

STATEMENT

To whom it may concern

We, Hangzhou Realy Tech Co., Ltd. recently received questions from the German competent authority regarding the target protein of the company's Novel Coronavirus (SARS-Cov-2) antigen rapid test cassette (swab) through several customers. The company's response to the target protein of the company's Novel Coronavirus (SARS-Cov-2) antigen rapid test cassette (swab) is as follows:

- a) which antigen proteins are detected in your test and

Answer:

Our Novel Coronavirus (SARS-Cov-2) antigen rapid test cassette (swab) product can detect SARS-Cov-2 nucleoprotein (mainly) and spike protein.

- b) If the relevant antigen test detects the SARS-CoV-2 surface protein ("spike"), whether the antigen detection also reliably detects the spike protein of genetic SARS-CoV-2 variants. Please explain this in a comprehensible manner.

Answer:

More than 90% antibody used in Novel Coronavirus (SARS-Cov-2) antigen rapid test cassette (swab) is anti-nucleoprotein of SARS-Cov-2 and target protein is SARS-Cov-2 nucleoprotein. So, our product can reliably detect the SARS-Cov-2 variants.

The rest antibody used in Novel Coronavirus (SARS-Cov-2) antigen rapid test cassette (swab) is anti-Spike protein and target protein is SARS-Cov-2 Constant fragment of Spike protein.

At present, whether the N501Y in the United Kingdom or the 501Y.V2 in South Africa, the variant fragments are mainly the RBD fragment of the S protein, and the target fragments of the antibodies we used in Novel Coronavirus (SARS-Cov-2) antigen rapid test cassette (swab) have not been mutated.

So, our product can reliably detect the spike protein of genetic SARS-Cov-2 variants.

Hangzhou Realy Tech Co., Ltd.

Signature:

Function: Quality manager

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Hangzhou Realy Tech Co., Ltd.

Tel: +86-571-5605 0794

Add: 4th Floor, #12 Building, Eastern medicine town; Hangzhou Eco & Tech Development Area, Zhejiang 310018, China.

Email: info@realytech.com

Web: www.realytech.com