

SARS-CoV-2 antigen Test Kit (LFIA)
Mutation Virus (NPs) Detection Performance
Report

Sponsor: Jiangsu Medomics Medical Technology Co., Ltd.

F3, Building C, No.3-1 XinjinhuRoad, Jiangbei New Area, 210000, Nanjing, Jiangsu,
P.R.China

1. Aim

The study is performed to verify SARS-CoV-2 antigen Test Kit (LFIA) detection performance of mutation virus (NPs).

2. Background

The Medomics antigen test kit detects the nucleocapsid protein, NOT the spike protein of SARS-CoV-2. The mutation of B.1.1.7 is at positions 3, 203, 204, and 235 on the nucleocapsid protein, the mutation of variant B.1.351 is at position 205 on the nucleocapsid protein. The mutation B.1.1.28 is at position 80 on the nucleocapsid protein. The mutation B.1.617 is at position 203 and 377. The B.1.526 is at position 199 and 234. The B.1.617.2 is at position 63, 203 and 377. The B.1.427/B.1.429 is at position 152, 452 and 614 of S protein. The B.1.525 is at position 12 and 205. The C.37 is at position 13, 203, 204 and 214. The B.1.621 is at position 205.

It is necessary to verify the Medomics test kit performance to SARS-CoV-2 mutation strain mentioned above.

3. Materials and Methods

Recombinant Nucleocapsid Proteins (NPs) of British variant, South African variant, Brazil variant, United States variant and Wild type were used to verify the detection performance. The details of NPs were listed as follow.

WHO label	Pango lineage	Mutation site	Expression host	Manufacturer	Lot number
Alpha	B.1.1.7	D3L, R203K, G204R, S235F	<i>E. coli</i>	Sino Biological	40588-V07E7
Beta	B.1.351 or 20C/501Y.V2	T205I	<i>E. coli</i>	Sino Biological	40588-V07E9
Gamma	B.1.1.28/P.1	P80R	<i>E. coli</i>	Sino Biological	40588-V07E11
Kappa	B.1.617/B.1.617.1	R203M, D377Y	<i>E. coli</i>	Sino Biological	40588-V07E20
Delta	B.1.617.2	D63G, R203M, D377Y	<i>E. coli</i>	Sino Biological	40588-V07E29
Iota	B.1.526	P199L, M234I	<i>E. coli</i>	Sino Biological	40588-V07E18
Epsilon	B.1.427/B.1.429	W152C, L452R, D614G	<i>E. coli</i>	Sino Biological	40591-V08H17
Eta	B.1.525	A12G, T205I	<i>E. coli</i>	Sino Biological	40588-V07E19

Lambda	C.37	P13L, R203K, G204R, G214C	<i>E. coli</i>	Sino Biological	40588-V07E31
Mu	B.1.621	T205I	<i>E. coli</i>	Sino Biological	40588-V07E9
/	Wild Type	/	<i>E. coli</i>	Sino Biological	40588-V07E

Nucleocapsid Protein is added into lysis buffer and mixed sufficiently, and then diluted to 50ng/ml, 25ng/ml, 10ng/ml, 5ng/ml, 2.5ng/ml, 1.0ng/ml, 500pg/ml with lysis buffer. Lysis buffer is used as negative control.

Add 100 μ l diluent into each test well. Results should be observed within 15-20 minutes.

Record the lowest concentration which can be detected.

4. Results

The test results are listed in the following table.

***Note:** “ - ” means negative. “ +++ ” means strong positive. “ ++ ” means medium positive. “ + ” means positive. “ +- ” means weak positive.

Variant Level	Alpha	Beta	Gamma	Kappa	Delta	Lambda	Iota	Epsilon	Eta	Mu	Wild Type
50ng/ml	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++
25ng/ml	++	++	++	++	++	++	++	++	++	++	++
10ng/ml	++	++	++	++	++	++	++	++	++	++	++
5ng/ml	+	+	+	+	+	+	+	+	+	+	+
2.5ng/ml	+	+	+	+	+	+	+	+	+	+	+
1.0ng/ml	+-	+-	+-	+-	+-	+-	+-	+-	+-	+-	+-
500pg/ml	-	-	-	-	-	-	-	-	-	-	-

5. Conclusion

Medomics SARS-CoV-2 Ag test kit can detect the nucleocapsid protein of mutation virus strain B.1.1.7, B.1.351 or 20C/501Y.V2, B.1.1.28/P.1, B.1.617/B.1.617.1, B.1.617.2, B.1.526, B.1.427/B.1.429, B.1.525, C.37, B.1.621 and test results is consistent with wild type. Therefore, virus mutation above has no effect on the detection performance of the Medomics SARS-CoV-2 Ag test kit. The lowest Sino Biological Nucleocapsid Protein concentration which can be detected is around 1 ng/ml.