# COVID-19 Ag Test

# Diagnostic Sensitivity and Diagnostic Specificity Test Report

| | |
|---|---|
| File No. | CORE-CE-COVID Ag-09 |
| Version | V1.0 |
| Eff Date | 2020.07.05 |
| Prepared by | Lu Qiyong |
| Prepared on | 2020.07.05 |
| Approved by | Chen Lizhu |
| Approval date | 2020.07.05 |

**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：国械注准 20203400063

2.2 Experimental design

2.2.1 Selection of samples

In this study, 170 samples of nasopharyngeal swabs were tested by nucleic acid test for novel coronavirus, and the results were recorded. 80 samples were positive for nucleic acid test. The remaining samples were negative for novel coronavirus nucleic acid test, including some non-novel coronavirus 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

2.3.1 Core test result

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

| Reference | | Results of Nucleic acid detection test | | Total Result |
|---|---|---|---|---|
| | | Positive | Negative | |
| Results of Coretests COVID-19 Ag test | Positive | 78（A） | 0（B） | 78 |
| | Negative | 2（C） | 90（D） | 92 |
| Total Results | | 80 | 90 | 170 |

Analysis of results: There were 2 discrepancies in the test results, They are with low copies in the early stage of infection.

Positive coincidence rate (diagnostic sensitivity): A / (A + C) × 100% = 97.5%（95%CI 91.26%~99.70%）

Negative coincidence rate (diagnostic specificity): D / (B + D) × 100% = 100%（95%CI 95.98%~100%）

Total compliance rate (accuracy): (A + D) / (A + B + C + D) × 100% = 98.8%（95%CI 95.81%~99.86%）

Calculation of Kappa (K) value of consistency coefficient: Kappa (K) = 2 (AD-BC) /

$[(A + B) (B + D) + (A + C) (C + D)] = 0.9764$

**3 Results analysis**

The "COVID-19 Ag Test" produced by Core Technology Co., Ltd. tested 170 nasopharyngeal swab samples:

The positive coincidence rate was 97.5%, the negative coincidence rate was 100%, and the total coincidence rate was 98.8%. K = 0.9764 showed good consistency.