STATEMENT

To: whom it may concern:

This letter is to declare for the detection of Omicron (B.1.1.529) using COVID-19 Antigen Rapid Test Cassette manufactured by Hangzhou Biotest Biotech Co., Ltd.

Hangzhou Biotest Biotech Co., Ltd continues to focus on the development and evolution of SARS-CoV-2 mutations worldwide and closely tracking the mutant strains reported by WHO and GISAID. In November 2021, a new SARS-CoV-2 variant Omicron(B.1.1.529) was identified in South Africa. Key mutations include 34 mutations on the spike protein of the virus, where 15 mutations occurs in the RBD of the spike protein. Despite the significant mutation on the spike protein and its significant potential to influence this variant's immune escape and transmissibility, based on preliminary analysis(professional bioassay and sequence alignment, N protein recombinant antigen testing), it is estimated that the COVID-19 Antigen Rapid Test Cassette manufactured by Hangzhou Biotest Biotech Co., Ltd will still be able to detect the new variant.

The COVID-19 Antigen Rapid Test Cassette manufactured by Hangzhou Biotest Biotech Co., Ltd is a qualitative, lateral flow immunoassay for the detection of the nucleocapsid protein of SARS-CoV-2. Comparing the mutations that occur on the nucleocapsid protein of the new variant Omicron (B.1.1.529) : P13L, E31del, R32del, S33del, R203K and G204R and the epitopes (the part of the antigen that binds to the antibody) of the antibodies used on the test, it was determined that all 6 mutations are outside the epitopes of the antibodies used in the test. This indicates that the binding of the antibodies and the antigen will likely not be affected, therefore, the risk of the new variant not being detected by the COVID-19 Antigen Rapid Test Cassette is low.

Details are as follows:

1. N protein mutations of Omicron mutant strains: P13L, E31del, R32del, S33del, R203K, G204R. The epitopes locations of anti-SARS-CoV-2 antibodies which used in COVID-19 Antigen Rapid Test Cassette product aren't in the range of N protein mutations, has no influence on the detection results theoretically.

Compared and analyzed the Epitope(s) locations of anti-SARS-CoV-2 antibody and the sequences of each mutant virus strain

1.1 Intended use of COVID-19 Antigen Rapid Test Cassette

The identification of the COVID-19 Antigen Rapid Test Cassetteis based on monoclonal antibodies specific to the **Nucleocapsid(N)protein** of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

1.2 Reagents of COVID-19 Antigen Rapid Test Cassette

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein antibody particles conjugate and anti-SARS-CoV-2 Nucleocapsid protein antibody coated onto the membrane.

The Epitope(s) locations of anti-SARS-CoV-2 antibody used for coating on the membrane is 44-175aa, and the Epitope(s) locations of anti-SARS-CoV-2 antibody used for conjugation is 74-105.

1.3 Nucleocapsid(N)protein Comparison results of the Epitope(s) locations of anti-SARS-CoV-2 antibody and the sequences of Omicron (B.1.1.529) mutant strains.

1.4 The result of analysis

By comparison of N-protein, there was no variation in the overlap of Epitope(s) locations of anti-SARS-CoV-2 antibody used for coating on the membrane and conjugation.

It can be inferred that the **COVID-19 Antigen Rapid Test Cassette** product is capable of detecting the micron (B.1.1.529) mutant strains

2. The N protein recombinant antigen of Omicron mutant was tested under laboratory conditions, and the results showed that the T-Line intensity of different protein concentrations was consistent with that of wild strain. The following are the results of the laboratory conditions:

The Detection of Omicron (B.1.1.529) N protein recombinant antigen

2.1 Material:

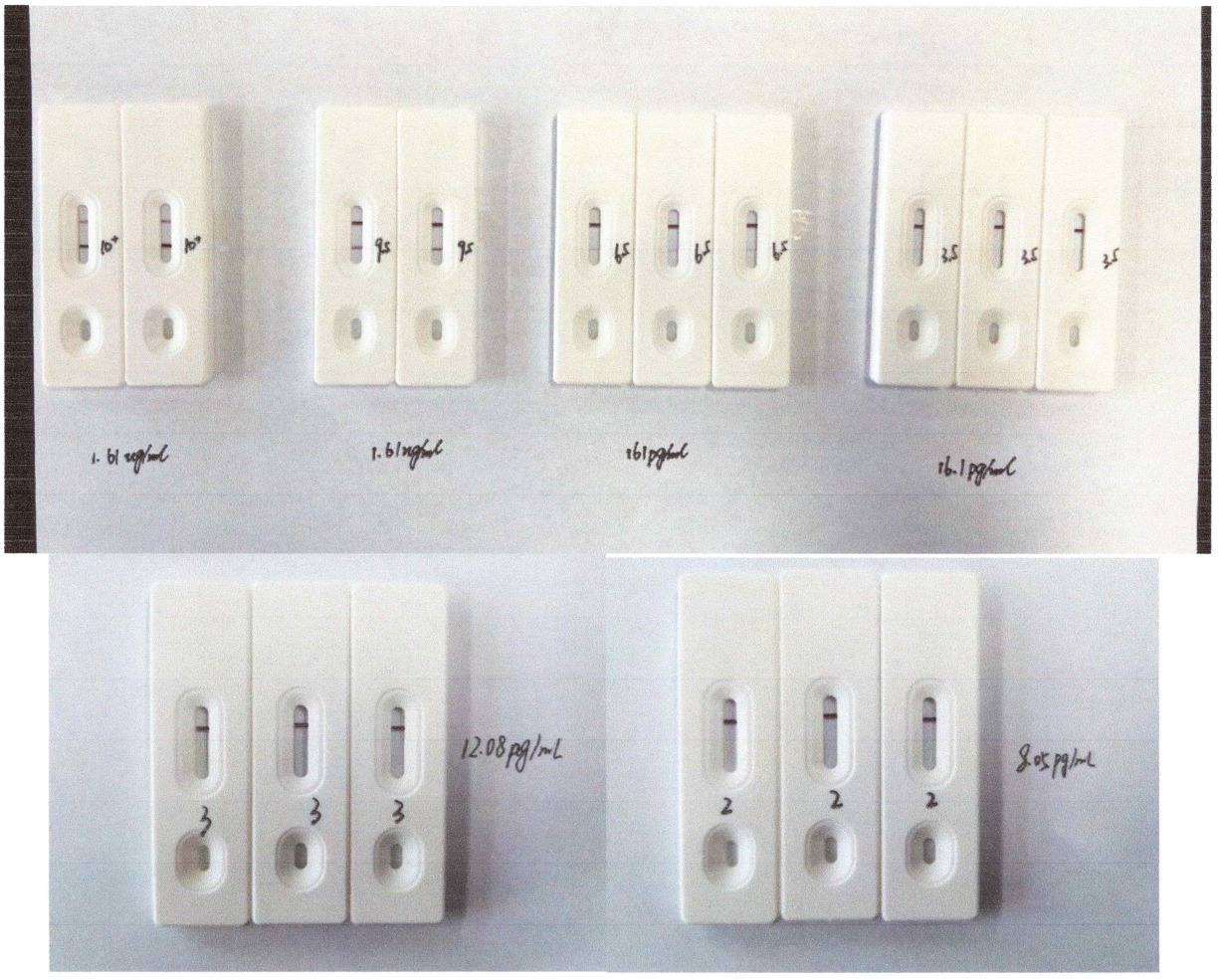
Omicron (B.1.1.529) N protein recombinant antigen
Lot: 20211201-2 Concentration: 1.61mg/ml

COVID-19 Antigen Rapid Test Cassette
Lot: MCOVG2112004-T

2.2 Method:

The Omicron (B.1.1.529) N protein recombinant antigen was gradient diluted with buffer solution. The dilution of each concentration was repeated for Test.

2.3 Result:



Cncentration of Omicron (B.1.1.529) N protein recombinant antigen	COVID-19 Antigen Rapid Test Cassette Lot: MCOVG2112004-T		
	Test 1	Test 2	Test 3
1.61μg/ml	10	10	/
1.61ng/ml	9.5	9.5	/
161pg/ml	6.5	6.5	6.5
16.1pg/ml	3.5	3.5	3.5
12.08pg/ml	3	3	3
8.05pg/ml	2	2	2

Note: "According to the BT's color card, 1~<3 for the intensity of T line was considered negative and 3~10 was considered positive."

2.4 Conclusion:

The minimum detection limit of Omicron (B.1.1.529) N protein recombinant antigen was 12.08pg/ml.

3. This statement is limited to the verification results of the N recombinant antigen test of the mutant strain under this laboratory conditions, and the detection of the mutant strain by COVID-19 Antigen Rapid Test Cassette needs to be made by clinical specimens of the mutant strain.

4. According to the statement issued by the Society of Virology (Gfv) and German Society for Immunology (DGfl), on 28th November 2021 (https://g-f-v.org/en/ad-hoc-stellungnahme-schnelles-politisches-handeln/), "According to current knowledge, the common PCR methods for detecting SARS-CoV-2 can also detect the omicron variant. Rapid antigen tests should also be suitable. The extent to which this is true is currently under review. "

So it can be inferred that, to a large extent, COVID-19 Antigen Rapid Test Cassette is capable of detecting the following mutant virus strain: Omicron (B.1.1.529).

Our company will continue to pay attention to the virus mutation situation at home and abroad, and timely evaluate the detection ability and product performance of our products on mutant strains, to ensure that the accuracy and sensitivity of the COVID-19 Antigen Rapid Test Cassette will not be affected. Quickly upgrade the product if necessary to ensure the accuracy of COVID-19 Antigen Rapid Test Cassette product testing on SARS-CoV-2 variants

Thank you for your support and trust on our COVID-19 Antigen Rapid Test Cassette products.

Your Sincerely,

RDT Director: 2021.12.08

Hangzhou Biotest Biotech Co., Ltd