Zhejiang GENE SCIENCE Novel Coronavirus(Covid-19) Ag Detection Kit Validity Report

With the global pandemic of novel coronaviruses, multiple viral mutant strains were generated from 2019 onwards, including Alpha (B1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Lambda (C.37), Kappa (B.1.617.1), Eta (B.1525), Lota (B.1526), Mu (B.1.621), Zeta (P.2), Omicron (B.1.1.529). Novel coronaviruses are mainly composed of the Spike Protein (S protein), the Nucleocapsid Protein (N protein), the Envelope Protein (E protein) and the Membrane Protein (M protein), while most of the mutations of the mutant viruses occur mainly in the virus is the S protein, and their mutations lead to the expanding ability and range of transmission of novel coronaviruses.

In novel coronaviruses, a large number of N proteins are present, which undergo relatively low frequency of mutations. As the main target in the antigen detection kit, we have evaluated the N protein in various virus mutant strains, and through analysis and testing, we have demonstrated that our new coronavirus antigen detection kit does not produce missed detection of the above virus mutant strains.

Table 1 Results of N protein testing of various mutant strains by Novel Coronavirus(Covid-19) Ag Detection Kit

mutant strains	Recombinant protein type	1ng/ml	100pg/ml	50pg/ml
Alpha	Nucleocapsid Protein	++	+	+/-
Beta	Nucleocapsid Protein	++	+	+/-
Gamma	Nucleocapsid Protein	++	+	+/-
Delta	Nucleocapsid Protein	++	+	+/-
Lambda	Nucleocapsid Protein	++	+	+/-
Kappa	Nucleocapsid Protein	++	+	+/-
Eta	Nucleocapsid Protein	++	+	+/-
Lota	Nucleocapsid Protein	++	+	+/-
Mu	Nucleocapsid Protein	++	+	+/-
Zeta	Nucleocapsid Protein	++	+	+/-
Omicron	Nucleocapsid Protein	++	+	+/-

"++" indicates strong positive; "+" indicates weak positive; "+/-" indicates

unstable test result; The above controls were purchased from Sino Biological, Catalog NO: 40588-V07E34/40588-V07E29/40588-V07E9/40588-V07E31/40588-V07E2/40588-V07E18