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股票代码: 688767

杭州博拓生物科技股份有限公司
Hangzhou Biotest Biotech Co., Ltd.

STATEMENT

Date: September 8, 2023

To whom it may concern:

This letter is to declare for the detection of SARS-CoV-2 new mutant strains using COVID-19 Antigen Rapid Test Cassette manufactured by Hangzhou Biotest Biotech Co., Ltd.

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 variants(BA.1, BA.2, BA2.10, BA.2.12, BA.2.12.1, BA.2.75, XE, BF.7, BJ.1, XBB, BA.2.75.2, BN.1, BA.5.2.35, XBB.1.5, CH.1.1, CH1.1.1, CH1.1.2, XBF(BA.5 x CJ.1), XBB.1.9.1, XBB.1.9.2, XBB.1.16, XBB.2, XBB.2.3, XBB.2.3.2, XBB.1.16.1, XBB.1, FL.3 (XBB.1.9.1.3), XBB.1.5.7, FL.3.1, FL.4, FL.3.3, FY.1.2, EG.5.1 and BA.2.86.) 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 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.

Comparing the mutations that occur on the nucleocapsid protein of the new variant B.1.617.2(Delta), BA.4, BA.4.6, BA.5, BE.3, BQ.1, BQ.1.1, BQ.1.1.20 and the epitopes(the part of the antigen that binds to the antibody) of the antibodies used on the test, for variant B.1.617.2(Delta), BA.4, BA.4.6, BA.5, BQ.1, BQ.1.1 and BQ.1.1.20, there was one Amino Acid (AA) change in the overlap of Epitope(s) locations of anti-SARS-CoV-2 antibody used for coating on the membrane, and no variation in the overlap of anti-SARS-CoV-

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2 antibody used for conjugation, for variant BE.3, there were two Amino Acid (AA) Change in the overlap of Epitope(s) locations of anti-SARS-CoV-2 antibody used for coating on the membrane, and no variation in the overlap of anti-SARS-CoV-2 antibody used for conjugation. So it can be inferred that to a large extent COVID-19 Antigen Rapid Test Cassette product is capable of detecting.

The B.1.617.2(Delta) inactivated virus were tested under laboratory conditions, and the results showed that the T-Line intensity of different protein concentrations was consistent with that of wild strain when tested by COVID-19 Antigen Rapid Test Cassette.

The N protein recombinant antigen of new variant(BA.2, BA.2.10, BA.2.12, BA.2.12.1, XE, XBB, BA.2.75, BA.2.75.2, BN.1(BA.2.75.5.1), BA.5.2.35, XBB.1.5, CH.1.1, CH1.1.1, CH1.1.2, XBF(BA.5 x CJ.1), XBB.1.9.1, XBB.1.9.2, XBB.2, EG.5.1, BA.4, BA.4.6, BA.5, XBB.2.3, XBB.2.3.2, XBB.1.16.1, XBB.1, FL.3 (XBB.1.9.1.3), XBB.1.5.7, FL.3.1, FL.4, FL.3.3, FY.1.2, BE.3, BQ.1, BQ.1.1 and XBB.1.16) 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 when tested by COVID-19 Antigen Rapid Test Cassette.

From what has been discussed above, the COVID-19 Antigen Rapid Test Cassette effectiveness against virus mutations(B.1.617.2(Delta), BA.1, BA.2, BA.2.10, BA.2.12, BA.2.12.1, BA.4, BA.4.6, BA.5, BA.2.75, XE, BE.3, BF.7, BQ.1, BQ.1.1, BJ.1, XBB, BA.2.75.2, BN.1 (BA.2.75.5.1), BA.5.2.35, XBB.1.5, CH.1.1, CH1.1.1, CH1.1.2, XBF(BA.5 x CJ.1), BQ.1.1.20, XBB.1.9.1, XBB.1.9.2, XBB.1.16, EG.1, XBB.2.3, XBB.2.3.2, XBB.1.16.1, XBB.1, FL.3 (XBB.1.9.1.3), XBB.1.5.7, FL.3.1, FL.4, FL.3.3, FY.1.2, EG.5.1(XBB.1.9.), BA.2.86), the risk of the new variant not being detected by the COVID-19 Antigen Rapid Test Cassette is low.

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The COVID-19 Antigen Rapid Test Cassette was placed on the market from 2021.09.01, the reagents used for this product was not changed, so above analysis was applicable to the products manufactured from 2021.09.01.

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:

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HANGZHOU BIOTEST BIOTECH CO., LTD.

Hangzhou Biotest Biotech Co., Ltd

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