## 深圳市绿诗源生物技术有限公司 Shenzhen Lvshiyuan Biotechnology Co., Ltd

Add: D Building, National Biological Industrial Park of Marinelife, No.2 Binhai Road, Dapeng, Shenzhen, 518120, China.

# Statement of Omicron detection according to the PEI's bridging test

Date: 28th Mar, 2022

Dear ZINNZ GmbH,

according to your company's inquiry about PEI Bridging-Test, our company's reply is as follows: Our Product:

Green Spring® SARS-CoV-2-Antigen- Selbsttest-Set (kolloidales Gold)

is able to detect Omicron variants. The required paperwork has been submitted to PEI for Omicron detection bridging test. The information on the PEI list will be updated after PEI has reviewed the documents. The process depends on the working time of PEI.

Attached you will find our company's instructions on the Omicron variant detection.

We are committed to providing high-quality products to the german market to support the fight against the epidemic. If you do have any questions, please do not hesitate to contact us. We look forward to your reply.

with best regards

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#### The Statement on detection of mutant viruses

WHO held an emergency meeting on 26 November 2021 to discuss the recently discovered mutant strain of the novel coronavirus B.1.1.529. After the meeting, WHO issued a statement, has designated B.1.1.529 as a "Variant of Concern", named Omicron.

The B.1.1.529 variant was first reported to WHO from South Africa on 24 November 2021 and the first sample infected with the mutant strain was collected on 9 November, the WHO said in a statement .This variant has a large number of mutations, some of which are concerning

Preliminary studies suggest that this variant causes an increased risk of reinfection in humans compared to other "concerns" variants. The number of cases of this variant appears to be increasing in almost all provinces in South Africa.

Since the outbreak of the SARS-CoV-2 virus, it has been reliably reported that there have been at least hundreds of mutations in the gene sequence, all of which have resulted in the virus being more infectious and more pathogenic. The most famous strains include Alpha, which first appeared in Kent, England, Beta in South Africa, Gamma in Brazil, Delta in India and Mu which was first discovered in Colombia and officially named by the WHO on August 30. And Omicron, recently discovered in South Africa. Among them, Omicron variant virus has recently invaded many countries and regions around the world with its strong infectivity and pathogenicity.

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.



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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 Omicron 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 called 'Omicron'.

Shenzhen Lvshiyuan Biotechnology .Co., Ltd.

Chief Director: Mr Jiang Date: 28th November .2021

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