

Statement

To Whom It May Concern:

Regarding the product Coronavirus (2019-nCoV)-Antigentest- produced by Beijing Hotgen Biotech Co., Ltd., the following statement are especially made:

Coronavirus (2019-nCoV)-Antigentest- by our company detects N protein of SARS-CoV-2 in human anterior nasal swab samples. While the mutation of the virus found in England (B.1.1.7 strain), SouthAfrica (B.1.351 strain, Omicron variant (B.1.1.529 strain, BA.2 strain, BA.2.75 strain, BA.4 strain, BA.5 strain, BF.7 strain, BF.15 strain, BQ.1 strain, BQ.1.1 strain, XBB strain and XBB.1 strain), Brazil (P.1 strain), India (B.1.617 strain, Delta variant B.1.617.2), U.S., U.K. and Canada, etc. (FLiRT variant (KP.2 strain and KP.1.11 strain)), U.S. (KP.3.1.1 strain, KP.2.3 strain, KP.3strain, LB.1 strain), XE variant, EG.5 variant, Pirola (BA.2.86) variant, JN.1 variant, JN.1.16 variant, JN.1.4 variant, XDV.1, JN.1.18, XEC, LP.8.1 variant, NB.1.8.1 variant were verified not to significantly affect the detection sensitivity of the reagents and the mutation will not affect the detection result of our product. So our product is still effective to detect the antigen of novel coronavirus.

Beijing Hotgen Biotech Co., Ltd.

May 29th, 2025

