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(ABI7500).
Fresh positive COVID-19 samples were collected from CDC and validated by PCR(ABI7500).
Product used: COV20082701

3. Operator and site:

The test was preformed by Wei Lihua/Zhen CaiWen at Safecare R&D lab.

4. Statistical methods:

		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%

5. Evaluation indicators:

The total PPA should be no less than 80%.
The total NPA should be no less than 90%.

6. Statistical results of the clinical evaluation

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	32	0	32
	Negative	1	83	84
Total		33	83	116

7. Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity（%）	32/33	96.97%（84.24%~99.92%）
Relative Specificity（%）	83/83	100%（95.65%~100%）
Positive expectation Rate（%）	32/32	100.00% (89.11%～100.00%)
Negative expected Rate（%）	83/84	98.81% (93.54%～99.97%)
Overall Agreement（%）	115/116	99.14%（95.29%~99.98%）

Kappa consistency test

According to the literature [5.1], 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	0.9786, Good consistency.
Standard Error Se(K)	0.0213
95% Confidence Interval	0.9369～1.0203
Standard Error Se0(K)	0.093
Test Value Z	Z=10,5426 Probability value P=0.0000
Test Result	P<0.05,refuse H0， Kappa values come from populations other than 0.

8. Conclusion

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

The Relative Sensitivity is 96.97%, the Relative Specificity is 100%, the Overall Agreement is 99.14%.

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: Wei Lihua Date: 2020.10.23