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, α = 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≦40)	
	Ct<30	Ct≧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.

Reporter: Wu Gang Date: 2021.02.19