Clinical Evaluation Report

1 Purpose:

In order to verify the clinical performance of the improved test

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: COV20101001

3 Protocol:

1）Sample Size:

Positive Sample: >100

Negative Sample:>100

2）Sample's collection:

1oropharyngeal saliva and 1 oropharyngeal swab were collected at the same time from each patient. The oropharyngeal saliva was tested directly with Safecare COVID-19 Ag Card test kit according to product instructions. The oropharyngeal swab was eluted in viral transport media (VTM) .All samples were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

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.

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.

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:
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

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

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 95%.
The total NPA should be no less than 95%.

7 Statistical results of the clinical evaluation
1) Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	131	1	132
	Negative	2	182	184
Total		133	183	316

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA（%）	131/133	98.50%（94.67%~99.82%）
Relative Specificity-NPA（%）	182/183	99.45%（96.99%~99.99%）
Overall Agreement（%）	313/316	99.05%（97.25%~99.80%）

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	0.9805, Good consistency.
Standard Error Se(K)	0.0112
95% Confidence Interval	0.9585～1.0025
Standard Error Se0(K)	0.056
Test Value Z	Z=17.4302 Probability value P=0.0000
Test Result	P<0.05,refuse H0， Kappa values come from populations other than 0.

3) Specimens correlation

The performance of Safecare COVID-19 Antigen Rapid Test Kit(Saliva) 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	128	3
Negative	0	2
Total	128	5
Positive Agreement(95% CI)	100.00% (97.16%～100.00%)	60.00% (0.51%～71.64%)

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

8 Conclusion

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

The Relative Sensitivity is 98.50%, the Relative Specificity is 99.45%, the Overall Agreement is 99.05%.

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: 2021.01.25