COVID-19 Ag Test

Diagnostic Sensitivity and Diagnostic Specificity Test Report

File No.	CORE-CE-COVID Ag-09
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Prepared by	Lu Qiyong
Approved by	Chen Lizhu

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.

2. Reagents and materials

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

3. Protocol

3.1 Sample Size:
Positive Sample: >100
Negative Sample:>200

3.2 Selection of samples

Nasal swab specimen can be used by Coretests COVID-19 Ag Test to detect the presence of COVID-19 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on nasal swab specimens. All swabs were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

3.3 Sample Entry criteria:

The samples from hospital outpatient screening cases and COVID-19 Patients who presented within 9 days of symptom onset;

Samples of people that gender and age are not limited.

3.4 Sample Exclusion criteria:

Samples without PCR test results;

Samples that the quantity is not enough to complete the test; Samples with failed test results (C-line has not appeared); Freeze samples repeatedly.

3.5 Comparator method

All samples was confirmed by PCR.

PCR tests used from Da An Gene Co., Ltd. Of Sun Yat-sen University

4. Clinical stuy site:

Site 1：Shijiazhuang No.5 hospital,

Site 2：Chongqing Public health medical treatment center,

Site 3：Wuhan Jinyintan Hospital.

5. Statistical methods

5.1 Statistical of test result

Reference		Referencing reagent Test		Total Result
		Positive	Negative	
Research reagents	Positive	A	B	A+B
	Negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

Percent Positive Agreement=A/(A+C)*100%

Negative Percent Agreement=D/(B+D)*100%

Overall Agreement=(A+D)/(A+B+C+D)*100%

5.2 Statistical of Specimens correlation

Record and statistics the correlation of antigen-positive/PCR-positive and antigen-negative/PCR-positive samples with the Ct values of the PCR to determine the mean Ct value of antigen-positive samples

6. Evaluation indicators:

The total PPA should be no less than 85%.

The total NPA should be no less than 95%.

7. Statistical results of the clinical evaluation

7.1 Test result

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

7.2 Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA（%）	152/155	98.1%(94.5%~99.6%)
Relative Specificity-NPA（%）	258/260	99.2%(97.3%~99.9%)
Overall Agreement（%）	410/415	98.8%(97.2%~99.6%)

7.3 Kappa consistency test

Kappa Value :0.9742, Good consistency.

Standard Error Se(K) :0.0115

95% Confidence Interval :0.9518～0.9967

Standard Error Se0(K) :0.049

Test Value Z :Z=19.8467, Probability value P=0.0000

Test Result: P<0.05,refuse H0，Kappa values come from populations other than 0.

7.4 Specimens correlation

The performance of Coretests COVID-19 Ag Test with positive results stratified by the comparator method (Ct) counts were collected and assessed to determine the correlation of assay performance to the Ct.

Coretests COVID-19Ag Test	Comparator Method (POS by Ct≦40)		
	Ct≤25	25<Ct≤32	Ct>32
Positive	120	25	4
Negative	0	1	2
Total	120	26	6
Positive Agreement(95% CI)	100.0% (97.0%～100.0%)	96.2% (80.4%～99.9%)	66.7% (22.3%～95.7%)

Based on above table, the positive agreement of the Coretests COVID-19 Ag Test is higher with samples of a Ct count≤32.

8. Conclusion

A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:

The Relative Sensitivity is 98.1%, the Relative Specificity is 99.2%, the Overall Agreement is 98.8%.

In summary, The study showed that there is a high coincidence rate between the test-strip and RT-PCR, and have the equivalence on the clinical usage.