

Clinical Evaluation Supplementary Report

1. Purpose:

Additional verify the clinical performance of the improved test (used sample matrix: nasal swab samples)

2. Material:

Fresh negative COVID-19 samples were collected from the hospital and validated by PCR.

Fresh positive COVID-19 samples were collected from CDC and validated by PCR.

Product used: COV20082701

3. Protocol:

3.1 Sample Size:

Positive Sample: >100

Negative Sample:>150

3.2 Sample's collection:

Two nasal swabs were collected from patients. All swabs were randomly blinded. One nasal swab was tested directly with Safecare COVID-19 Ag Card test kit according to product instructions. The other swab was 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 7 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 RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing) manufactured by Sansure BioTech Inc.

PCR tests performed on ABI7500.

4. Operator and site:

Site 1: CDC-Immunology Laboratory

Researcher: Dr. Zhang Lei

Site 2: Hospital- Immunology Laboratory

Researcher: Dr.Xuwei

5. Statistical methods:

5.1 Statistical of test result

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	A	B	A+B
	Negative	C	D	C+D
Total		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 80%.

The total NPA should be no less than 90%.

7. Statistical results of the clinical evaluation

7.1 Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	118	1	119
	Negative	3	165	168
Total		121	166	287

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA (%)	118/121	97.52% (92.93%~99.49%)
Relative Specificity-NPA (%)	165/166	99.40% (96.69%~99.98%)
Overall Agreement (%)	283/287	98.61% (96.47%~99.62%)

7.2 Kappa consistency test

Calculate the Kappa value and standard error; test hypothesis is established for Kappa: H0: $k = 0$, Kappa value comes from 0 population, H1: $k > 0$, Kappa value comes from non-0 population, $\alpha = 0.05$.

Project	Value
Kappa Value	0.9714, Good consistency.
Standard Error Se(K)	0.0142
95% Confidence Interval	0.9435~0.9992
Standard Error Se0(K)	0.059
Test Value Z	Z=16.4575 Probability value P=0.0000
Test Result	P<0.05, refuse H0, Kappa values come from populations other than 0.

7.3 Specimens correlation

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

Safecare COVID-19 Antigen Rapid Test	Comparator Method (POS by Ct \leq 40)	
	Ct<30	Ct \geq 30
Positive	117	1
Negative	0	3
Total	117	4
Positive Agreement(95% CI)	100.00% (97.14%~100.00%)	25.00% (0.63%~80.59%)

Based on above table, the positive agreement of the Safecare COVID-19 Antigen Rapid Test Kit (Swab) is higher with samples of a Ct count <30.

8. Conclusion

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

The Relative Sensitivity is 97.52%, the Relative Specificity is 99.40%, the Overall Agreement is 98.61%.

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.

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