A1 LIFE SCIENCES

DIAGNOVITAL

Diagnovital SARS-CoV-2 Mutation Detection Assays (RUO)

Knowing Matters
Get the Results You Need, Today

At the end of 2019, a novel coronavirus was identified as the cause of a cluster of pneumonia cases in Wuhan, a city in the Hubei Province of China. SARS-CoV-2, causing the Coronovirus disease 2019 (COVID-19), rapidly spread, resulting in an epidemic throughout China, followed by a global pandemic.

The continuous evolution of SARS-CoV-2 and accumulation of critical mutations has lead to emergence of variants of concern and variants of interest. Because these mutations can confer selective advantages, SARS-CoV-2 variants are rapidly becoming the most widespread strains[1,2].

In particular, SARS-CoV-2 mutations can cause neutralizing antibody escape and increased transmissibility.

SARS-CoV-2 Mutations and Variants

Since the beginning of the pandemic, SARS-CoV-2 has continued to mutate, resulting in genetic variations in the population of circulating strains of the virus. A new variant of SARS-CoV-2 may have one or more mutations that differentiate it from the predominant virus variants already circulating in the population. Table 1 shows the major mutations in the Spike protein for the known Variants of Concern (VOC), Variants of Interest (VOI) and other variants.

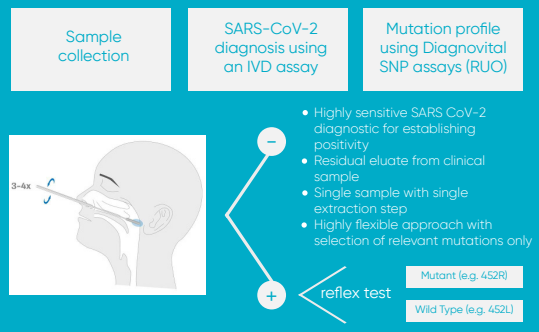
Table 1. Mutation profiles for Variants of Concern, Variants of Interest and other variants

	Variants of Concern*				Variants of Interest*		Other Variants						
Country first identified	UK	ZA	BRA	Indian	Peru	Colombia	Indian	BRA	Philippines	USA (Cal)	Indian	USA (NY)	UK
WHO label	Alpha	Beta	Gamma	Delta	Lambda	Mu		Zeta	Theta	Epsilon	Kappa	Iota	Eta
Lineage (Pango)	B1.1.7	B.1.351	P.1 / B.1.1.28.1	B.1.617.2	C.37	B.1.621	B.1.617.3	P.2/ B.1.1.28.2	P.3	B.1.427/ 429	B.1.617.1	B.1.526	B.1.525
Major amino acid substitutions in Spike protein: HV69/70del	x												x
K417N		x											
L452R				x			x			x	x		
E484K		x	x			x		x	x			x	x
E484Q							x				x		
N501Y	x	x	x			x			x				
P681H	x					x			x				
P681R				x			x				x		
L452Q					x								
T478K				x									
K417T			x										

References
1: Jiang C, Li X, Ge C, Ding Y, Zhang T, Cao S, Meng L, Lu S. Molecular detection of SARS-CoV-2 being challenged by virus variation and asymptomatic infection. J Pharm Anal. 2021 Jun;11(3):257-264. doi: 10.1016/j.jpha.2021.03.006.
2: Weisblum Y, Schmidt F, Zhang F, DaSilva J, Poston D, Lorenzi JC, Muecksch F, Rutkowska M, Hoffmann HH, Michailidis E, Gaebler C, Agudelo M, Cho A, Wang Z, Gazumyan A, Cipolla M, Luchsinger L, Hillyer CD, Caskey M, Robbiani DF, Rice CM, Nussenzweig MC, Hatziioannou T, Bieniasz PD. Escape from neutralizing antibodies by SARS-CoV-2 spike protein variants. Elife. 2020 Oct 28;9:e61312. doi: 10.7554/eLife.61312.
*https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/

A1 Life Sciences Solution for Detection of SARS-CoV-2 Mutations and Identification of Variants

Figure 1. Detection of SARS-CoV-2 mutations using reflex testing approach



DIAGNOVITAL SARS CoV 2 Mutation Detection kits (RUO) are designed to be used as a reflex test that detects both mutant and wild type alleles using residual eluates from samples that have previously been shown to be SARS-CoV-2 positive (Figure 1).

A1 Life Sciences solution for detection of SARS- CoV-2 mutations and variants is flexible, enabling labs to select only those mutation kits that are necessary based upon their specific needs. Working in an agile development environment, A1 Life Sciences can quickly expand its RUO product portfolio to meet the evolving needs and dynamic situation for SARS-CoV-2 mutations and variants.

Benefits of Diagnovital SARS-CoV-2 Mutation Detection Assays:

- Comprehensive portfolio of kits for mutation profiling
- Flexible and regionalized solution to detect mutations and identify variants
- Fast and easy to implement without disrupting routine operations for COVID-19 testing
- Reflex test which uses residual extracted nucleic acid from positive SARS-CoV-2 sample
- Compatible with commonly used thermal cycler platforms

General Product Information

Portfolio of assays for Single Nucleotide Polymorphisms (SNPs) in S gene	Targets
Triplex RT PCR assay for the detection of WT (FAM), mutant (HEX/VIC) and IC (Cy5)	Assay Design
50 reactions	Kit Size
Extracted RNA from SARS-CoV-2 positive samples: human nasopharyngeal swabs and human oropharyngeal swabs	Sample Types
94	Maximum number of samples per 96-well plate
2 target positive controls:1 each for WT and mutant	Controls per 96-well plate
RTA Viral RNA Isolation Kit QIAamp® MinElute Virus Spin Kit Tianlong Generotex96 Extraction System	Tested extraction methods
BioRad CFX96 Thermo/Applied Biosystems Quant Studio 5 VERSANT kPCR AD Module*	Tested thermal cyclers
Thermal cyclers that have the FAM, HEX/VIC and Cy5 channels	Technically compatible thermal cyclers**

* QuantStudio 5 Dx with TF TD software
** It is the responsibility of the laboratory to test and validate use of technically compatible thermal cycler for use in their lab.

List of Products

Product Name
Diagnovital SARS CoV 2 delH69V70 Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 E484K Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 E484Q Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 K417N Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 L452R Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 N501Y Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 P681H Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 P681R Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 T478K Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 K417T Mutation Detection Kit (RUO)
Diagnovital SARS CoV 2 L452Q Mutation Detection Kit (RUO)*

*Under development

Products are for research use only (RUO) and not intended for diagnostic use.

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