

**Performance Study on the detection of recombinant Neucleoprotein of  
COVID-19 mutant strain Omicron (B.1.1.529)**

## **1. Introduction**

The recent emerging COVID-19 mutant variant Omicron (B.1.1.529) has attracted wide public attention, and was classified to VOC (Variants of Concern) by WHO. WESAIL is also very concerned about the evolution of this new mutant strain.

The WESAIL COVID-19 Ag Test Kit is based on the detection of the N protein by a matched pair of monoclonal antibodies each specific for the N-terminal and C-terminal domain structure of the N protein of the COVID-19 virus (mainly target N protein of the virus). In consideration of the Omicron mutant strain has several N protein mutation site: P13L, E31del R32del, S33del R203K, G204R, we have decided to perform corresponding performance verification on our COVID-19 Ag Test Kit.

## **2. Purpose of the study**

The purpose of this study is to evaluate the potential impact on the performance of WESAIL COVID-19 Ag Test Kit in the detection of mutant variant of Omicron (B.1.1.529).

## **3. Experimental evaluation of the detection rate of mutant strain by WESAIL COVID-19 Ag Test Kit**

### **3.1 Experimental Procedure**

By analyzing the mutation sites of N protein and their proportion according to the coronavirus sequences released by the GISAID database and developed full-length N protein recombinant antigen, both wild type recombinant N-protein and recombinant N-protein of Omicron(B.1.1.529) were obtained by Guangdong Fapon Biological Co., Ltd. The performance of the WESAIL COVID-19 Ag Test Kit to detect the mutated recombinant protein was then evaluated against the wild-type SARS-CoV-2 recombinant antigen.

Representative samples of the recombinant N-protein expressed with the wild-type sequence and the mutant viral strain were diluted using viral lysate to a concentration of 0.1ng/mL and 1 ng/mL recombination protein and tested on the WESAIL COVID-19 Ag Test Kit as described in the "Instruction For Use" (IFU). The evaluation endpoint is to examine if the WESAIL COVID-19 Ag Test Kit continue its ability to detect the mutated recombinant N-protein from the corresponding mutant strain Omicron(B.1.1.529).

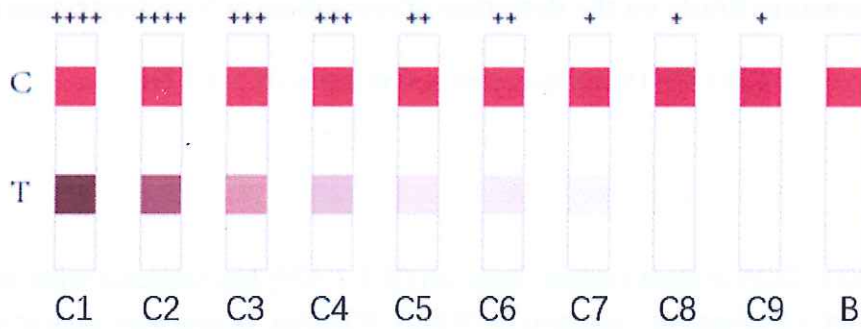


Figure 1. Colorimetric Card for qualitative scoring of test signal

### 3.2 Experimental Results

Results of SARS-CoV-2 wild-type and mutant strain Omicron (B.1.1.529) recombinant antigen of WESAIL COVID-19 Ag Test Kit:

Table 2 Summary of SARS-CoV-2 wild-type and mutant strain Omicron results

Categories	Repeat	WHO label	Pango lineage	GISAID clade/lineage	0.1 ng/mL	1 ng/mL
ncov-PS-Ag6	1	/	Wild type	/	+	+++
	2				+	+++
	3				+	+++
	4				+	+++
	5				+	+++
	Detection rate					100%
ncov-PS-Ag150	1	Omicron	B.1.1.529	GR/484A	+	+++
	2				+	+++
	3				+	+++
	4				+	+++
	5				+	+++
	Detection rate					100%







Figure 2. Raw data recording

#### 4. Study Conclusion

By performing the SARS-CoV-2 N-protein antigen test using recombinant antigen (include 1 wild-type and mutant strain Omicron) on the WESAIL COVID-19 Ag Test Kit at concentration of 0.1ng/mL and 1ng/mL, the results show that the WESAIL COVID-19 Ag Test Kit remains capable of detecting the mutated recombinant N-protein from COVID-19 mutant strain of Omicron (B.1.1.529) with a 100% detection rate from designed experiment.

#### Note:

This report is limited to the results of recombinant antigen verification of mutant strain N under the conditions of WESAIL laboratory, thus the verification of detection of relevant COVID-19 N protein antibodies against mutant strain requires further research on the clinical specimens. The result in the report is only for detect the Nucleocapsid recombinant antigen of the mutant strain based on WESAIL 's laboratory condition, thus test on clinical samples are needed for further validation.

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