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Nov 28, 2021,

To Whom It May Concern:

Thank you for your interest in the Flowflex SARS-CoV-2 Antigen Rapid Test.

We, ACON Biotech (Hangzhou) Co., Ltd. as the manufacturer of Flowflex SARS-CoV-2 Antigen Rapid Test, hereby declare that ACON are monitoring the emergence of a new strain of SARS-CoV-2 which has become prevalent in the UK, South Africa, Brazil/Japan, India, USA, Philippines, Peru, Colombia and other communities. SARS-CoV-2 of Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Zeta (P.2), Eta (B.1.525), Theta (P.3), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), Mu(B.1.621), Delta plus (AY.4.2), Omicron(B.1.1.529) have several mutations in the spike protein and a few mutations in the nucleocapsid protein.

There is no obvious difference observed when testing with different nucleocapsid protein recombination antigens (Alpha, Beta, Gamma, Delta, Epsilon, Zeta, Eta, Theta, Iota, Kappa, Lambda, Mu and Delta plus) basing on these different variants of SARS-CoV-2. For Omicron, by theoretical analysis of the mutations in the nucleocapsid protein, it should not interfere the detection of Flowflex SARS-CoV-2 Antigen Rapid Test. So we do not anticipate that these variants will have any effect on test performance.

Sincerely,

ACON Biotech (Hangzhou) Co., Ltd.



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