)***	EX00025T

* 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

VARI-EN210427F-01

References

1) https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html#Concern
2) Mahase E. Covid-19: Where are we on vaccines and variants? BMJ (2021)
3) Christensen KD, et al. Cost Analyses of Genomic Sequencing: Lessons Learned from the MedSeq Project. Value Health (2018)
4) Mohammad Ilyas. Next-Generation Sequencing in Diagnostic Pathology. Pathobiology (2017);84:292–305
5) Bhavesh D. Kevadiya, Jatin Machhi et al. Diagnostics for SARS-CoV-2 infections. Nature Materials (2021)
6) https://www.ssi.dk/aktuelt/nyheder/2021/antigentest-gav-47-falsk-negative-svar

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