



ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Website:<http://www.dbluemedical.com/>

Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei,Anhui,China

Statement about the new variant

To whom it may concern:

We, Anhui Deepblue Medical Technology Co., Ltd located at 4th floor, D-1 Zone, Pearl Industrial Park,106 Innovation Avenue, Hi-tech Development Zone Hefei 230088, Anhui, China. Here to confirm that:

Our COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) has been validated by UK PHE Porton Down. And the test have been tested against the the VOC1 Kent, UK, B.1.1.7 and VOC2 South Africa, B.1.351. Porton Down did not identify a reduction in sensitivity in the Deepblue LFT against either the Kent variant or the South African variant.

And we also confirm that our COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) (Both POCT professional use and self testing) is detecting the N Proteins, the current variants are based on the S area, so our test is able to detect the new variants including Alpha, Beta, Delta, Gamma, Lambda, Omicron (B.1.1.529) . Meanwhile, we will keep validate it with any new variants.

Date: November 28, 2021

Sign:

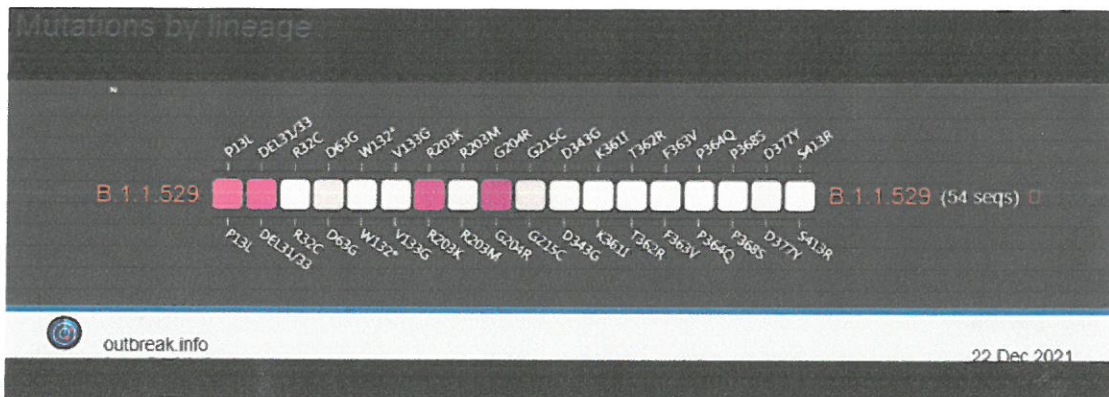
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安徽深蓝医疗科技股份有限公司
ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.



Statement on Omicron variant

In the past few weeks, we have searched for information on mutant virus strains. According to the information disclosed by the WHO, on November 25, 2021, the WHO announced that the B.1.1.529 mutant strain was listed as a "Variants of Concern" (Variants of Concern, VOC), named Omicron and this strain immediately attracted widespread attention. We immediately checked the literature for specific information about Omicron. The number of mutant sequences reported on omicron mutant strains is 54 so far. Most of them are on the S protein. The target amino acid sequence we detected is located on the N protein. The N protein mutation sequence reported on the omicron mutant strain is shown in the figure below:



As can be seen from the figure above, the mutation sequences on the N protein are: P13L,DEL31/33,R32C,D63G,W132*,V133G,R203K,R203M,G204R,G215C,D343G,K361I,T362R,F363V,P364Q,P368S,D377Y,S413R . The target sequence we detected is YYLGTGPEAGLPYGANKDGI, located at 111-130 in the NTD region. The comparison of all reported mutation sequences of N protein with the target sequence we detected is as follows:

nucleocapsid protein [Severe acute respiratory syndrome coronavirus 2]

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1  msdngpqnr napritfggp sdstgsnqng ersgarskqr rpqglpnnta swftaltqhg
61  kedlkfprgq gvpintnssp ddqigyrra trringgdgk mkdlsprwyf yylgtgpeag
121 lpygankdgi iwvategaln tpkdhigtrn pannaavilq lpqgttlpkg fyaegsrggs
181  qassrssrs mssrnstpg ssrgtsparm agnggdaala lllldrlnql eskmsgkgqq
241  qqqqvtkks aaeaskkprq krtatkaynv tqafgrgpe qtqgnfgdqe lirgtdykh
301  wpqiaqfaps asaffgmsri gmevtpsgtw ltygaikld dkdpnfdqv illnkhiday
361  kfpptepkk dkkkadetq alpqrkkqq tvllpaadl ddfskqlqqs mssadstqa

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Note:

*Yellow highlighted part: Target sequence

Red highlighted part: Sequences where mutations have been reported



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It can be seen from the above results that all N protein mutation sites are not in our target detection area. Therefore, the N protein mutation of omicron will not affect the detection performance of our products.

We, Anhui Deepblue Medical Technology Co., Ltd located at 4th floor D-1 Zone, Pearl Industrial Park, 106 Innovation Avenue, Hi-tech Development Zone Hefei 230088, Anhui, China. Here to confirm that:

For the Omicron variant, the performance of the COVID-19 antigen test series produced by our company will not be affected, and it can be used and tested normally.

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Date: Dec. 22, 2021

Sign:

Stamp:

安徽深蓝医疗科技股份有限公司
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