

Statement

With the emergence of genetic variation of SARS-CoV-2, multiple mutant strains of viruses have emerged, including but not limited to the following variants: B.1.1.7 lineage (Alpha), B.1.351 lineage (Beta), B.1.617.2 lineage (Delta), P.1 lineage (Gamma), and so on. The 2019-nCoV variant Alpha also known as Variant of Concern 202012/01 (VOC-202012/01) 201/501Y.V1, is a highly transmissible variant. The variant is characterized by 17 mutations, 8 of which occur in the gene for the spike (S) protein. Beta, also known as 20H/501Y.V2 (formerly 20C/501Y.V2) and 501 Y.V2 variant, this variant has multiple mutations in the S protein, including K417N, E484K, N501Y. Delta has multiple mutations in the S protein including L452R, T478K and D614G. Gamma, also known as 20.1/501Y.V3 variant, is a branch off the B.1.1.28 lineage. Gamma contains three mutations in the S protein receptor binding domain: K417T, E484K, and N501 Y. The mutation sites of these mutants are mainly concentrated on the S protein, while the Nucleocapsid (N) protein is relatively conservative.

Goldsite SARS-CoV-2 Antigen Kit (Colloidal Gold) is based on the principle of immunochromatography sandwich for detection of SARS-CoV-2 Nucleocapsid antigen extracted from the specimen. We would like to declare that the product is mainly use two Nucleocapsid antibody raw materials, the names and details are listed as follows:

No.	Material Name	Material concentration
1	2019-nCoV Nucleocapsid Antibody 1 (Colloidal gold labeled)	Concentration: 100 µg/100µL
2	2019-nCoV Nucleocapsid Antibody 2 (coated on T line)	Concentration: 2.0 mg/mL

Based on the above points, our product "SARS-CoV-2 Antigen Kit (Colloidal Gold)" manufactured by Goldsite Diagnostics Inc. detects mainly 2019-nCoV nucleocapsid, therefore the result of our test reagents is not affected by the SARS-CoV-2 variants including but not limited to the following: Alpha strain, Beta strain, Delta and Delta plus strain, Gamma strain, Lambda strain, Epsilon strain.

Rina Qi

Director

Goldsite Diagnostics Inc.

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