

# Seegene Solution for emerging COVID-19 Variants

Ver. 1.1

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## COVID-19 variants Alerts in the globe

- Health authorities warn the spread of three virus variants (VOC 202012/01, 501Y.V2, and P.1)
- The transmissibility of these variants is significantly higher than SARS-CoV-2 previously circulating
- In turn, it leads to higher hospitalization and mortality across all age, especially in older or with comorbidities
- At this stage, it is uncertain and no clinical data on their severity or vaccine match/effectiveness

➔ The risk of variants is assessed as **HIGH/VERY HIGH**

### Summary of variants

Variant information		VOC 202012/01	501Y.V2	501Y.V3
Country first reported		United Kingdom (UK)	South Africa (SA)	Japan (Brazilian traveler)
Nomenclature	GISAID clade	GR	GH	GR
	PANGOLIN lineage	B.1.1.7	B.1.351	P.1
No. Spike (S) gene mutation sites		9	10	12

- Above variants are quickly spreading out all around the world
- They are more likely to become the dominant type

Reference.

<https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html>

<https://www.medicaldevice-network.com/features/covid-19-variant-tests/>



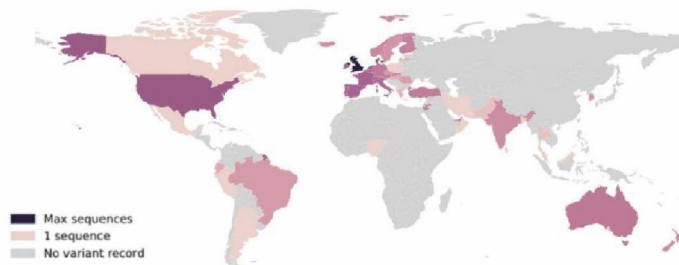
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## Global distribution of Variant\_VOC 202012/01 (UK)

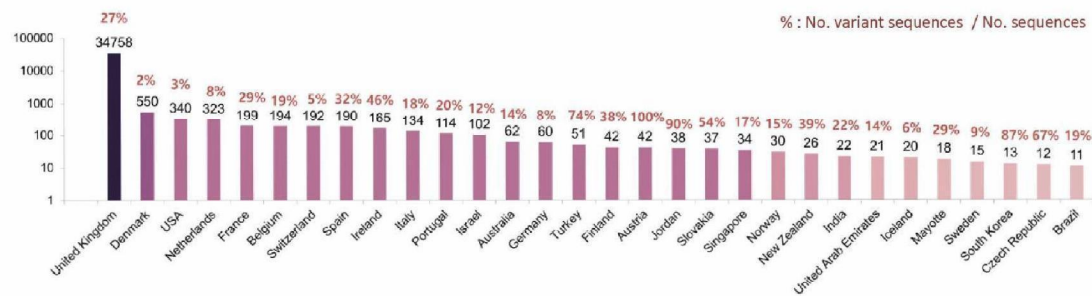
- Found in 73 countries
- Increase transmissibility
- Not related with the severity of disease or vaccine efficacy

As of Jan. 31, 2021

VOC 202012/01 (UK) map



VOC 202012/01 (UK) counts



References.

[https://cov-lineages.org/global\\_report\\_B.1.351.html](https://cov-lineages.org/global_report_B.1.351.html)

<https://virological.org/t/transmission-of-sars-cov-2-lineage-b-1-1-7-in-england-insights-from-linking-epidemiological-and-genetic-data/576>

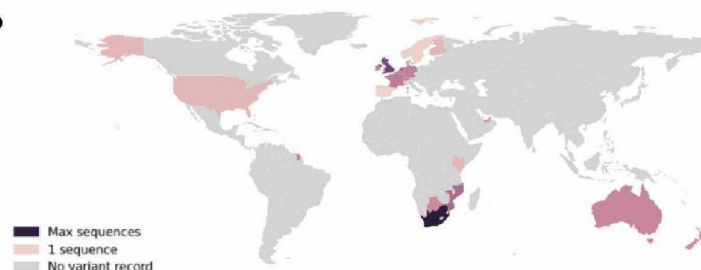


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## Global distribution of Variant\_501Y.V2 (SA)

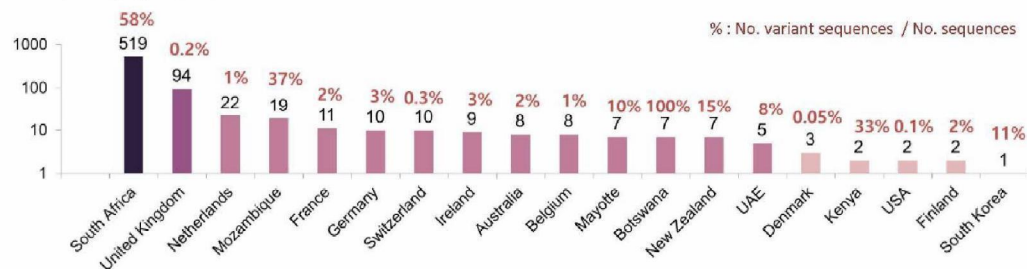
- Found in 31 countries
- Contain the multiple mutation (K417N, E484K, and N501Y) within the receptor-binding domain (RBD) of the S (spike) gene
- Some evidence on affecting antibody neutralization, leading to “evading immunity”

501Y.V2 (SA) map



As of Jan. 31, 2021

501Y.V2 (SA) counts



References.

[https://cov-lineages.org/global\\_report\\_B.1.351.html](https://cov-lineages.org/global_report_B.1.351.html)

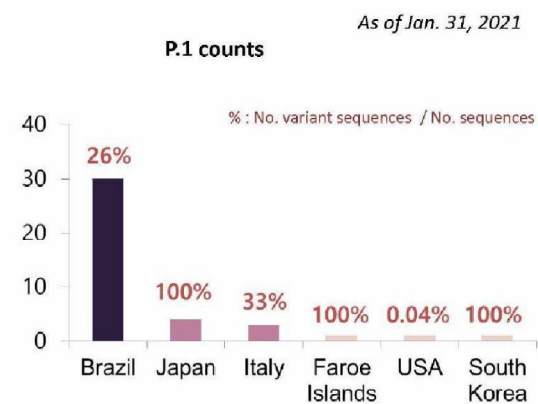
<https://virological.org/t/transmission-of-sars-cov-2-lineage-b-1-1-7-in-england-insights-from-linking-epidemiological-and-genetic-data/576>



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## Global distribution of Variant\_P.1

- Found in 9 countries
- Has the multiple mutation (K417T, E484K, and N501Y) within the receptor-binding domain (RBD) of the S (spike) gene
- Affect transmissibility and antibody-neutralization



References.  
[https://cov-lineages.org/global\\_report\\_P.1.html](https://cov-lineages.org/global_report_P.1.html)

## Allplex™ SARS-CoV-2 Variants I Assay

- Detect and Differentiate SARS-CoV-2 variants first reported from England, South Africa, and Japan
- Pre-screen new or existing SARS-CoV-2 variant/strain

<b>Specification</b>	Targets	FAM	S_E484K	
		HEX	RdRP	
		Cal 610	S_N501Y	
		Q 670	Endogenous IC	
		Q 705	S_HV69/70 deletion	
	PCR Turn around time	1 hr 55 min		
	Validated specimens	Nasopharyngeal swab, Nasopharyngeal aspirate, Oropharyngeal swab, BAL, Sputum		
	Validated system	Extraction	Seegene STARlet, Seegene NIMBUS, Seeprep32	
		Cycler	CFX96 IVD, CFX96 Dx	
Regulation	RUO & CE-IVD			

## Unique Feature I : Cutting-Edge technology

- Seegene's core technologies have been applied to the development of COVID-19 multiple variants assay
    - mTOCE : Able to detect multiple mutation sites
    - DPO : Able to increase the specificity of primer
    - AI-based *in silico* development : Able to monitor sequences of COVID-19 DB and design optimized diagnostic assay based on the proprietary algorithm by AI
    - And 7 more core technologies applied
- ➔ Accurate detection and differentiation three point mutations in S (Spike) gene and highly conserved region in RdRP gene in a single reaction

All in a tube

Mutation site in S gene	Major variant	Allplex SARS-CoV-2 variants I assay
HV 69/70 deletion	VOC 202012/01	Covered and distinguish ALL
E484K	501Y.V2 P.1	
N501Y	VOC 202012/01 501Y.V2 P.1	

## Unique Feature II : Identifying and pre-screening variant/strain

Key features

1. Qualitative detection of SARS-CoV-2
  2. Precisely identification of two mutation sites (i.e., N501Y, HV69/70 deletion) found in VOC 202012/01
  3. Accurately characterization of two mutation sites (i.e., N501Y, E484K) found in 501Y.V2
  4. Pre-screen a new variant or other strains
- Provide insight and qualified information for surveillance program in each country

The example of interpretation

Targets	Case 1	Case 2	Case 3			
S_HV69/70 deletion	POS	-	-	-	POS	POS
S_E484K	-	POS	POS	-	POS	POS
S_N501Y	POS	POS	-	POS	-	POS
<b>Interpretation</b>	<b>Variant detected</b>	<b>Variant detected</b>	<b>A new variant or existing strain detected</b>			
<b>Type</b>	A variant with HV69/70 and N501Y found in VOC 202012/01 (UK)	A variant with E484K and N501Y found in 501Y.V2 (SA**) and P.1 (Japan)	Unknown variant/strain → Sequencing for further analysis → Report to surveillance system			

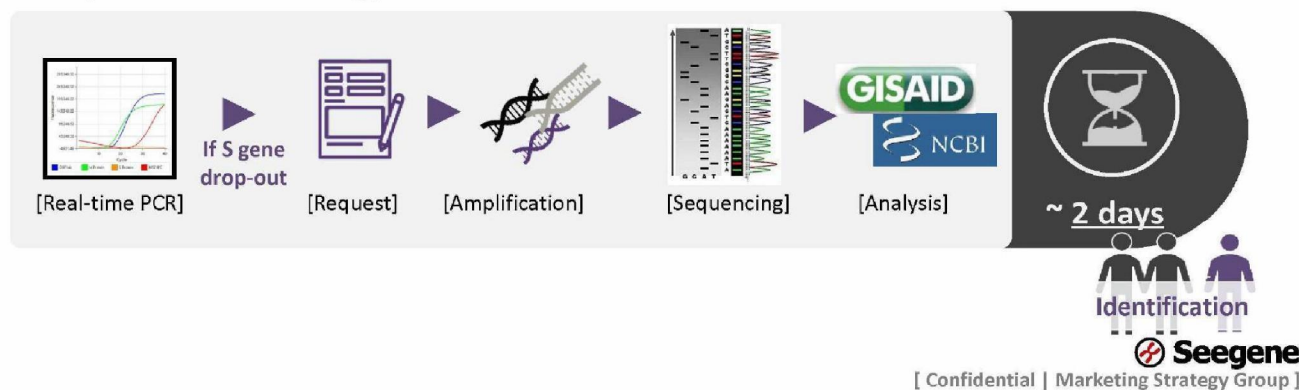
## Unique Feature III : Time saving through mass screening

- Mass scaled analysis to filter out variants from COVID-19 positive cases
- Simplify a process to provide results in a half day
- Save time and cost through no need for further analysis

### Seegene's solution



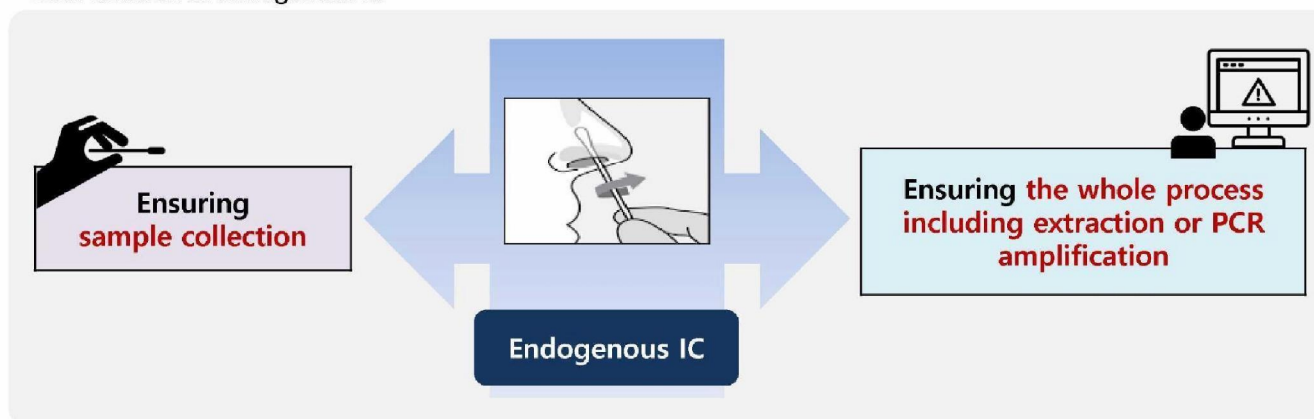
### Competitors' time-consuming process



## Unique Feature IV : Endogenous internal control (IC)

- Monitor any trouble or mistake in a workflow
  - Prevent false negative due to insufficient sampling or sampling error
- Verifying the ENTIRE process

Dual function of endogenous IC



## Unique Feature V : Gold standard for SARS-CoV-2 diagnosis

- According to the UK PHE (public health England), popular commercial rapid antigen tests (RAT) below can detect VOC 202012/01 (UK) variant
- However, they all target the Nucleocapsid (N) protein, which means that their performance is not able to distinguish any variants generated by mutated in the Spike (S) protein

RAT Manufacturer	Target	The ability of COVID-19 variant differentiation
Abbott Panbio	Nucleocapsid (N) protein	No
Fortress		
Innova		
Roche / SD Biosensor		
Surescreen		
SEEGENE	3 mutation sites in Spike (S) gene	YES
	RdRP gene	

Reference.

<https://www.gov.uk/government/publications/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201>



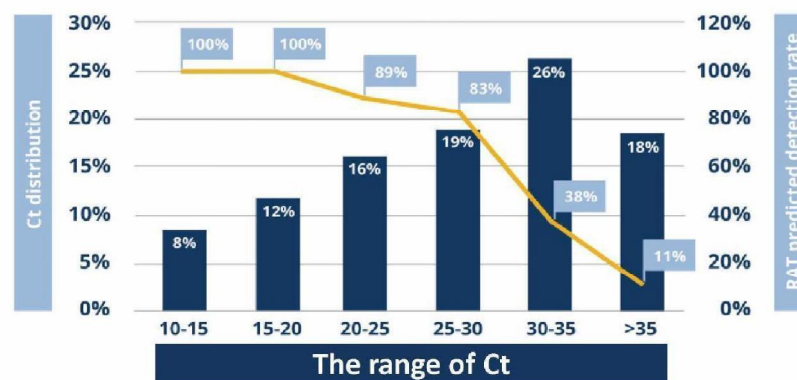
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## Unique Feature VI : Gold standard for SARS-CoV-2 diagnosis

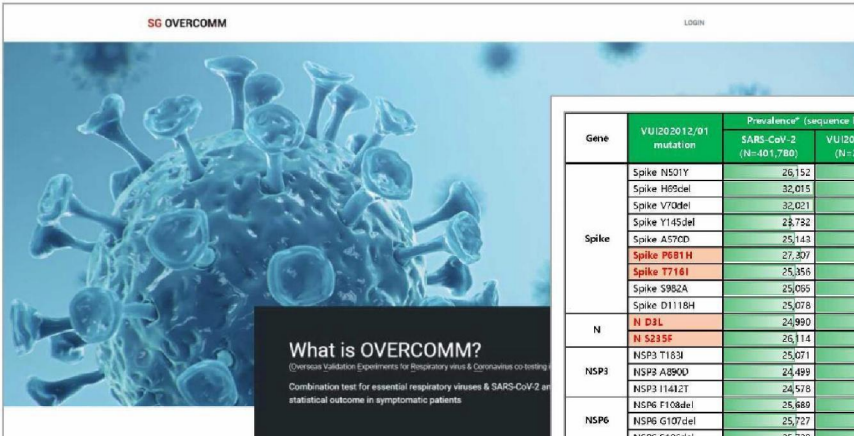
- The Real-Time PCR is considered as a gold standard because of the most accurate and reliable methods for SARS-CoV-2
- The rapid antigen tests (RAT) are getting popular in the supply chain limitation, but low sensitivity may cause severe results and loss in your community, typically in emerging various variants era

The high risk of false positive of RAT in Ct dependent manner



Reference.  
SYNLAB\_data\_on\_Rapid\_Antigen\_Tests\_Press\_Release\_201125\_(Germany)

## Unique Feature VI : Web-based sharing on variants



**What is OVERCOMM?**  
Overseas Validation Experiments for Respiratory viruses & Coronavirus co-binding  
 Combination test for essential respiratory viruses & SARS-CoV-2 at statistical outcome in asymptomatic patients

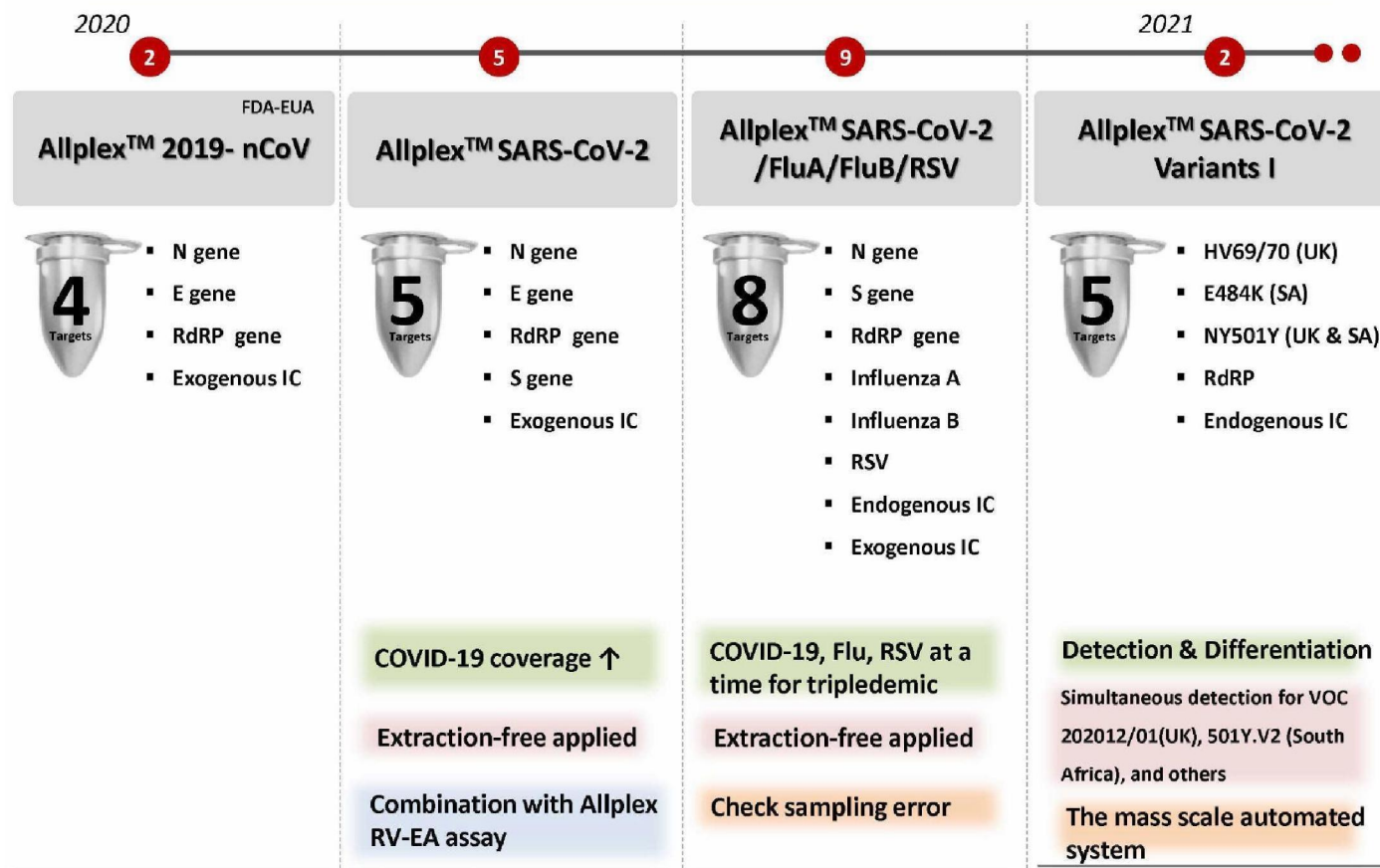
Gene	VUI202012/01 mutation	Prevalence* (sequence based)	
		SARS-CoV-2 (N=401,780)	VUI202012/01 (N=23,087)
Spike	Spike NS01Y	26,152	23,087
	Spike H95del	32,015	23,087
	Spike V70del	32,021	23,085
	Spike Y145del	28,732	23,087
	Spike A570D	25,148	23,087
	Spike P681H	27,307	23,065
	Spike T716I	25,355	23,073
	Spike S962A	25,065	23,011
N	Spike D1118H	25,078	23,013
	N D3L	24,990	22,900
NSP3	N S235F	26,114	22,993
	NSP3 T183I	25,071	22,731
	NSP3 A890D	24,499	22,488
NSP6	NSP3 I1442I	24,578	22,563
	NSP6 F108del	25,680	23,039
	NSP6 G107del	25,727	23,038
NS8	NSP6 S106del	25,729	23,041
	NS8 Q27stop	24,786	22,475
	NS8 R52	24,629	22,476
	NS8 Y73C	25,073	22,989

Gene	S01Y.V2 mutation	Prevalence* (sequence based)	
		SARS-CoV-2 (N=401,781)	S01Y.V2 (N=500)
Spike	Spike NS01Y	26,152	500
	Spike L18F	37,845	139
	Spike E484K	871	500
	Spike K417N	545	500
	Spike D60A	522	464
	Spike D215G	494	375
	Spike L242del	533	465
	Spike L243del	587	465
	Spike L244del	500	465
	Spike A701V	999	499
	Spike R246I	101	86
	E	E D71L	815
N	N T205I	4,305	500
NSP2	NSP2 T65I	56,299	497
NSP3	NSP3 K837N	1,164	493
NSP5	NSP5 K90R	5,389	499
NS3	NS3 Q57H	85,392	477
	NS3 S171L	1,942	413

### Regular analysis of SARS-CoV-2 database

- Providing information on a webpage (<https://overcomm.seegene.com/>)
- Fluctuation rate of the major mutation
- Status of product coverage for emerging mutations

## Unique Feature VII : Streamlined COVID-19 product portfolio



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THANK YOU

