COVID-19 Ag Test

Diagnostic Sensitivity and Diagnostic Specificity Test Report

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1.Test purpose

The "COVID-19 Ag Test" product produced by Core Technology Co., Ltd. was used to detect different samples confirmed by nucleic acid detection, and the diagnostic sensitivity and specificity were analyzed according to the detection.

Researchers and responsibilities

Coordinator:Lu Qiyong

Responsibilities:Project leader, report drafter and product performance evaluation reviewer.

Investigator: Cui Weina

Responsibilities: Test the samples and record the test results.Summary of final test results.

Investigator: Zeng Luying

Responsibilities:Blind number the collected samples.

Performance evaluation location: Shijiazhuang No.5 hospital, Chongqing Public health medical treatment center and Wuhan Jinyintan Hospital.

2. Reagents and materials

2.1 Test strip

Assessment reagent: COVID-19 Ag Test

Manufacturer: Core Technology Co., Ltd.

Model: Cassette 1 test /pouch

Lot: 20200525

Storage conditions: 2-30℃

Nucleic acid diagnostic reagent：Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR- Fluorescence Probing)

Manufacturer: Da An Gene Co., Ltd. Of Sun Yat-sen University

Registration Certificate No： National Medical Instrument Registration Approval No. 20203400063

2.2 Experimental design

2.2.1 Selection of samples

In this study, 655 samples of nasopharyngeal swabs were tested by nucleic acid test for COVID-19, and the results were recorded. 155 samples were positive for nucleic acid test. 500 were negative for COVID-19 nucleic acid test, including some non-COVID-19 positive and other virus positive specific nasopharyngeal swab samples.

Table1 Clinical sample information

Country	China
Total Number	655
Age[mean (min-max), N]	40 (4-84), 655
Gender [%F, (n/N)]	54.2%(355/655)
Days < 0-3 (n, %)	285(43.5%)
Days 4-7 (n, %)	180(27.5%)
Days 8+ (n, %)	190(29.0%)
Positivity [%, (n/N)]	23.7%(155/655)
PCR Ct > 33 (n, %)	12(7.7%)
33≥PCR Ct > 25 (n, %)	75(48.4%)
PCR Ct≤25（n, %）	68(43.9%)

2.2.2 Sample requirements

It is recommended to treat the sample immediately after collection.The sample can be stored at 2℃~8℃ for 72 hours, and it needs to be frozen at -20℃ for long-term storage, avoiding repeated freezing and thawing.

2.2.3 Test method

Strictly operate in accordance with the reagent instructions, and determine the test results within the time specified in the instructions. Synchronous blind operation must be performed by professional laboratory testers during operation.

2.3 Test results

2.3.1 Core test result

The diagnostic sensitivity and specificity of the test results are given as below:

		Results of Nucleic acid detection test		Total Result
		Positive	Negative	
Results of Coretests COVID-19 Ag test	Positive	152（A）	2（B）	154
	Negative	3（C）	498（D）	501
Total Results		155	500	655

Analysis of results: 3 samples were false negative for examination reagent, and the samples were early samples of infection. 2 samples showed examination reagent false positive..

Positive coincidence rate (diagnostic sensitivity): A / (A + C) × 100% =98.1%（95%CI 94.5%~99.6%）

Negative coincidence rate (diagnostic specificity): D / (B + D) × 100% = 99.6%（95%CI 98.6%~100%）

Total compliance rate (accuracy): (A + D) / (A + B + C + D) × 100% = 99.2%（95%CI 98.2%~99.8%）

Calculation of Kappa (K) value of consistency coefficient: Kappa (K) = 2 (AD-BC) / [(A + B) (B + D) + (A + C) (C + D)] = 0.9788

3 Results analysis

Table2 Estimations of Clinical and Analytical Performance

Country	China
Clinical Sensitivity (95% CI), n/N	98.1%(94.5%~99.6%),152/155
Sensitivity days ≤7, (%,n/N)	98.6%,136/138
Sensitivity days ＞7, (%,n/N)	94.7%,18/19
Sensitivity PCR Ct ≤ 33,(%,n/ N)	99.3%,142/143
Sensitivity PCR Ct ≤ 25, N	98.5%,67/68
Clinical Specificity (95% CI), n/N	99.6%(98.6%~100%),498/500
Invalid rate (%, n/N)	0%,0/655
Accuracy(95%CI),n/N	99.2%(98.2%~99.8%),650/655

The "COVID-19 Ag Test" produced by Core Technology Co., Ltd. tested 655

nasopharyngeal swab samples.

The positive coincidence rate was 98.1%, the negative coincidence rate was 99.6%, and the total coincidence rate was 99.2%. K = 0.9788 showed good consistency.

There were 138 samples with symptom onset ≤ 7 days, 2 cases were missed, and the positive detection rate was 98.6%. There were 18 samples with symptom onset> 7 days, and 1 case was missed, with a positive detection rate of 94.7%.

Within 7 days of the onset of symptoms, the virus multiplies rapidly in the body, excretes a large amount of toxins, high antigen content, and high detection rate. As the human immune system takes effect, the virus is gradually eliminated, the amount of toxins discharged is reduced, the antigen content is reduced, and the detection rate is reduced.

Nucleic acid reagents detected 143 samples with Ct ≤ 33, and 1 missed the test, with a positive detection rate of 99.3%, 68 samples with a Ct value ≤ 25, and 1 missed the test with a positive detection rate of 98.5%.

The Ct value of nucleic acid detection represents the content of virus in the sample. The larger the Ct value, the lower the virus content.

655 samples of nasopharyngeal swabs were tested, no invalid results were found, and the inefficiency was 0%.