

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.

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.

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, all mutation sites are outside the epitope region recognized by our pair of antibodies.

The mutants analyzed included the following : Alpha(b.1.1.7), Beta (B.1.351/B.1.351.2/B.1.351.3) , Gamma (P.1/P.1.1/P.1.2), Delta(B.1.617.2/AY.1/AY.2/AY.3), Eta (B.1.525), Iota(B.1.526), Kappa(B.1.617.1), Lambda (C.37), Mu (B.1.621), Zeta (P.2), IHU (B.1.640.2) Omicron(B.1.1.529/BA.1/BA.1.1/BA.2/BA.3/XE/BA.4/BA.5,), Finland B.1.1.318, France B.1.616, Britain A.23.1, America B.1.427, America B.1.429, America B.1.375, Brazil N9, France B.1, France A.27, India B.1.618 et al.

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.

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