



## Guangzhou Wondfo Biotech Co., Ltd.

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## Statement

To whom it may concern,

We,

Guangzhou Wondfo Biotech Co., Ltd.

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) or 20I/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 501Y.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 20J/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 N501Y. The mutation sites of these mutants are mainly concentrated on the S protein, while the Nucleocapsid (N) protein is relatively conservative.

Wondfo 2019-nCoV Antigen Test is based on the principle of immunochromatography sandwich for determination of 2019-nCoV 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 performance
1	2019-nCoV Nucleocapsid Antibody 1	Concentration $\geq$ 2.0mg/mL, purity $\geq$ 95%
2	2019-nCoV Nucleocapsid Antibody 2	Concentration $\geq$ 2.0mg/mL, purity $\geq$ 95%

Based on the above points, our product "Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)" manufactured by Guangzhou Wondfo Biotech Co., Ltd. detects mainly 2019-nCoV nucleocapsid, the recent Alpha strain, Beta strain, Delta strain and Gamma strain don't affect the result of our test reagents.





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As the manufacture of the product:

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method), REF: W196/W634

Wondfo 2019-nCoV Saliva/Sputum Antigen Test (Lateral Flow Method), REF: W633

Wondfo 2019-nCoV Antigen Test (Fluorescence Immunoassay), REF:W286

Sincerely yours,  
Guangzhou Wondfo Biotech Co., Ltd.  
8th Jun. 2021

