



Guangzhou Wondfo Biotech Co., Ltd.

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Statement

To whom it may concern,

We,

Guangzhou Wondfo Biotech Co., Ltd.

As the manufacture of the product:

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method), REF: W196/W634/W633

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

Would like to declare that the products is mainly use three antibody raw materials, the names and details are listed as follows:

No.	Material Name	Cat.	Material performance
1	2019-nCoV Nucleocapsid Antibody	COVID19-MAB30	Concentration \geq 2.0mg/mL, purity \geq 95%, Titer \geq 1 :4000
2	2019-nCoV Nucleocapsid Antibody	COVID19-MAB117	Concentration \geq 2.0mg/mL, purity \geq 95%, Titer \geq 1 :4000

Our product "Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)" and "Wondfo 2019-nCoV Antigen Test (Fluorescence Immunoassay)" manufactured by Guangzhou Wondfo Biotech Co., Ltd. detects mainly 2019-nCoV nucleocapsid phosphoprotein (NP protein), the B.1.1.7 strain arose in UK, B.1.351 strain arose in South Africa, the B.1.617 strain arose in India, the P.1 and P.2 strain arose in Brazil, C.37 strain arose in Peru, B.1.526 strain arose in USA, the B.1.525 strain arose in multiple countries, B.1.621 strain arose in Columbia and the recent B.1.1.529 strain arose in South Africa don't affect the result of our test reagents.

The 2019-nCoV variant B.1.1.529 lineage also known as Omicron. Omicron NP protein mutations are P13L, Δ 31-33, R203K, G204R. The epitope of our current antibody pair is not located in the Omicron mutation sites. In theory, our antibody pair can normally detect the Omicron mutant strain. The laboratory verification and clinical detection performance test are still in progress.

Sincerely yours,

Guangzhou Wondfo Biotech Co., Ltd.

29th Nov 2021

