

## **COVID-19 Saliva Ag**

### **Diagnostic sensitivity and diagnostic specificity test report**

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## 1. Test purpose

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

## 2. Reagents and materials

### 2.1 Test information

Assessment reagent: COVID-19 Saliva Ag Test

Manufacturer: Core Technology Co., Ltd.

Specification: 1 test /pouch

Batch number: 20200528

Storage conditions: 2-30°C

### 2.2 Experimental design

#### 2.2.1 Selection of samples

In this study, 712 samples of saliva were tested by nucleic acid test for COVID-19, and the results were recorded. 165 samples were positive for nucleic acid test. 547 samples were negative for COVID-19 nucleic acid test, including non COVID-19 positive and virus positive specific saliva samples.

#### 2.2.2 Sample requirements

It is recommended to treat the sample immediately after collection. The sample can be stored at 2~8 °C for 72 hours, and it needs to be frozen at -20 °C 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

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

	Results of Nucleic acid detection test	Total Results
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		Positive	Negative	
Results of Coretests	Positive	161 (A)	5(B)	166
COVID-19 Saliva Ag Tset	Negative	4 (C)	542(D)	546
Total Results		165	547	712

Positive coincidence rate (diagnostic sensitivity):  $A / (A + C) \times 100\% = 97.6\%$

(95%CI 93.9%~99.3%)

Negative coincidence rate (diagnostic specificity):  $D / (B + D) \times 100\% = 99.1\%$

(95%CI 97.9%~99.7%)

Total compliance rate (accuracy):  $(A + D) / (A + B + C + D) \times 100\% = 98.7\%$

(95%CI 97.6%~99.4%)

Calculation of Kappa (K) value of consistency coefficient:  $Kappa (K) = 2 (AD-BC) / [(A + B) (B + D) + (A + C) (C + D)] = 0.9646$

### 3.Conclusion

The "COVID-19 Saliva Ag Test" produced by Core Technology Co., Ltd. tested 712 saliva samples:

The positive coincidence rate was 97.6%, the negative coincidence rate was 99.1%, and the total coincidence rate was 98.7%.  $K = 0.9646$  showed good consistency.