Clinical Evidence Report

1. Purpose

The CoV-19 IgG/IgM Rapid Test Device (Whole Blood/Plasma/Serum) is a lateral flow immunoassay for the simultaneous detection and differentiation of anti-COVID-19 virus in human whole blood, serum or plasma. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with COVID-19 viruses. Any reactive specimen with the anti-COVID-19 Rapid Test must be confirmed with alternative testing method(s).. In order to evaluate the positive coincidence rate and negative coincidence rate of the COVID-19 Test Reagent, and validate that the COVID-19 Test Reagent is equivalent to a similar product, we designed this experiment.

2. Method

Testing was performed on approximately 229 specimens previously collected from ZHE FIRST AFFILIATED HOSPITAL ZHEJIANG UNIVERSITY and ZHEJIANG PROVINCIAL CENTER FOR DISEASE CONTROL AND PREVENTION. We provided the research reagent (The COVID-19 Test Reagent, Produced by Safecare Biotech (Hangzhou) Co. Ltd), They conduct a side-by-side comparison. The research reagent's result is compared with the the referencing method PCR (Novel Corona-virus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), Produced by Sansure Biotech Inc.). After a statistical study on the positive coincidence rate , negative coincidence rate and total coincident rate, we could judge the suitability of the tests.

3. Result

3.1 The result of ZHE FIRST AFFILIATED HOSPITAL ZHEJIANG UNIVERSITY.

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	21	5	26
	Negative	3	70	73
Total		24	75	99

3.1.1 Statistical results of test data

Project	Value	Percentage (95% Confidence Interval)
Relative Sensitivity（%）	21/24	87.50% (67.64% ~ 97.34%)
Relative Specificity（%）	70/75	93.33% (85.12% ~ 97.80%)
Positive expectation Rate（%）	21/26	80.77% (60.65% ~ 93.45%)
Negative expected Rate（%）	70/73	95.89% (88.46% ~ 99.14%)
Overall Agreement（%）	91/99	91.92% (84.70% ~ 96.45%)

3.1.2 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, $\alpha = 0.05$.

Project	Value
Kappa Value	0.79, Good consistency.
Standard Error Se(K)	0.072
95% Confidence Interval	0.64 ~ 0.93
Standard Error Se0(K)	0.100
Test Value Z	Z=7.83, Probability value P=0.0000
Test Result	P<0.05,refuse H0, Kappa values come from populations other than 0.

3.2 The result of ZHEJIANG PROVINCIAL CENTER FOR DISEASE CONTROL AND PREVENTION.

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	24	9	33
	Negative	5	87	92
Total		29	96	125

3.2.1 Statistical results of test data

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity（%）	24/29	82.76% (64.23% ~ 94.15%)
Relative Specificity（%）	87/96	90.63% (82.95% ~ 95.62%)
Positive expectation Rate（%）	24/33	72.73% (54.48% ~ 86.70%)
Negative expected Rate（%）	87/92	94.57% (87.77% ~ 98.21%)
Overall Agreement（%）	111/125	88.80% (81.92% ~ 93.74%)

3.2.2 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	0.70, Good consistency.
Standard Error Se(K)	0.074
95% Confidence Interval	0.55 ~ 0.85
Standard Error Se0(K)	0.089
Test Value Z	Z=7.86, Probability value P=0.0000
Test Result	P<0.05,refuse H0, Kappa values come from populations other than 0.

3.3 Total:

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	45	14	59
	Negative	8	157	165
Total		53	171	224

3.3.1 Statistical results of test data

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity（%）	45/53	84.91% (72.41% ~ 93.25%)
Relative Specificity（%）	157/171	91.81% (86.65% ~ 95.45%)
Positive expectation Rate（%）	45/59	76.27% (63.41% ~ 86.38%)
Negative expected Rate（%）	157/165	95.15% (90.67% ~ 97.88%)
Overall Agreement（%）	202/224	90.19% (85.51% ~ 93.74%)

3.3.2 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	0.75, Good consistency.
Standard Error Se(K)	0.0524
95% Confidence Interval	0.64 ~ 0.84
Standard Error Se0(K)	0.067
Test Value Z	Z=11.08, 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. The test results showed the positive coincidence rate is 84.91%, the negative coincidence rate is 91.81%, and the total coincident rate is 90.19%.

In summary, the research reagent and referencing reagent have a high coincidence rate of the results, and have the equivalence on the clinical usage.

5. Attachment

5.1 Joseph L. Fleiss. Statistical Methods For Rates And Proportions - 3Ed, 2003, 598-607