Klinische Test-Studie

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: COV20082701

3. Protocol:
3.1 Sample Size:
Positive Sample: >100
Negative Sample:>150

3.2 Sample's collection:
Nasal swab specimen or nasopharyngeal swab specimen can be used by Safecare COVID-19 Antigen Rapid Test Kit(Swab) to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on both nasal swab specimens and nasopharyngeal swab specimen, no statistic difference was observed among those specimens. All swabs were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

3.3 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.

3.4 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.

3.5 Comparator method
All samples was confirmed by PCR.
PCR tests used from Sansure Biotech Inc. and performed on ABI7500.

4. Operator and site:
Site 1:
Study Site Info: ZHEJIANG PROVINCIAL CENTER FOR DISEASE CONTROL AND PREVENTION
Researcher: Dr. ZHANG LEI
Lab Name (or Hospital or Doctor's office) : Immunology Laboratory
Address: 3399 Binsheng Road, Binjiang District, Hangzhou City, Zhejiang Province
Site 2:
Study Site Info: THE FIRST AFFILIATED HOSPITAL ZHEJIANG UNIVERSITY SCHOOL OF MEDICINE
Researcher: Dr.Xuwei
Lab Name (or Hospital or Doctor's office):Immunology Laboratory
Address: No. No. 366, Wutong Road, Xihu District, Hangzhou, Zhejiang

5. Statistical methods:
5.1 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

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

5.2 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 80%.
The total NPA should be no less than 90%.

7. Statistical results of the clinical evaluation
7.1 Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	131	1	132
	Negative	4	179	183
Total		135	180	315

7.2 Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA (%)	131/135	97.04% (92.59%~99.15%)
Relative Specificity-NPA (%)	179/180	99.44% (96.94%~99.99%)
Overall Agreement (%)	310/315	98.41% (96.35%~99.48%)

7.3 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, a = 0.05.

Project	Value
Kappa Value	0.9675, Good consistency.
Standard Error Se(K)	0.0144
95% Confidence Interval	0.9392~0.9958
Standard Error Se0(K)	0.016
Test Value Z	Z=17.1747 Probability value P<0.0000
Test Result	P<0.05,refuse H0, Kappa values come from populations other than 0.

7.4 Specimens correlation

The performance of Safecare COVID-19 Antigen Rapid TestKit(Swab) 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<28	Ct ≥ 28
Positive	130	1
Negative	0	4
Total	130	5
Positive Agreement(95% CI)	100.00% (97.20%~100.00%)	20.00% (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 <28.

8. Conclusion

A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:
The Relative Sensitivity is 97.04%, the Relative Specificity is 99.44%, the Overall Agreement is 98.41%.
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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