Clinical Trial Report and Performance Analysis

Research Summary

From March 5, 2020 to March 25, 2020, the COVID-19 IgM / IgG Rapid Test Cassette (colloidal gold method) (examination reagent) produced by Zhejiang Orient Gene Biotech Co., Ltd. conducted clinical trials with a total of 600 plasma samples in NINGBO HWA MEI HOSPITAL, UNIVERSITY Of CHINESE ACADEMY Of SCIENCE, and WENZHOU CENTRAL HOSPITAL (Among them: 6 samples was repeatedly enrolled; 5 samples had incomplete subject information, and there is no diagnosis/exclusion information. The above 11 samples were later deleted, and the final statistical analysis data was 589 plasma samples), as well as with a total of 354 serum samples in WUHAN THIRD HOSPITAL (Among them: 1 sample was deleted due to no clear diagnosis/exclusion information,; 3 cases were deleted due to the use of plasma samples; 1 human subject was repeatedly enrolled and deleted; total of 349 serum samples were included in the final statistical analysis data)

Based on statistical analysis, the positive coincidence rate of the results of Oriental Gene Reagent (589 plasma samples) and clinical diagnosis results was 92.97%, the negative coincidence rate was 98.76%, and the overall coincidence rate was 96.94% The results were tested by Kappa consistency, *Kappa*=0.93. The positive coincidence rate of the results of Oriental Gene Reagent (349 serum samples) and the clinical diagnosis results were 86.98% positive, the negative coincidence rate was 97.78%, and 92.55% overall. The results were tested by Kappa consistency, *Kappa*=0.85. It shows that the assessment reagents have a high degree of consistency with the clinical diagnosis results.

Based on the consistency study of serum, plasma and whole blood, the assessment reagents showed a high degree of consistency and sensitivity in the detection of novel coronavirus IgM / IgG antibodies in human serum, plasma and whole blood

1. Test Purpose

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Serum/ Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and lgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings. Through the clinical trial, the consistency of the test result of COVID-19 IgG/IgM Rapid Test Cassette (Colloidal Gold Method) produced by Zhejiang Orient Gene Biotech and the diagnostic result of new coronavirus infected pneumonia based on disease progress and diagnostic standard in clinical practice were evaluated and validated. The positive coincidence rate and negative coincidence rate of COVID-19 IgG/IgM Rapid Test Cassette is also evaluated, as well the clinical performance results of the product. The clinical trial data provided strong support for the product launch in several major markets.

2. Test Design

2.1 Design and Scheme of Experiment

This clinical trial used COVID-19 IgG/IgM Rapid Test Cassette to test plasma samples of suspected and confirmed cases of new coronavirus infection, and compared the test results with the pneumonia diagnostic criteria and disease progress of the new coronavirus infection in the clinical practice (recommended to refer to test results of nucleic acid method for diagnosis at the meantime, to facilitate the full evaluation of the clinical performance of such antibody testing reagents). The trial also tested the conformity of the test results between serum, plasma and whole blood samples of the same patient. The Kappa value was calculated by using a 2 x 2 column table to perform a hypothesis test on the counting data. The trial evaluated the consistency of the evaluation reagents and the results of the control method.

For test results that were inconsistent with clinical results from the diagnostic criteria and disease progress of the new coronavirus infection pneumonia, the test would be further verified with assessment reagents with associate analysis of possible causes in the results analysis.

2.2 Test Design and Test Method

2.2.1 Sample Size

According to the principles of product classification and naming in the Measure for the Registration and Administration of In Vitro Diagnostic Reagents from CFDA, COVID-19 IgG/IgM Rapid Test Cassette is categorized as the Type III of In Vitro Diagnostic Reagents that related to the detection of pathogens, antigens, antibodies, and nucleic acids. Based on the requirement of the Technical Guides for Clinical Trials of In Vitro Diagnostic Reagents by CFDA, the total number of the clinical samples of such trial should be no less than 1,000 from three or more hospitals.

As such, testing was performed on no less than 1,000 cases. For the purpose of clinical statistical significance, a total of three major hospitals were selected for the trial, with a theoretical requirement of no less than 350 cases of plasma samples from clinical cases in each hospital, of which the clinically confirmed cases should be not less than 30% (That is 105 cases). At the same time, consecutive samples of more than 10 patients with pneumonia infected by new coronavirus were collected at different times. In order to verify the consistency of the test results between the serum, plasma and whole blood samples of the same patient, each clinical trial hospital conducted a consistency study of 70 cases of serum, plasma and whole blood samples, of which the clinically confirmed cases should be not less than 30% (That is 21 cases). According to the characteristics of the new coronavirus epidemic, the three hospitals of this clinical trial can adjust the number of samples into the group according to the actual situation of the hospital. A retrospective serum or plasma specimen stored below 20 ± 5 ℃ can be used.

2.2.2 Sample selection basis, selection criteria, exclusion criteria and deletion criteria

Selection Criteria:

A. The sample information is complete, including the subject's age, gender, specimen collection date, clinical diagnosis, etc.

   Confirmed cases of new coronavirus infection (positive);

B. Coronavirus pneumonia excluded cases (negative), new coronavirus cured cases (positive when diagnosed, became negative after treatment);
C. Simultaneously select blood samples of patients with influenza virus infection and patients with lower respiratory tract infection;
D. Considering the characteristics of the new coronavirus epidemic, a certain percentage of retrospective samples that meet the requirements of the product manual is accepted.

Exclusion Criteria:

A. The sample size is too small to complete the entire test;
B. Expired samples that have not been collected, processed and stored as required;

Deletion Criteria

A. Test samples with quality problems;
B. Samples that were mistakenly included in the group or the test results were unreliable due to human factors during the test;
C. Samples that were not traceable.

2.2.3 Sample collection, processing and storage

Whole Blood Sample:

- Disinfect the blood collection area;
- Collect venous blood samples and collect them in clean, dry test tubes pre-embedded with heparin, EDTA or sodium citrate anticoagulants, and mix well after collection to prevent blood clotting.

Plasma Sample:

- Disinfect the blood collection area;
- Collect venous blood samples and collect them in clean, dry test tubes pre-embedded with heparin, EDTA or sodium citrate anticoagulants. After collection, mix well to prevent coagulation, centrifuge, and separate the supernatant, which is the plasma sample.

Serum Sample:

- Disinfect the blood collection area;
- Collect venous blood in a dry, clean test tube without anticoagulant;
- The venous blood sample, after coagulation, the supernatant obtained by centrifugal separation is the serum sample.

Serum and plasma samples should be stored a temperature from 2 to 8 ℃ for no more than 1 week. If the measurement cannot be performed within 1 week after blood collection, seal the sample and store it at a temperature below 20 ℃ for long-term storage. Avoid repeated freezing and thawing, such repeats should not exceed 3 times. The reconstituted frozen samples should be fully equilibrated to room temperature before being used for testing

Whole blood samples must be tested within 8 hours of collection; samples of severe hemolysis and lipemia should not be used for testing.

Control Reagent Selection:

The test results of this clinical trial are compared with the judgement results from the clinical diagnostic criteria and disease progression of pneumonia with new coronavirus infection that the clinical trial hospitals are currently using (It is recommended to also refer to the nucleic acid test results used for diagnosis to facilitate the full evaluation of the clinical performance of antibody detection reagents).

Confirmation of Inconsistent Samples:

For test results that are inconsistent with the clinical diagnosis of new coronavirus infection pneumonia and the judgment results of the disease process, use test reagents to test and verify again, and analyze the possible causes in the result analysis.

2.2.4 Statistical analysis method of clinical trial data

This test is a statistical analysis of pair count data. It is planned to use 2 × 2 contingency table for recording and analysis, as follows:

Four-division Table for Evaluating Diagnostic Tests

Reagent II	Reagent I		Total
	Positive	Negative	
Positive	a	b	a+b (γ1)
Negative	c	d	c+d (γ2)
Total	a+b (C1)	a+b (C2)	a+b+c+d (N)

Positive coincidence rate=[a/(a+c)]*100%

Negative coincidence rate=[d/(b+d)]*100%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%

At the same time, the Kappa consistency test was performed on the results, and the 95%

confidence interval was taken. The Kappa value was between 0 and 1, and the closer to 1, the better the consistency of the test results of the two reagents. Generally, the Kappa value is greater than 0.75, which means that the two reagents are highly consistent.

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)}$$

The above statistical analysis method is used for individual evaluation of each sub-center and summary evaluation of all samples.

3. Clinical Trial Results and Analysis

3.1 General Case Information

Serum Sample: A total of 354 serum samples were tested in this trial, of which: 1 sample was excluded without clear diagnosis/exclusion information; 3 samples were excluded due to the wrongful use of plasma samples; 1 subject was repeatedly enrolled and excluded; There were total of 349 serum samples included in the final statistical analysis data, including 182 of male, accounting for 52%; 167 of female, accounting for 47.9%; the male to female ratio is 1.09:1, the oldest was 98 years old, the youngest was 7 years old, and the average age was 59.8 year old. The deleted serum samples are showed in Table 1 below.

Plasma samples: A total of 600 plasma samples were tested in this trial, of which: 6 samples with repeated enrollment of subjects; 5 samples with incomplete subject information and no diagnosis/exclusion information. The above 11 samples were later removed. There were total of 589 plasma samples included in the final statistical analysis data, including 318 of male, accounting for 53.99%; 271 of female, accounting for 46.01%; the male to female ratio is 1.17:1, the oldest was 91 Years old, the youngest was 2 years old, the average age is 49.55 years old. The deleted plasma samples are also showed in Table 1 below.

Table 1 - Deleted Sample Information

Number	Sample Type	Sample Number	Comment	Clinical Hospital
1	Serum Sample	084S	No clear diagnosis/exclusion information	Wuhan No.3 Hospital
2		268S	Deletion due to wrongful use of plasma samples	
3		272S	Deletion due to wrongful use of plasma samples	
4		273S	Deletion due to wrongful use of plasma samples	
5		294S	Deletion due to wrongful use of plasma samples	
1		BA117	Repeated enrollment	
2		BA190	Repeated enrollment	

3	Plasma Sample	BA207	Repeated enrollment	Wenzhou Central Hospital
4		BA268	Repeated enrollment	
5		BA282	Repeated enrollment	
6		BA318	Repeated enrollment	
7		BA231	No diagnosis/exclusion information	
8		BA112	No diagnosis/exclusion information	
9		BA152	No diagnosis/exclusion information	
10		BA154	No diagnosis/exclusion information	
11		BA254	No diagnosis/exclusion information	

This trial conducted a consistency study of plasma, serum and whole blood in 160 cases. Among them: 13 cases whose whole blood exceeded the use period were excluded from the corresponding test results of the serum, plasma, and whole blood test; 1 case was excluded due to incomplete information. There were total of 146 cases of dataset included in the final statistical analysis.

In this trial, 22 cases were selected for three consecutive samplings of plasma samples. One of the human subjects was deleted due to incomplete continuous sampling. There were total of 21 cases of dataset included in the final statistical analysis.

3.2 Clinical Trial Performance Results and Analysis

3.2.1 Analysis of the consistency of serum and control methods

A total of 349 serum samples of the target population, including 169 confirmed cases, the assessment reagent tested 147 positive and 22 negative cases; including 180 excluded cases, the assessment reagent tested 4 positive and 176 negative cases. See Table 2 for details.

Table 2 - Consistency of serum test results

Serum Sample		Control Method		Total
		Confirmed Cases	Excluded Cases	
Assessment Reagent	Positive	147	4	151
	Negative	22	176	198
Total		169	180	349

Positive coincidence rate=[a/(a+c)]*100%=86.98%

Negative coincidence rate=[d/(b+d)]*100%=97.78%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=92.55%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.850$$

According to the above data in the table, the positive coincidence rate of Oriental Gene Reagent and the new coronavirus IgM / IgG of clinical diagnosis information is 86.98%, the negative coincidence rate is 97.78%, and the total coincidence rate is 92.55%. Kappa consistency test on the above results, *Kappa*=0.850.

3.2.2 Analysis of the consistency of plasma and control methods

A total of 589 plasma samples of the target population, including 185 confirmed cases, the assessment reagent tested 172 positive and 13 negative cases; including 404 excluded cases, the assessment reagent tested 5 positive and 399 negative cases. See Table 3 for details.

Table 3 - Consistency of plasma test results

Plasma Sample		Control Method		Total
		Confirmed Cases	Excluded Cases	
Assessment Reagent	Positive	172	5	177
	Negative	13	399	412
Total		185	404	589

Positive coincidence rate=[a/(a+c)]*100%=92.97%

Negative coincidence rate=[d/(b+d)]*100%=98.76%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=96.94%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.93$$

According to the above data in the table, the positive coincidence rate of Oriental Gene Reagent and the clinical diagnosis information is 92.97%, the negative coincidence rate is 98.76%, and the total coincidence rate is 96.94%. Kappa consistency test on the above results, *Kappa*=0.93.

3.2.3 Analysis of the consistency results of the examination reagent plasma, serum and whole blood

3.2.3.1 IgM - Consistency analysis of plasma and serum

A total of 146 samples of plasma and serum of the same patient, 57 cases were tested positive, 81 cases were negative, and 8 samples were inconsistent. See Table 4 for details.

Table 4 – Testing results of plasma and serum samples

Assessment Reagent		Serum Samples		Total
		Positive	Negative	
Plasma Samples	Positive	57	6	63
	Negative	2	81	83
Total		59	87	146

Positive coincidence rate=[a/(a+c)]*100%=96.61%

Negative coincidence rate=[d/(b+d)]*100%=93.10%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=94.52%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.89$$

According to the above data in the table, the positive coincidence rate of IgM detection in plasma and serum by Oriental Gene Reagent is 96.61%, the negative coincidence rate is 93.10%, and the total coincidence rate is 94.52%. Kappa consistency test on the above results, *Kappa*=0.89.

3.2.3.2 IgM - Consistency analysis of plasma and whole blood

A total of 146 samples of plasma and whole blood of the same patient, 60 cases were tested positive, 82 cases were negative, and 4 samples were inconsistent. See Table 5 for details.

Table 5 – Testing results of plasma and whole blood samples

Assessment Reagent		Plasma Samples		Total
		Positive	Negative	
Whole Blood Samples	Positive	60	1	61
	Negative	3	82	85

Total	63	83	146

Positive coincidence rate=[a/(a+c)]*100%=95.24%

Negative coincidence rate=[d/(b+d)]*100%=98.80%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=97.24%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.94$$

According to the above data in the table, the positive coincidence rate of IgM detection in plasma and whole blood by Oriental Gene Reagent is 95.24%, the negative coincidence rate is 98.80%, and the total coincidence rate is 97.24%. Kappa consistency test on the above results, *Kappa*=0.94.

3.2.3.3 IgM - Consistency analysis of serum and whole blood

A total of 146 samples of serum and whole blood of the same patient, 56 cases were tested positive, 82 cases were negative, and 8 samples were inconsistent. See Table 6 for details.

Table 6 – Testing results of plasma and whole blood samples

Assessment Reagent		Serum Samples		Total
		Positive	Negative	
Whole Blood Samples	Positive	56	5	61
	Negative	3	82	85
Total		59	87	146

Positive coincidence rate=[a/(a+c)]*100%=94.92%

Negative coincidence rate=[d/(b+d)]*100%=94.25%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=94.52%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.89$$

According to the above data in the table, the positive coincidence rate of IgM detection in serum and whole blood by Oriental Gene Reagent is 94.92%, the negative coincidence rate is 94.25%, and the total coincidence rate is 94.52%. Kappa consistency test on the above results, *Kappa*=0.89.

3.2.3.4 IgG - Consistency analysis of plasma and serum

A total of 146 samples of plasma and serum of the same patient, 98 cases were tested positive, 46 cases were negative, and 2 samples were inconsistent. See Table 7 for details.

Table 7 – Testing results of plasma and serum samples

Assessment Reagent		Plasma Samples		Total
		Positive	Negative	
Serum Samples	Positive	98	2	100
	Negative	0	46	46
Total		98	48	146

Positive coincidence rate=[a/(a+c)]*100%=100%

Negative coincidence rate=[d/(b+d)]*100%=95.83%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=98.63%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.97$$

According to the above data in the table, the positive coincidence rate of IgG detection in plasma and serum by Oriental Gene Reagent is 100%, the negative coincidence rate is 95.83%, and the total coincidence rate is 98.63%. Kappa consistency test on the above results, *Kappa*=0.97.

3.2.3.5 IgG - Consistency analysis of plasma and whole blood

A total of 146 samples of plasma and whole blood of the same patient, 98 cases were tested positive, 48 cases were negative, and 4 samples were inconsistent. See Table 8 for details.

Table 8 – Testing results of plasma and whole blood samples

Assessment Reagent		Plasma Samples		Total
		Positive	Negative	
Whole Blood Samples	Positive	98	0	98
	Negative	0	48	48
Total		98	48	146

Positive coincidence rate=[a/(a+c)]*100%=100%

Negative coincidence rate=[d/(b+d)]*100%=100%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=100%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 1.0$$

According to the above data in the table, the positive coincidence rate of IgG detection in plasma and whole blood by Oriental Gene Reagent is 100%, the negative coincidence rate is 100%, and the total coincidence rate is 100%. Kappa consistency test on the above results, *Kappa*=1.0.

3.2.3.6 IgG - Consistency analysis of serum and whole blood

A total of 146 samples of serum and whole blood of the same patient, 98 cases were tested positive, 46 cases were negative, and 2 samples were inconsistent. See Table 6 for details.

Table 6 – Testing results of plasma and whole blood samples

Assessment Reagent		Serum Samples		Total
		Positive	Negative	
Whole Blood Samples	Positive	98	0	98
	Negative	2	46	48
Total		100	46	146

Positive coincidence rate=[a/(a+c)]*100%=98%

Negative coincidence rate=[d/(b+d)]*100%=100%

Total coincidence rate=[(a+d)/(a+b+c+d)]*100%=98.63%

$$Kappa = \frac{N(a+d)-(\gamma 1C1+\gamma 2C2)}{N^2-(\gamma 1C1+\gamma 2C2)} = 0.97$$

According to the above data in the table, the positive coincidence rate of IgG detection in serum and whole blood by Oriental Gene Reagent is 98.00%, the negative coincidence rate is 100%, and the total coincidence rate is 98.63%. Kappa consistency test on the above results, *Kappa*=0.97.

3.2.4 Analysis of clinical inconsistent sample results

3.2.4.1 Analysis of inconsistency between serum and control methods

In this clinical trial, a total of 26 serum samples showed an inconsistency between the results of the assessment reagent and the control method. Among the 26 inconsistent results, 4 were false positive and 22 were false negative.

The reasons for the false negative result could be:

1. The antibody level in the sample is lower than the minimum detection limit of the assessment reagent;
2. The antibody level in the sample is low, which leads to an unclear result. Because the product results need to be judged by the naked eye, there will be cases where the judgment is wrong due to vague scale lines.

The reasons for the false positive result could be:

1. The sample contains substances such as heterophilic antibodies and internal rheumatoid factors that will cause false positive interference to the assessment reagent,;
2. Positive results will also appear in samples of asymptomatic patients during the recovery period.

3.2.4.2 Analysis of inconsistency between plasma and control methods

In this clinical trial, a total of 18 plasma samples showed an inconsistency between the results of the assessment reagent and the control method, while 13 results were from Hwa Mei Hospital, University of Chinese Academy of Science, 5 results were from Wenzhou Central Hospial.

Among the 13 inconsistent results from Hwa Mei Hospital, University of Chinese Academy of Science, 10 were wrongfully tested negative. The reasons for the negative result could be:

1. The antibody level in the sample is lower than the minimum detection limit of the assessment reagent;
2. The sample concentration is near the cutoff value of the assessment reagent, the spell line is not clear, which made tester difficult in accurately interpreting the result.

Among the 13 inconsistent results, 3 results were wrongfully tested positive. The reasons for the positive result could be:

1. The antibody level in the sample is lower than the minimum detection limit of the assessment reagent;
2. The sample may contain substances such as heterophilic antibodies and internal rheumatoid factors that can cause false positives of the test reagent, resulting in abnormal test results.

The analysis of 5 results from Wenzhou Central Hospital, please see Table 7 for details:

Table 7 – Plasma clinically inconsistent samples

Data from Wenzhou Central Hospital											
Sample Number	Age	Sex	Sample Type	Confirmed /Excluded Cases	Clinical Diagnostic Information	Test Result of Assessment Reagent		Retest Result of Assessment Reagent		Nucleic Acid Test Result	Sampling Time
						IgM	IgG	IgM	IgG		
BA081	21	Male	Plasma	Confirmed	New coronavirus infectious pneumonia	Negative	Negative	Negative	Negative	Negative	2020/2/27
BA105	63	Female	Plasma	Confirmed	New coronavirus infectious pneumonia	Negative	Negative	Negative	Negative	Negative	2020/2/25
BA344-3	27	Female	Plasma	Confirmed	New coronavirus infectious pneumonia	Negative	Negative			Negative	2020/3/16
BA177	37	Female	Plasma	Excluded	Fever	Negative	Positive	Negative	Positive	Negative	2020/2/29
BA243	49	Male	Plasma	Excluded	Fever	Negative	Positive	Negative	Positive	Negative	2020/3/3

Result analysis:

For sample number of BA081, the human subject was diagnosed with 2019-nCoV Pneumonia on February 3, and was discharged from the hospital on February 20 (the nucleic acid test result was negative on that day). The sample was collected on February 27, which is the re-examine sample after recovery. The main reasons for the inconsistency are: 1. The sample has slight hemolysis, which may affect the test results. 2. The assessment reagent is a colloidal gold product, due to the characteristics of its product principle, there may be false negatives in the test.

For sample number of BA105, the human subject was diagnosed with 2019-nCoV Pneumonia on February 13, and was discharged from the hospital on February 26 (the nucleic acid test result was negative on February 23). The sample was collected on February 25, which is the sample of the late stage of recovery period. The main reasons for the inconsistency are: 1. The assessment reagent is a colloidal gold product, due to the characteristics of its product principle, there may be false negatives in the test.

For sample number of BA344-3, since the sample is used for the consistency test of plasma, serum and whole blood samples at the same time, no retest is performed. The human subject was diagnosed with 2019-nCoV Pneumonia on February 5, and was discharged from the hospital on February 17 (the nucleic acid test result was negative on March 3). The sample was collected on March 16, which is the re-examine sample after recovery. The main reasons for the inconsistency are: 1. The assessment reagent is a colloidal gold product, due to the characteristics of its product principle, there may be false negatives in the test.

For sample number of BA177, the human subject was an excluded case. The nucleic acid test result was negative on February 29. The sample collection time was February 29. The test reagent test result was lgM negative and IgG positive. The main reasons for the inconsistency are: 1. The subject may be an asymptomatic infected person, and the nucleic acid test result is false negative; 2. The assessment reagent is a colloidal gold product, due to the characteristics of its product principle, there may be false negatives in the test.

For sample number of BA243, the human subject was an excluded case. The nucleic acid test result was negative on March 3. The sample collection time was March 3. The test reagent test result was lgM negative and IgG positive. The main reasons for the inconsistency are: 1. The subject may be an asymptomatic infected person, and the nucleic acid test result is false negative; 2. The assessment reagent is a colloidal gold product, due to the characteristics of its product principle, there may be false negatives in the test.

3.2.4.3 Analysis of inconsistent results of homology samples

In the homology study of serum, plasma and whole blood in this clinical trial, a total of 17 samples were inconsistent, including 14 cases of inconsistent IgM results and 3 cases of inconsistent IgG results.

Among the 14 inconsistent cases from Wuhan Third Hospital: 11 samples contained low concentration of IgM, and the cutoff value of the test reagent was not obvious, which was likely to cause interpretation bias. 3 samples contained low concentration of IgG, and the cutoff value of the test reagent was not obvious, which was likely to cause interpretation bias.

Among the 3 inconsistent cases from Wenzhou Central Hospital, 3 samples contained low concentration of IgM. The spell line was not obvious during the detection, which was likely to cause the deviation of weak positive and negative interpretation.

4. Conclusion

The test results of the assessment reagents (COVID-19 IgG/IgM Rapid Test Cassette) are highly consistent with the clinical diagnostic information. In addition, the assessment reagents are stable, easy to store, easy and fast to operate, and require no additional testing equipment. As such, COVID-19 IgG/IgM Rapid Test Cassette from Zhejiang Orient Gene Biotech is recommended for the initial screening of 2019-nCoV Pneumonia in medical institutions.

Date: April 2020