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

Specimen：Nasal Swab

Manufacturer: Core Technology Co., Ltd.

Model: Cassette 1 test /pouch

Lot: 20200621

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：国械注准 20203400063

2.2 Experimental design

2.2.1 Selection of samples

In this study, 415 samples of nasal swabs were tested by nucleic acid test for COVID-19, and the results were recorded. 155 samples were positive for nucleic acid test. 260 were negative for COVID-19 nucleic acid test, including some non-COVID-19 positive and other virus positive specific nasopharyngeal swab samples.

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

A study using a total 415 nasal swab samples was conducted. Test results of Coretests ® COVID-19 Ag test were compared with nucleic acid detection test. The diagnostic sensitivity and specificity of the test results are shown in Table ：

Coretests ® COVID-19 Ag Test(nasal Swab)

Reference		Results of Nucleic acid detection test		Total Result
		Positive	Negative	
Results of COVID-19 Ag test	Positive	152	2	154
	Negative	3	258	261
Total Results		155	260	415

Results gave sensitivity is 98.1% (152/155), specificity is 99.2%(258/260), and a total agreement of 98.8%(410/415).

3. Conclusion

The "COVID-19 Ag Test" produced by Core Technology Co., Ltd. tested 415 nasal swab samples.

The Clinical Sensitivity was 98.1%(94.45%~99.06%), the Clinical Specificity was

99.2%(97.25%~99.91%), and the accuracy was 98.8%(97.21%~99.61%).