SARS-CoV-2-Antigen Rapid Qualitative Test Kit Clinical Report

Project Name:SARS-CoV-2-Antigen Rapid Qualitative Test Kit clinical test

Testing Time:2020.01~2020.7

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目 录

1. Experimental design

1.1 Overall design and scheme description of the test

Blind data analysis was used in this clinical study， Use Xiamen Biotime Biotechnology Co., Ltd. Manufacture SARS-CoV-2-Antigen Rapid Qualitative Test Kit (Colloidal Gold). The detection results of the samples were compared with PCR method for comparative study. After the end of the test, the blinding was uncovered, the cause of the inconsistencies was analyzed, and all the inconsistencies in the test should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, disease outcome and other information.

1.2 Test Methods

（1）The nasal swabs of 75 patients with novel Coronavirus nucleic acid positive and 220 subjects with novel Coronavirus nucleic acid negative were tested simultaneously using the product and PCR method to evaluate the sensitivity, specificity and accuracy of the product。

（2）Homologous pharyngeal swab samples were collected from the above samples: 25 positive samples, 20 weakly positive samples, and 25 negative samples were required to evaluate the consistency of nasal swabs and pharyngeal swabs。

1.3 Test sample requirements

1.3.1 Sample type

The samples were nasal swabs and pharyngeal swabs。

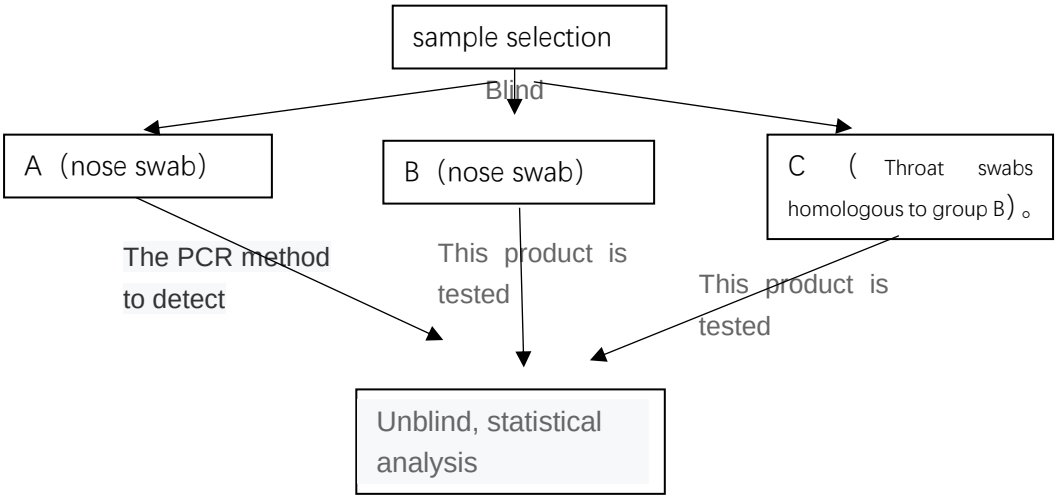
1.3.2 Inclusion criteria for clinical trial samples

(1) Confirmed cases of pneumonia infected by novel Coronavirus: patients with positive nucleic acid from novel Coronavirus were selected。

(2) Confirmed cases of pneumonia infected with pneumonia other than novel Coronavirus: patients with nucleic acid negative of Novel Coronavirus were selected。

1.4 Sample Test

1.4.1 Test flow chart



2. Clinical trial results and analysis

2.1 Basic data statistics

The sensitivity, specificity and accuracy were calculated and the 95% confidence intervals were calculated respectively。

Method		PCR Test		Total Results
Biotime KIT	Results	positive	Negative	
	positive	72	0	72
	Negative	3	220	223
Total Results		75	220	295

Relative Sensitivity:	72/75	96.00% (88.75%～99.17%)
Relative Specificity:	220/220	100.00% (98.34%～100.00%)
Accuracy:	292/295	98.98% (97.06%～99.79%)

2.2 Homology comparison analysis

2.2.1 Homology comparison test results

Sample NO.	Nasal swab	Throat swab
P1	+++	+++
P2	+	+
P3	++	+

P4	+	+
P5	++	++
P6	+	+
P7	++	+
P8	+	+
P9	++	++
P10	+	+
P11	+++	++
P12	+	+
P13	++	++
P14	++	+
P15	+	+
P16	+++	+++
P17	+	+
P18	+++	+++
P19	++	++
P20	+++	++
P21	+	+
P22	+	+
P23	+	+
P24	+	+
P25	+	+
N1	-	-
N2	-	-
N3	-	-
N4	-	-
N5	-	-
N6	-	-
N7	-	-
N8	-	-
N9	-	-

N10	-	-
N11	-	-
N12	-	-
N13	-	-
N14	-	-
N15	-	-
N16	-	-
N17	-	-
N18	-	-
N19	-	-
N20	-	-
N21	-	-
N22	-	-
N23	-	-
N24	-	-
N25	-	-

Annotation：P1-P25 of samples are from infected people , and NI-N25 are from uninfected people. P21-P25 are weekly positive.

3. Conclusion

The consistency between PCR method and this product is good. There was no difference between nasal and pharyngeal swabs.