Clinical Evaluation Report

1. **Purpose:**
   In order to verify the clinical performance of the registered test, this clinical evaluation is conducted in R&D lab.

2. **Product information:**
   COVID-19 Antigen Rapid Test Device (Swab) was produced by Safecare Biotech(Hangzhou) Co.,Ltd., Lot number is COV20081201, 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:**
   Researcher: Dr. ZHANG LEI

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	0	30
	Negative	2	52	54
Total		32	52	84

Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity (%)	30/32	93.75% (79.19%~99.23%)
Relative Specificity (%)	52/52	100.00% (93.15%~100.00%)

Positive expectation Rate (%)	30/30	100.00% (88.43%~100.00%)
Negative expected Rate (%)	52/54	96.30% (87.25%~99.55%)
Overall Agreement (%)	82/84	97.62% (91.66%~99.71%)

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	0.9489, Good consistency.
Standard Error Se(K)	0.0357
95% Confidence Interval	0.8790~1.0188
Standard Error Se0(K)	0.109
Test Value Z	Z=8.7082, 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 93.75%, the Relative Specificity is 100%, the Overall Agreement is 97.62%.