

Verification report of the COVID-19 antigen rapid test kit for spike protein and nucleocapsid protein

Test purpose

The purpose of this test is to verify the sensitivity of Gensure COVID-19 antigen rapid test kit against COVID-19 Spike protein and nucleocapsid protein.

Materials

Spike protein (S-RBD his tag): concentration: 30ug/ml; Nucleocapsid protein: concentration: 30ug/ml;

Test Method

Prepare 4 concentrations for each protein: 0.1ng/ml, 0.05ng/ml, 0.01 ng/ml, 0.005 ng/ml. Use the COVID-19 antigen rapid test kit (produced by Gensure Biotech Inc). for testing. Repeat the test 10 times for each concentration, statistical results.

Table 1 Test results for Nucleocapsid protein of different concentrations

Test \ Con.	0.1ng/ml	0.05 ng/ml	0.01 ng/ml	0.005 ng/ml
1	+	+	+	+
2	+	+	+	+
3	+	+	+	-
4	+	+	+	+
5	+	+	+	+
6	+	+	+	-
7	+	+	+	+
8	+	+	+	-
9	+	+	+	+
10	+	+	+	+
Positive rate	100%	100%	100%	70%

Remarks: "+" means positive result; "-" means negative result.

Table 2 Test results for Spike protein of different concentrations

Test \ Con.	0.1ng/ml	0.05 ng/ml	0.01 ng/ml	0.005 ng/ml
1	-	-	-	-
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
7	-	-	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Positive rate	0	0	0	0

Remarks: "+" means positive result; "-" means negative result.

Conclusion

Due the conservation of the Nucleocapsid protein sequence and its strong immunogenicity, the Nucleocapsid protein coronavirus is chosen as a diagnostic tool. According to the recent report, most variants, such as B.1.1.7(UK),B.1.351(South Africa), P.1(Brazil) are related to the Spike protein RBD. Few reports showed the mutants for Nucleocapsid protein.

As indicated in the tables above, Gensure COVID-19 antigen rapid test kit has a high detection sensitivity for the COVID-19 Nucleocapsid protein and there is no cross-reaction with Spike protein. Therefore, Spike protein mutants might not affect the detection of the COVID-19 by this product.



Reference

1. <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html>
2. <https://elifesciences.org/articles/61312>
3. <https://pubmed.ncbi.nlm.nih.gov/33014893>

