

The Statement on Detection of Mutant Viruses

Date: 7th September, 2023

Product : Green Spring® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

We, Shenzhen Lvshiyuan Biotechnology Co., Ltd., as the manufacturer, hereby declare that Green Springs SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) which produced after September 2021 can detect the following SARS-CoV-2 Virus variants which is listed as ‘variants of concern (VOC)’& ‘variants of interest (VOI) & Variants under monitoring (VUMs)’by the World Health Organization. VOC refers to the large number and wide range of cases caused worldwide, and data confirms its transmission ability, strong toxicity, or reduced effectiveness of vaccines and clinical treatments. VOI refers to a confirmed case of community transmission, or has been found in multiple countries, but has not yet formed a large-scale infection. VUM refers to a SARS-CoV-2 variant with genetic changes that are suspected to affect virus characteristics with some indication that it may pose a future risk, but evidence of phenotypic or epidemiological impact is currently unclear, requiring enhanced monitoring and repeat assessment pending new evidence.

WHO Categories	WHO Label	Pango Lineage	Date of Designation
Variants Of Concern (VOC)	Alpha	B.1.1.7	September, 2020
	Beta	B.1.351	May 2020
	Gamma	P.1	November 2020
	Delta	B.1.617.2	October 2020
	Omicron	B.1.1.529	November 2021
Variants Of Interest (VOI)	Epsilon	B.1.427	February, 2021
		B.1.429	June 2021
	Eta	B.1.525	February 2021
	Iota	B.1.526	February 2021
	Kappa	B.1.617.1	May, 2021
	N/A	B.1.617.3	May, 2021
	Zeta	P.2	February 2021
	Mu	B.1.621, B.1.621.1	September, 2021
	IHU	B.1.640.2	September, 2021
Variants under monitoring (VUMs)		BA.1 x AY.4 recombinant	09-Mar-2022

	B.1.640	22-Nov-2021
	BA.1	Nov-2021
	BA.2	Feb-2022
	BA.2.12.1	Feb-2022
	BA.3	Feb-2022
	BA.4	Jan-2022
	BA.5	Jan-2022
	BF.7	Mar-2022
	BA.2.75	May-2022
	BQ.1.1	Aug-2022
	XBB	Sep-2022
	BQ.1	Sep-2022
	EG.5	Feb-2023
	Pirola(BA.2.86)	Aug-2023

The new coronavirus (SARS-CoV-2 or 2019-nCoV) is a non-segmented forward RNA virus. This is the cause of the new type of coronavirus pneumonia (COVID-19), which is highly contagious in humans. The SARS-CoV-2 virus has several structural proteins, including spikes (S), envelope (E), membrane (M) and nucleocapsid (N).

The SARS-CoV-2 virus has the characteristics of strong nucleocapsid (N) protein stability. The mutant virus strains that have been found worldwide are derived from the SARS-CoV-2 20B/GR evolutionary strain (lineage B.1.1.7), including many mutation, the mutation location is the spike (S) protein of the new coronavirus, which is the location where the SARS-CoV-2 virus uses to bind to the cell's ACE2 receptor.

The SARS-CoV-2 Antigen Rapid Test Kit produced by Shenzhen Lvshiyuan Biotechnology Co., Ltd. is used for in vitro qualitative detection of SARS-CoV-2 virus nucleocapsid (N) protein in human nasopharyngeal , oropharyngeal , anterior -nasal or saliva samples.

It can be seen that the mutation sites of mutated virus strains including Pirola(BA.2.86) strain have no effect on the detection rate of the kits produced by our company. The kit is suitable for assay of the SARS-CoV-2 variant virus as listed in the table above.

Shenzhen Lvshiyuan Biotechnology Co., Ltd.

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