Clinical Evaluation Report

1. **Purpose:**
   In order to verify the clinical performance of the registered test, this clinical evaluation is conducted.
2. **Product information:**
   COVID-19 Antigen Rapid Test Kit(Swab) was produced by Safecare Biotech(Hangzhou) Co.,Ltd., Lot number is COV20081001, valid until August,2022.
3. **Sample requirement:**
   Fresh samples were collected from CDC and validated by PCR.
4. **Supporting equipment:**
   PCR tests are performed on ABI7500.
   The test-strips are manually operated and visually interpreted.
5. **Clinical evaluation:**
   The test was preformed by Wei Lihua/Zhen CaiWen at R&D lab.
6. **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%

7. **Evaluation indicators:**

   The total PPA should be no less than 80%.
   The total NPA should be no less than 90%.
8. **The test data: Refer to the Data Sheet.**
9. **Statistical results of the clinical evaluation**

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	30	1	31
	Negative	3	52	55
Total		33	53	86

Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity（%）	30/33	90.91% (75.67%～98.08%)
Relative Specificity（%）	52/53	98.11% (89.93%～99.95%)
Positive expectation Rate（%）	30/31	96.77% (83.30%～99.92%)
Negative expected Rate（%）	52/55	94.55% (84.88%～98.86%)
Overall Agreement（%）	82/86	95.35% (88.52%～98.72%)

3) 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	0.9005, Good consistency.
Standard Error Se(K)	0.0485
95% Confidence Interval	0.8055 ~ 0.9956
Standard Error Se0(K)	0.108
Test Value Z	Z=8.3614, Probability value P=0.0000
Test Result	P<0.05,refuse H0 ， Kappa values come from populations other than 0.

4) Conclusion

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

The Relative Sensitivity is 90.91%, the Relative Specificity is 98.111%, the Overall Agreement is 95.35%.

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.