HIGHTOP

Test report of different variant of

HIGHTOP SARS-CoV-2 Antigen Rapid Test

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1 Purpose

The purpose of this report was to confirm whether Qingdao Hightop SARS-CoV-2 Antigen Rapid Test can detect different SARS-CoV-2 variants.

HIGHTOP Antigen Rapid Test for self-application is used to detect SARS-CoV-2 nucleoprotein antigens within 7 days of the onset of symptoms suspected of coronavirus infection. Positive test results can be used for early isolation and rapid treatment of suspected cases, but they cannot serve as a basis for a definitive diagnosis of coronavirus infection.

2 Experimental materials

2.1 Trial reagent

Product Name: SARS-CoV-2 Antigen Rapid Test

Lot no.: 200801

Manufacturer: Qingdao Hightop Biotech Co., Ltd.

2.2 Comparator reagent for negative sample

Product name: COVID–19 Coronavirus Real Time PCR Kit

Specifications: 25 tests

Manufacturer: Jiangsu Bioperfectus Technologies Co., Ltd.

PCR System: ABI 7500 Fast Real-Time PCR System

Viral RNA extraction kit: QIAamp Viral RNA Mini Kit

3 Experimental samples

The different SARS-CoV-2 variant samples were established by using different recombination nucleocapsid protein from different SARS-CoV-2 variants list in table below. The protein was spiked into the pooled negative sample matrix from multiple healthy volunteers confirmed by nucleic acid

detection.

Sample No.	Variants	First found in
Var001	B.1.1.7	United Kingdom
Var002	B.1.351	South Africa
Var003	P.1	Brazil
Var004	B.1.429	United States of America
Var005	B.1.427	United States of America
Var006	B.1.617	India
Var007	B.1.617.1	India
Var008	B.1.617.2	India
Var009	B.1.617.3	India
Var0010	P.2	Brazil
Var0011	A.23.1 with E484K	England, UK
Var0012	B.1.1.7 with E484K	England, UK
Var0013	B.1.525 previously designated UK1188	England, UK
Var0014	B.1.1.318	England, UK
Var0015	P.3	Philippines
Var0016	AV.1	TBC
Var0017	B.1.1.529	Many countries

4 Experimental process

The study for Qingdao Hightop SARS-CoV-2 Antigen Rapid Test on different SARS-CoV-2 Variants was performed by diluting above protein to 0.1ng/mL with the pooled negative sample matrix obtained from multiple healthy volunteers eluted. Test above diluted SARS-CoV-2 variant protein samples with Qingdao Hightop SARS-CoV-2 Antigen Rapid Test and record the test results.

5 Test result

The test results of 17 SARS-CoV-2 Variant protein samples in triplicate were as table 1.

Table 1 The test results of 17 SARS-CoV-2 Variant protein samples

SARS-CoV-2 Variants	200801		
	Rep1	Rep2	Rep3
Var001	+	+	+
Var002	+	+	+
Var003	+	+	+
Var004	+	+	+
Var005	+	+	+
Var006	+	+	+
Var007	+	+	+
Var008	+	+	+
Var009	+	+	+
Var0010	+	+	+
Var0011	+	+	+
Var0012	+	+	+
Var0013	+	+	+
Var0014	+	+	+
Var0015	+	+	+
Var0016	+	+	+
Var0017	+	+	+

Note: “-” means negative; “+” means positive.

6 Conclusion

Qingdao Hightop SARS-CoV-2 Antigen Rapid Test detect nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab from patients who are suspected of SARS-COV-2 infection. From results above, current test can detect all recombinant nucleocapsid protein from different SARS-CoV-2 variants at cut-off level 0.1ng/mL. That the study can conclude that Qingdao Hightop SARS-CoV-2 Antigen Rapid Test can detect the nucleocapsid protein of the following variants – B.1.1.7 , B.1.351, P.1, B.1.429, B.1.427, B.1.617, B.1.617.1, B.1.617.2 , B.1.617.3, P.2, A.23.1 with E484K, B.1.1.7 with E484K, B.1.525 previously designated UK1188, B.1.1.318, P.3, AV.1 and B.1.1.529.

Dec.2nd, 2021

Statement on the Detection of SARS-CoV-2 Variants B 1.1.1.529 (WHO Label: Omicron)

To Whom It May Concern:

We, Qingdao Hightop Biotech Co., Ltd., as the manufacturer of HIGHTOP SARS-CoV-2 Antigen Rapid Test, hereby declare that we have been continuously monitoring the emergence of a new strain of SARS-CoV-2. The variants of SARS-CoV-2 have some mutations in the spike protein and a few mutations in the nucleocapsid protein. According to verification, HIGHTOP SARS-CoV-2 Antigen Rapid Test can effectively detect Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2).

There is no evidence showing that the recently discovered SARS-CoV-2 Variants B 1.1.1.529 (WHO Label: Omicron) will affect the test performance of our SARS-CoV-2 Antigen Rapid Test based on bioinformatic analysis and the fact that according to the currently publicly available information mainly the Spike protein is mutated, and our rapid tests measure the N protein of the virus. Lab tests are being carried out for further assessment. We will continue to track the latest viral information and adapt the detection ability of our test kit against the SARS-CoV-2 variants to maintain the sensitivity and specificity.

Sincerely
QINGDAO HIGHTOP BIOTECH CO., LTD.