

## 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:  
 $H_0: k = 0$ , Kappa value comes from 0 population,  $H_1: k > 0$ , Kappa value comes from non-0 population,  $\alpha = 0.05$ .

Project	Value
<b>Kappa Value</b>	0.9786, Good consistency.
<b>Standard Error Se(K)</b>	0.0213
<b>95% Confidence Interval</b>	0.9369~1.0203
<b>Standard Error Se0(K)</b>	0.093
<b>Test Value Z</b>	Z=10,5426 Probability value P=0.0000
<b>Test Result</b>	P<0.05, refuse $H_0$ , 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.

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