

Dec.2nd, 2021

Statement on the Detection of SARS-CoV-2 Variants B

1.1.1.529 (WHO Label: Omicron)

To Whom It May Concern:

We, Qingdao Hightop Biotech Co., Ltd., as the manufacturer of HIGHTOP SARS-CoV-2 Antigen Rapid Test, hereby declare that we have been continuously monitoring the emergence of a new strain of SARS-CoV-2. The variants of SARS-CoV-2 have some mutations in the spike protein and a few mutations in the nucleocapsid protein. According to verification, HIGHTOP SARS-CoV-2 Antigen Rapid Test can effectively detect Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2).

There is no evidence showing that the recently discovered SARS-CoV-2 Variants B 1.1.1.529 (WHO Label: Omicron) will affect the test performance of our SARS-CoV-2 Antigen Rapid Test based on bioinformatic analysis and the fact that according to the currently publicly available information mainly the Spike protein is mutated, and our rapid tests measure the N protein of the virus. Lab tests are being carried out for further assessment. We will continue to track the latest viral information and adapt the detection ability of our test kit against the SARS-CoV-2 variants to maintain the sensitivity and specificity.

Sincerely

青島江唐生物科技股份有限公司

QINGDAO HIGHTOP BIOTECH CO., LTD.

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