

Declaration on detection of SARS-CoV-2 variant

Subject : Performance of COVID-19 Antigen Rapid Test (Colloidal Gold)(FGCOVG100/FGCOVG300) are theoretically not be impacted by recently discovered variants including United Kingdom variant etc.

Dear Valued customers:

Joinstar Biomedical Technology Co.,Ltd , would like to confirm that our COVID-19 Antigen Rapid Test (Colloidal Gold) remains suitable for the detection of SARS-CoV-2 antigen even in the outbreak of newly discovered variants including United Kingdom variant etc.

Based on open information, several epitope mutations have occurred on spike protein at epitope of, including but not limited to N501Y, E484K, K417N for SA mutant strain Beta(501Y.V2) , and N501Y, P681H, 69-70 for UK mutant strain Alpha(b.1.1.7), Brazil mutant strain P.1 and India mutant strain Kappa(B.1.617.1) ,Delta(B.1.617.2) . The new variants Omicron (B.1.1.529) have nucleoprotein mutation points located at P6T, P13L and S33I, the same mutations innucleoprotein as Alpha, Gamma, Lambda. The recognition binding epitope of the raw materials used in our antigen test are from the nucleocapsid protein(N protein) and according to the analysis of the N protein sequence of these mutant virus(including Omicron), all mutation sites are outside the epitope region recognized by our pair of antibodies. In summary as all the Novel Coronavirus mutant strains will have no impact on the performance of our COVID-19 Antigen Rapid Test (Colloidal Gold).

We will continue to monitor the changing situation and will continue with our efforts to comply with high quality management standards to ensure we deliver consistently a high quality product which meets our customer expectations and the market needs. If you have any questions, please contact our sales representative.

No. S2106002

Joinstar Biomedical Technology Co.,Ltd
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