Overview of Ability to Detect New COVID-19 variant EG.5 and EG.5.1

Purpose

An overview for RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test) have been performed on the test's ability to detect new COVID-19 variant EG.5 and EG.5.1.

Material

Product: RIGHTSIGN COVID-19 Ag+ BSS
RIGHTSIGN Combo FLU/Covid
RIGHTSIGN Combo FLU/Covid/RSV
Samples: Nucleocapsid protein of COVID-19 variant EG.5 and EG.5.1

Method

1. Test the detection limit of RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test)by diluting Nucleocapsid protein of COVID-19 variant EG.5 and EG.5.1.
2. The Epitope(s) locations of anti-SARS-CoV-2 antibody used for RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid (COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV (COVID-19 antigen test) and the sequences of each mutant virus strain were compared and analyzed, so as to determine the detection status of each mutant virus strain by the coronavirus detection products.

Result:

1. Detection Limit of Nucleocapsid protein of COVID-19 variant EG.5 and EG.5.1

The detection limit of Nucleocapsid protein of COVID-19 variant EG.5 and EG.5.1 showed in table below:

WHO label	Nucleocapsid protein mutation site	Corresponding recombinant Nucleocapsid protein information		Detection limit
		Lot	Concentration	
EG.5	P13L, del31/33, R203K, G204R, S413R	20220105	3.68mg/ml	4.672pg/ml
EG.5.1	P13L, del31/33, R203K, G204R, S413R	20220105	3.68mg/ml	4.672pg/ml

2. Compared and analyzed the Epitope(s) locations of anti-SARS-CoV-2 antibody and the sequences of each mutant virus strain

2.1 Intended use of RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test)

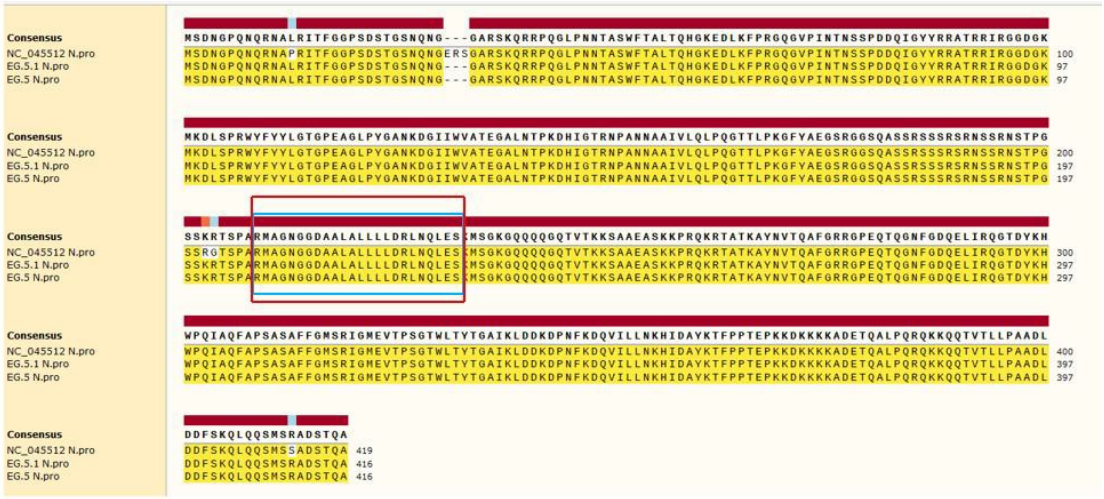
The RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen. The identification is based on monoclonal antibodies specific to the Nucleocapsid(N)protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

2.2 Reagents of RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test)

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein antibody particles conjugate and anti-SARS-CoV-2 Nucleocapsid protein antibody coated onto the membrane. The Epitope(s) locations of anti-SARS-CoV-2 antibody used for coating on the membrane is 209-232, and the Epitope(s) locations of anti-SARS-CoV-2 antibody used for conjugation is 209-232.

2.3 Nucleocapsid(N)protein Comparison results of the Epitope(s) locations of

anti-SARS-CoV-2 antibody and the sequences of New COVID-19 variant EG.5 and EG.5.1



2.4 The Result of analysis

Comparing the mutations that occur on the nucleocapsid protein of the New COVID-19 variant(EG.5 and EG.5.1) and the epitopes (the part of the antigen that binds to the antibody) of the antibodies used on the test, it was determined that all mutations are outside the epitopes of the antibodies used in the test. This indicates that the binding of the antibodies and the antigen will likely not be affected, therefore, the risk of the new variant not being detected by the RIGHTSIGN COVID-19 Ag+ BSS , RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test) ,RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test) is low.

Conclusion

From the above results of detecting diluted nucleocapsid protein of variant virus, comparing and analysing the Epitope(s) locations of anti-SARS-CoV-2 antibody and the sequences of each mutant virus strain, it can be inferred that to a large extent RIGHTSIGN COVID-19 Ag+

BSS, RIGHTSIGN Combo FLU/Covid(COVID-19 antigen test), RIGHTSIGN Combo FLU/Covid/RSV(COVID-19 antigen test) product is capable of detecting COVID-19 variant EG.5 and EG.5.1.