

STATEMENT

Date: January 27, 2022

From: Hangzhou Biotest Biotech Co. Ltd
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To: Whom It may concern

ExactSign™ COVID-19 Antigen Rapid Test Cassette- Detection of COVID-19 Variants

Biotest learned that on November 26, 2021, the World Health Organization listed the new SARS-CoV-2 mutant strain B.1.1529 discovered in South Africa as the highest-level "mutation of concern" and named it Omicron. Now Omicron sub-variant BA.2 spread rapidly. Biotest conducts detailed comparison and analysis based on the calculation sequence of the mutation site of the Omicron sub-variant BA.2 published by the GISAID database and the specific anti-N protein antibody recognition epitope used in our COVID-19 antigen rapid tests. The analysis results showed that the mutation site of the Omicron sub-variant BA.2 did not affect the COVID-19 antigen rapid tests developed, produced and sold by our company for the antigen detection of the mutant strain, that is, Biotest's COVID-19 antigen rapid test can effectively detect the mutant strain Omicron sub-variant BA.2.


Since the outbreak of COVID-19, Biotest has focused on the generation and evolution of related mutant strains and the impact on the detection performance of the test kit. Biotest has verified the detection performance of the rapid tests for COVID-19 antigen developed by our company by using methods such as clinical sample detection and analysis, biological mutation sequence analysis, and artificially simulated mutant strain sample analysis. Up to now, through evaluation and verification, the rapid test for COVID-19 antigen developed by Biotest can effectively detect the following mutant strains: Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Lambda (C.37), Eta (B.1.525), Iota (B.1.526), Mu (B.1.621), Kappa (B.1.617.1), Theta, C.36.3, C.1.2, B.1.1.318, B.1.617.3, Zeta, AV.1, A.23.1, Epsilon, etc.

In the future, Biotest will continue to track and monitor the mutation of SARS-CoV-2, and will follow up the latest information in a timely manner. It has ensured that the rapid tests for COVID-19 antigen produced and sold by our company can cover all major SARS-CoV-2 mutant strains. Avoid the occurrence of missed inspections and other situations.

Best regards,

Wade Wu
General Manager

Hangzhou Biotest Biotech Co., Ltd



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