Preliminary clinical assessment results

1. Material

1.1 Kit: The COVID-19 IgG/IgM Rapid Test Cassette.

1.2 Subject samples: 523 clinical samples were used for verification, the clinical negative samples included 134 cases of clinical random venous whole blood samples, 30 cases of fingertip whole blood samples, 30 cases of clinical serum samples, and 187 cases of clinical plasma samples. The confirmed positive clinical samples included 57 cases of whole venous blood samples in the early period of 1-2 weeks and 85 cases of serum samples after rehabilitation.

2. Methods

2.1 Basic calculation:

Positive coincidence rate =A/(A+C)×100%

Negative coincidence rate =D/(A+B) ×100%

Positive expected value =D/(B+D) ×100%

Negative expected value =D/(C+D) ×100%

Total coincidence rate =A+D/(A+B+C+D) ×100%

The 95% confidence interval of probability is calculated by binomial distribution method (same as the MedCalc program), and the formula is as follows:, where a is numerically specific numerator, and n is numerically proportional numerator. $\alpha/2=\sum_{k=a}^{n}\binom{n}{k}p_{LB}^{k}(1-p_{LB})^{n-k}$ $\alpha/2=\sum_{k=0}^{a}\binom{n}{k}p_{UB}^{k}(1-p_{UB})^{n-k}$

2.2 Kappa consistency test (results were the same as SAS, MedCalc, etc.)

For the behavior I =2, the data listed as j=2: the calculation formula is as follows:

Where is the consistency coefficient Kappa=; $\frac{p_o-p_e}{1-p_e}$. $p_o=\sum_{i=1}^{k}p_{ii}$,

$$p_e=\sum_{i=1}^{k}p_{i.}p_{.i}.$$

The standard error calculation formula for estimating the 95% confidence limit is as follows: Se(k)=, where: $\frac{\sqrt{A+B-C}}{(1-p_e)\sqrt{n}}$

$$A=\sum_{i=1}^{k}p_{ii}[1-(p_{i.}+p_{.i})(1-\hat{\kappa})]^2,$$

$$B=(1-\hat{\kappa})^2\sum_{i\neq j}\sum p_{ij}(p_{.i}+p_{j.})^2,$$

$$C=[\hat{\kappa}-p_e(1-\hat{\kappa})]^2.$$

95% confidence interval of Kappa value =Kappa+/-1.96Se(k).

The non-0 test of Kappa value is to test whether Kappa value comes from the population with 0, that is, whether the difference of Kappa value is caused by sampling error. The calculation formula is as

follows: Z=Kappa/Se0 (k), where

Se0(k)=, and then calculate the probability value P according to the Z value and the standard normal distribution function. $\frac{1}{(1-p_e)\sqrt{n}}\sqrt{p_e+p_e^2-\sum_{i=1}^{k}p_{i.}p_{.i}(p_{i.}+p_{.i})}$

3. Results

3.1 Test data

After the samples were paired with diagnostic results of clinical samples and clinical assessment reagents, the paired test results were input into table 1:

Table 1: test results of pairing of control reagent and clinical examination reagent

The inspection reagent	Referencing Reagent Test				Total	
	+		-			
+	A	129	B	0	A + B	129
-	C	13	D	381	C + D	391
Total	A +C	142	B + D	381	ABCD	523

Note: A, B, C and D represent the four results of paired detection respectively

3.2 Basic calculation

The basic calculation results are as follows:

Table 2: basic statistical results of test data

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity（%）	129/142	90.85% (84.85% ~ 95.04%)
Relative Specificity（%）	381/381	100.00% (99.04% ~ 100.00%)
Positive Expectation Rate（%）	129/129	100.00% (97.18% ~ 100.00%)
Negative Expectation Rate（%）	381/394	96.70% (94.42% ~ 98.23%)
Overall Agreement（%）	510/523	97.51% (95.79% ~ 98.67%)

3.3 Kappa consistency test

Kappa value and standard error were calculated.Test hypothesis was established for Kappa:

H0: K=0, Kappa value from the population of 0, H1: K>0, Kappa value comes from non-0 population, α =0.05.

The calculation results are as follows:

Table 3 statistical results of Kappa consistency test

Project	Value
Kappa value	0.9353, good consistency
Standard error Se (K)	0.0177
95% confidence interval	0.9007 ~ 0.9700
Standard error of Se0 (K)	0.044
Test value Z	Z=21.4346, probability value P=0.0000
Test results	P<0.05, refuse H0, Kappa value come from populations other than 0

4 Conclusion

The positive, negative and total coincidence rates were 90.85%, 100% and 97.51% respectively. In summary, the test results of research reagent in good agreement with the diagnosis results of clinical samples.