



Statement

To Whom it might concern

We, Shenzhen Microprofit Biotech Co., Ltd., as the manufacturer of SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (fluorecare® - REF MF-68), SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Self-test) (fluorecare® - REF MF-68), SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay) (fluorecare® - REF MF-67), SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) (fluorecare® - REF MF-69), SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) (fluorecare® - REF MF-71), SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic immunoassay) (Saliva) (fluorecare® - REF MF-91), SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) (Self-test) (fluorecare® - REF MF-71), SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Saliva) (Self-test) (fluorecare® - REF MF-91), hereby declare,

1. Further In-vitro studies to investigate the impact of mutated SARS-CoV-2 N proteins and the analysis performance of the product is finished, B.1.1.7, B.1.351, B.1.429, B.1.427, B.1.2, P.1, P.2, P.3, B.1.617.2, B.1.617.3, C.37, B.1.617.1, B.1.525, B.1.526, B.1.526.1, B.1.526.2, B.1.1.529, **BA.1**, **BA.2**, **XE**, **BA.4**, **BA.5**, **BA.5.2**, **BA.4.6**, **BF.7**, BA.2.75, B.1.1.318, C.36.3, AY.4.2, BA.2.10, **XBB**, **XBB.1.5**, XBC, **BQ.1**, **BQ.1.1**, BJ.1, BA.2.3.20, B.1.621, BM.2, BA.4.7, BN.1, BA.5.2.35, BQ.1.4, BQ.1.3, BQ.1.2, BA.5.9, BM.1.1.1, BS.1, BA.2.75.5, BA.2.75.2, BA.2.12.1, BA.2.86, EG.5.1 variants, the N protein mutation site is not in the recognition region of the coated and labeled antibody, can recognize the reaction well.

2. In the future, our company will continue to follow up the mutation of the new coronavirus, and timely evaluate and verify the detection ability of mutated recombinant protein and clinical performance to ensure the sensitivity and specificity of the detection kit.

Shenzhen Microprofit Biotech Co., Ltd



/2023.08.24