

To whom it may concern,

We, Suny (Xiamen) Biotechnology Co.,Ltd,as the manufacturer of Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) ,here by declare that our test is effective for, but not limited to,the mutant strain and the following variants;SARS-CoV-2 of Alpha (B1.1.7), 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) , Omicron(BA.5), Omicron(BQ.1),Omicron(BQ.1.1),Omicron(XBB.1.5).

The aforementioned variants have several mutations in the spike protein and minimal mutations in the nucleocapsid protein.

There is no obvious difference when testing with different recombinant nucleocapsid protein antigens (Alpha, Beta, Gamma, Delta, Epsilon, Zeta, Eta, Theta, Iota, Kappa, Lambda, Mu and Delta plus), based on these different variants of SARS-CoV-2.

The theoretical analysis of the mutations in the nucleocapsid protein suggests no apparent interference for the Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) with detecting the Omicron variant of COVID-19(Includes Omicron BA.1 ,Omicron BA.2 Omicron BA.5, Omicron BQ.1, Omicron BQ1.1,Omicron(XBB.1.5)and all related variants).

We anticipate our test will be able to detect these variants.

Sincerely

Suny (Xiamen) Biotechnology Co.,Ltd.

