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Clinical General Report
SARS-CoV-2 Antibody Test (Lateral Flow Method)

Test Time: January 21, 2020~February 19, 2020

Clinical Trial Medical Unit:

1. Guangzhou No.8 People's Hospital
2. Guangdong No.2 Provincial People's Hospital
3. Jiangmen Wuyi Chinese Medicine Hospital
4. Nanchang No.3 Hospital
5. Xinyu People's Hospital
6. Wuhan Yaxin Hospital

Principal of Statistics: Guoling Chen

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Report Date: February 19, 2020

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Completion Instructions:

1. Clinical trial institutions and researchers should conduct clinical trials strictly in accordance with the clinical trial protocol in a serious and responsible manner, and compile clinical trial reports impartially and objectively.

2. Clinical trial institutions and researchers should be responsible for the authenticity and science of the trial report.

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Clinical Trial Report (First Page)

Abstract of Research

According to the requirements of *Administrative Measures for Registration of In-vitro Diagnostic Reagents* issued by China Food and Drug Administration, SARS-CoV-2 Antibody Test (Lateral Flow Method), developed by Guangzhou Wondfo Biotech Co., Ltd, need to undergo clinical trial to determine whether it meets the use requirement or intended use.

This trial used clinical diagnostic results of patients as reference, conducted clinical application trial on SARS-CoV-2 Antibody Test (Lateral Flow Method) developed by Wondfo Company, examined the safety and effectiveness of Wondfo reagent.

Selected samples in this trial included human serum, plasma and whole blood samples. In this trial 768 samples were totally selected (including 248 serum samples, 257 plasma samples, 263 whole blood samples), with no excluded samples. 768 samples were included for statistics. The trial result is summarized as follows:

1. Analysis of Comparative Test Result

(1) Analysis of Results between Test Reagent and Confirmed Cases

In the comparative test, serum, plasma and whole blood samples of 235 excluded cases and 361 confirmed cases (including 101 early diagnosis patients) were collected from 6 clinical institutions, therefore 596 samples were totally included for statistics.

There were 546 samples in which test reagent's result for the detection of SARS-CoV-2 antibody were consistent with diagnostic result. 312 confirmed cases were detected as SARS-CoV-2 antibody positive (the detection rate for early periodearly diagnosis patients is 84/101=83.17%). 234 excluded cases were detected as SARS-CoV-2 antibody negative.

There were 50 samples in which test reagent's result for the detection of SARS-CoV-2 antibody were inconsistent with diagnostic result. 49 confirmed cases were detected as SARS-CoV-2 antibody negative (17 cases of early onset), 1 excluded case was tested as SARS-CoV-2 antibody positive.

Through statistical analysis, comparing with clinical diagnostic results, the sensitivity of test reagent was 86.43% (95% CI: 82.51%, 89.58%), the specificity was 99.57% (95% CI: 97.63%, 99.92%), overall coincidence rate is 91.61% (95% CI: 89.10%, 93.58%). This demonstrated that the detection results of test reagent and clinically diagnosed results were mostly consistent. The detection rate of early period confirmed patient was 83.17%.

(2) Statistical Analysis between Test Reagent Results and Marketed Nuclear Acid Detection Reagent PCR Results

For 596 samples included in statistics, 335 of them had PCR detection results tested by marketed SARS-CoV-2 nuclear acid detection reagent.

There were 318 samples in which test reagent's result were consistent with marketed nuclear acid detection reagent's PCR result. 221 cases with PCR result positive were tested as SARS-CoV-2 antibody positive. 97 cases with PCR result negative were tested as SARS-CoV-2 antibody negative.

There were 17 samples in which the test reagent's result for the detection of SARS-CoV-2 antibody were inconsistent with PCR results. 1 case with PCR negative was tested as SARS-CoV-2 antibody positive, while 16 cases with PCR positive were tested as SARS-CoV-2 antibody negative.

Through statistical analysis, comparing with PCR result of marketed nuclear acid detection reagent, the test reagent's positive coincidence rate was 93.25% (95% CI: 89.32%, 95.80%), negative coincidence rate was 98.98% (95% CI: 94.44%, 99.82%), overall coincidence rate was 94.93% (95% CI: 92.02%, 96.81%). These suggested that the detection results of test reagent were mostly consistent with results of marketed

nuclear acid detection reagent.

2. Analysis of Specimen Type Consistency Test Result

Compared with homologous serum/plasma sample results, whole blood samples' positive coincidence rate was 93.41% (95% CI: 86.35%, 96.94%), negative coincidence rate was 100.00% (95% CI: 92.60%, 98.39%). These suggested that detection results of whole blood samples were consistent with those of homologous serum/plasma samples.

Conclusion:

SARS-CoV-2 Antibody Test (Lateral Flow Method) manufactured by Guangzhou Wondfo Biotech Co., Ltd can meet clinical intended application.

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Clinical Trial Report

1. Preface

Coronaviruses are a large family of viruses that are known to cause colds and more serious diseases such as the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).

Since December 2019, some hospitals in Wuhan City, Hubei Province have successively found multiple cases of unexplained pneumonia with a history of exposure to the South China Seafood Market, which has now been confirmed to be an acute respiratory infectious disease caused by a new β-type coronavirus infection.

In January, 2020, the World Health Organization named the new coronavirus that caused the pneumonia epidemic in Wuhan since December 2019 as "SARS-CoV-2".

The current methods for detecting the SARS-CoV-2 include: nuclear acid diagnostic technology and immunological diagnostic technology. Nuclear acid diagnostic technology currently has commercial kits, but the disadvantages are: the existence of false negatives and false positives, the detection samples are easily contaminated, and the requirement for precision instruments and professional technicians. It is inconvenient for large-scale popularization, and it is not easy for grassroots hospitals to carry out. The positive rate for mild cases and for specimens submitted for more than one week is low. Immunological diagnostic technology: (1) Enzyme linked immunosorbent assay (ELISA). The ELISA method has the advantages of simple test operation, short time required, high sensitivity, and does not require special instruments, and is particularly suitable for serological detection of a large number of samples. However, the specificity of the detection results of this method is greatly affected by the purity of the coated antigen or antibody. (2) The immunocolloidal gold labeling technology has become a trend for the development of in vitro diagnostic reagents in recent years due to its simple operation, without any

special equipment, and without special training of operators. The test results are intuitive, convenient for grassroots units and field use.

SARS-CoV-2 Antibody Test (Lateral Flow Method) is in-vitro diagnostic product manufactured by Guangzhou Wondfo Biotech Co., Ltd, belongs to IVD. In order to further confirm the clinical performance, it was required to verify the clinical application value of our reagent in accordance with *Administrative Measures for Registration of In-vitro Diagnostic Reagents* issued by CFDA. Entrusted by Guangzhou Wondfo Biotech Co., Ltd, Guangdong No.2 Provincial People's Hospital, Guangzhou No.8 People's Hospital, Jiangmen Wuyi Chinese Medicine Hospital, Nanchang No.3 Hospital, etc., worked as clinical trial institutions, verified the clinical application value of the reagent in accordance with clinical trial protocol of SARS-CoV-2 Antibody Test (Lateral Flow Method), specific examination was conducted by relevant personnel in Laboratory. The objective was to obtain relevant experimental data through comparative experiments, and to perform appropriate statistical analysis on relevant evaluation indicators, so as to provide scientific basis for clinical performance evaluation of test reagent.

2. Trial Purpose

This trial used clinical diagnostic results of patients as reference, conducted clinical application research on SARS-CoV-2 Antibody Test (Lateral Flow Method) developed by Wondfo, and examined the safety and effectiveness of Wondfo reagent.

3. Trial Design

3.1 General Protocol of Trial

This clinical trial was established with reference to the requirement of *Guidelines of Clinical Trial of In Vitro Diagnostic Reagent*. The general design of clinical trial is as follows:

(1) Clinical diagnostic results were selected as reference, test reagent was used to perform comparative test on patient's serum/plasma samples results, to examine clinical performance of test reagent.

(2) Compare and study the results of homologous serum/plasma samples with those of whole blood samples, examine the consistency of detection results between serum/plasma samples and whole blood samples.

3.2 Trial Design and Test Method Selection

3.2.1 Test Sample Volume and Basis on Determination of Sample Volume

SARS-CoV-2 Antibody Test (Lateral Flow Method) belongs to Class III reagents related to detection of pathogenic antigens, antibodies and nuclear acid. According to *Guidelines of Clinical Trial of In Vitro Diagnostic Reagent* published on September, 2014 by China Food and Drug Administration, The specific requirements are as follows:

1) Clinical trial research of which the total sample number is no less than 500, there should be no less than 200 confirmed cases in it.

Table 1. Number and Requirement for Comparative Test Samples

Patient Category	**Confirmed Cases of SARS-CoV-2**			**Excluded Cases of SARS-CoV-2**
Clinical Typing	Early period	Intermediate period	Late treatment /Recovery	Exclude
Requirement for Sample Number	≥200 cases (early period ≥50)			≥300
Total	≥500			

Remarks: Early cases are cases where the sampling date is 1-7 days from the onset day. Intermediate period cases are those whose sampling date is 8-14 days from the onset day. Late treatment/recovery cases are those whose sampling day is over 15 days from onset day.

2) Evaluate applicable specimen type of test reagent: serum/plasma, whole blood

sample. Verify the consistency between serum/plasma and whole blood samples. Total number of samples for clinical trial institutions using test reagent to perform homologous specimen type detection should be no less than 100.

3.2.2 Specimen Selection Basis, Selection Criteria, Exclusion Criteria and Rejection Criteria

This clinical trial intended to examine the detection performance of SARS-CoV-2 Antibody Test (Lateral Flow Method). According to the results of the clinical diagnosis and treatment of the *Diagnosis and Treatment Program for Coronavirus Disease 19* (hereinafter referred to as COVID-19), with reference to the sample selection criteria, the samples tested by the clinical research institutions were randomly selected to meet the test reference requirements.

Selection Criteria

Unlimited age and gender, sufficient sample size, one or more of the following conditions:

1) According to *Diagnosis and Treatment Program for Coronavirus Disease 19*, select serum, plasma and whole blood samples with confirmation of infection of SARS-CoV-2.

2) Serum, plasma and whole blood samples from other patients who need to be tested for SARS-CoV-2 (if they had a history of contact with positive cases, clustered onset, etc.)

3) Blood samples of other fever and/or respiratory syndrome population.

Exclusion Criteria

Untraceable specimen.

Rejection Criteria

1) Data with invalid result;

2) The untraceable due to lack of required information for any one of clinical research

original record

Before the statistics, it was found that there was a lack of information required for the original records of any clinical study, which could not trace the source.

3.2.3 Analytical Methods and Evaluation Criteria for Clinical Trial Data Statistics

The statistics of data were based on Excel database. SPSS software and Excel were used for statistics and analysis.

1) Major Effectiveness Statistical Methods

Compared with diagnostic results, calculate the sensitivity, specificity, overall consistency and the 95% confidence interval (CI) of test reagents. Sensitivity, specificity, overall consistency: range from 0%~100%, the closer the value is to 100%, the higher the degree of compliance with clinical diagnosis.

2) Evaluation of Consistency of Specimen Types

Calculate the positive coincidence rate, negative coincidence rate, overall coincidence rate and the 95% confidence interval (CI) of test reagents' homologous serum/plasma samples with whole blood samples. Positive coincidence rate, negative coincidence rate, overall coincidence rate: range from 0% to 100%, the closer the value is to 100%, the higher the degree of compliance of test results with reference specimen type, and the smaller the difference is.

4. Clinical Test Results and Analysis

A total of 768 samples were included in this trial (including 248 serum samples, 257 plasma samples, 263 whole blood samples), with no excluded samples. 768 samples were included for statistics.

4.1 Analysis of Comparative Test Results

4.1.1 Overview of Trial Completion

From Table 2, we could see that in comparative test, serum/plasma/whole blood samples of 235 excluded cases and 361 confirmed cases (of which 101 were from early period patients) were collected from 6 clinical trial institutions, thus a total of 596 samples were included for statistics.

Table 2. Number of samples actually entered into the group and completed tests

Name of Institution	Case Number of Actually Entered into the Group			Total
	Excluded Cases	Confirmed Cases		
		Confirmed Patients	Early period Patients	
Guangdong No.2 Provincial People's Hospital	77	38	38	115
Guangzhou No.8 People's Hospital	0	206	33	206
Wuhan Yaxin Hospital	0	80	0	80
Xinyu People's Hospital	0	31	24	31
Jiangmen Wuyi Chinese Medicine Hospital	46	3	3	49
Nanchang No.3 Hospital	112	3	3	115
Total	235	361	101	596

4.1.2 Result Analysis of Test reagents and Confirmed Cases

Based on the diagnostic results of confirmed cases, grouped the tested samples as SARS-CoV-2 infection confirmed cases and SARS-CoV-2 excluded cases, and detection results of SARS-CoV-2 antibody of test reagents were used for comparative evaluation with diagnostic results. The detection results were shown as Table 3 and Table 4.

4.1.2.1 2*2 Contingency Table of Confirmed Cases of Test reagents Test Results

Table 3. Contingency Table of Comparative Test Result

Infection of SARS-CoV-2			
Test reagent	**Confirmed Cases**	**Excluded Cases**	**Total**
SARS-CoV-2 antibody positive	312	1	313

SARS-CoV-2 antibody negative	49	234	283
Total	361	235	596
Sensitivity	86.43%	95%CI	82.51%~89.58%
Specificity	99.57%	95%CI	97.63%~99.92%
Overall Coincidence rate	91.61%	95%CI	89.10%~93.58%

There were 546 samples whose detection results of SARS-CoV-2 antibody of test reagents were consistent with diagnosis. Among the confirmed cases, 312 were tested with SARS-CoV-2 antibody positive (the detection rate of early period confirmed cases was 84/101=83.17%). 234 were tested with SARS-CoV-2 antibody negative among excluded cases.

There were 50 samples whose detection results of SARS-CoV-2 antibody of test reagents were not consistent with diagnosis. Among the confirmed cases, 49 were tested with SARS-CoV-2 antibody negative (17 samples were early onset). 1 were tested with SARS-CoV-2 antibody positive among excluded cases.

The information on inconsistency between detection results of SARS-CoV-2 antibody of test reagents and diagnosis was shown in Table 4.

Table 4. Information on inconsistency between detection results of SARS-CoV-2 antibody of test reagents and diagnosis

Institution	No.	Patient Code	Hospitalization Date/Onset Date	Sampling Date	Clinical Diagnosis	Test reagent	PCR	Other information
Guangdong No.2 Provincial People's Hospital	1	2204969804	20200128	20200128	To be tested	Weak positive	negative	Intermediate period
Wuhan Yaxin Hospital	5	289189	20200218	20200210	Diagnosed COVID-19	negative	negative	Intermediate period
	6	289744	20200128	20200210	Diagnosed COVID-19	negative	negative	Intermediate period
	9	287624	20200128	20200210	Diagnosed COVID-19	negative	positive	Intermediate period
	10	286973	20200128	20200210	Diagnosed COVID-19	negative	positive	Intermediate

								period
	16	287803	20200128	20200210	Diagnosed COVID-19	negative	positive	Intermediate period
	22	288007	20200128	20200210	Diagnosed COVID-19	negative	positive	Intermediate period
	56	289693	20200128	20200210	Diagnosed COVID-19	negative	negative	Intermediate period
	57	287483	20200128	20200210	Diagnosed COVID-19	negative	negative	Intermediate period
	58	288668	20200128	20200210	Diagnosed COVID-19	negative	negative	Intermediate period
Xinyu People's Hospital	5	2020002404	20200211	20200214	Fever, to be tested (suspected COVID-19)	negative	positive	Early period
	10	2020002479	20200214	20200214	Suspected COVID-19	negative	positive	Early period
	25	2020002499	20200214	20200215	Preliminary determination of lung infection	negative	positive	Early period
	30	2020002174	20200203	20200214	1. Fever to be tested; 2. COVID-19	negative	positive	Intermediate period
Guangzhou No.8 People's Hospital	1	24082548	20200204	20200204	Diagnosed COVID-19, hospitalization	negative	negative	Early period
	3	24097427	20200213	20200213	Diagnosed COVID-19, hospitalization	negative	negative	Early period
	5	24098715	20200213	20200213	Diagnosed COVID-19, hospitalization	negative	negative	Early period
	7	24075100	20200126	20200127	Diagnosed COVID-19, hospitalization	negative	negative	Early period
	8	24075676	20200128	20200129	Diagnosed COVID-19, hospitalization	negative	positive	Early period
	10	24075753	20200128	20200129	Diagnosed COVID-19, hospitalization	negative	negative	Early period
	12	24078575	20200131	20200201	Diagnosed COVID-19, hospitalization	negative	positive	Early period
	13	24097328	20200212	20200213	Diagnosed COVID-19, hospitalization	negative	negative	Early period
	14	24097343	20200212	20200213	Diagnosed COVID-19, hospitalization	negative	positive	Early period
	15	24097385	20200212	20200213	Diagnosed COVID-19, hospitalization	negative	negative	Early period

	21	24085971	20200205	20200209	Diagnosed COVID-19, COVID-19	negative	positive	Early period
	25	24084238	20200204	20200209	Diagnosed COVID-19, COVID-19	negative	positive	Early period
	27	24084414	20200203	20200209	Confirmed COVID-19	negative	positive	Early period
	31	24079785	20200202	20200209	Confirmed COVID-19	negative	negative	Early period
	35	24079144	20200201	20200209	Confirmed COVID-19	negative	positive	Intermediate period
	37	24079266	20200201	20200209	Confirmed COVID-19	negative	negative	Intermediate period
	39	24079378	20200201	20200209	Confirmed COVID-19	negative	negative	Intermediate period
	48	24085925	20200131	20200209	Confirmed COVID-19	negative	negative	Intermediate period
	51	24085631	20200130	20200209	Confirmed COVID-19	negative	negative	Intermediate period
	52	24086474	20200130	20200209	Confirmed COVID-19	negative	positive	Intermediate period
	56	24085599	20200128	20200209	Confirmed COVID-19	negative	negative	Intermediate period
	57	24085607	20200129	20200209	Confirmed COVID-19	negative	positive	Intermediate period
	69	24085916	20200125	20200209	Confirmed COVID-19	negative	negative	Intermediate period
	80	24096332	20200129	20200213	Diagnosed COVID-19, hospitalization	negative	negative	Late stage
	89	24097248	20200129	20200214	Diagnosed COVID-19, hospitalization	negative	negative	Late stage
	116	24102830	20200127	20200218	Coronavirus infection	negative		
	124	24102020	20200129	20200218	Fever	negative		
	135	24101986	20200131	20200218	Coronavirus infection	negative		
	160	24101687	20200204	20200218	Coronavirus as the cause of diseases classified in other chapters	negative		
	178	24102672	20200206	20200218	Coronavirus infection	negative		
	180	24103508	20200208	20200218	Viral pneumonia	negative		
	183	24102163	20200208	20200218	Coronavirus infection	negative		
	195	24101830	20200213	20200218	Fever	negative		

	196	24101825	20200213	20200218	Cough	negative		
	199	24100277	20200214	20200218	Coronavirus infection	negative		
	203	24101529	20200215	20200218	Coronavirus as the cause of diseases classified in other chapters	negative		

Conclusion of Reason for Inconsistency Analysis :

One patient was a suspected outpatient in the outpatient clinic. His PCR was negative and the test reagent was shown as weak. There might be several reasons: (1) Visual angle or light problems, color development and C8-C9. (2) There are other unknown cross-reactants, no further judgments are given.

49 confirmed cases of SARS-CoV-2 infection were negative for antibody testing. Among them, 16 cases showed positive PCR results, 21 cases showed negative PCR results, and 12 cases had no PCR results. 17 of them were early-onset patients. There may be several reasons for this: (1) Visual angle or light problems, color development and C8-C9. (2) Early-stage patient antibody levels are too low to detect. (3) Detection rate is limited by methodology, missed detection is within acceptable range.

The test reagent is a new diagnostic product for COVID. For further confirmation, it is recommended to further confirm according to the judgment requirements in the *Diagnosis and Treatment Program for Coronavirus Disease 19*.

4.1.3 Statistical Analysis for Test reagent and Marketed Nuclear Acid Reagents

Of the 596 cases included in statistics, 335 cases have been tested for PCR with marketed nuclear acid detection reagent. According to the PCR results by marketed nuclear acid detection reagents, grouped the tested samples as SARS-CoV-2 nucleic positive and SARS-CoV-2 nucleic negative, and detection results of SARS-CoV-2 antibody of test reagents were used for comparative evaluation with PCR results. Test results were as Table 5.

4.1.3.1 Coincidence Rate Analysis of Results between Test reagent and Marketed Nuclear Acid Detection Reagent

Table 5. Contingency Table of Test reagent and Marketed Nuclear Acid Detection Reagent PCR Result

Marketed Nuclear Acid Detection Reagent			
Test reagent	**PCR positive**	**PCR negative**	**Total**
SARS-CoV-2 antibody positive	221	1	222
SARS-CoV-2 antibody negative	16	97	113
Total	237	98	335
Positive coincidence rate	93.25%	95%CI:	89.32%-95.80%
Negative coincidence rate	98.98%	95%CI:	94.44%-99.82%
Overall coincidence rate	94.93%	95%CI:	92.02%-96.81%

The number of samples with consistent results between results of test reagent and PCR results of marketed nuclear acid detection reagent was 318. Among them, 221 cases of PCR positive were detected as SARS-CoV-2 antibody positive, 97 cases of PCR negative were detected as SARS-CoV-2 antibody negative.

The number of samples with inconsistent results between results of test reagent and PCR results of marketed nuclear acid detection reagent was 17. Among them, 1 case of PCR negative was detected as SARS-CoV-2 antibody positive, 16 cases of PCR positive were detected as SARS-CoV-2 antibody negative.

4.2 Result Analysis of Specimen Type Consistency

4.2.1 Overview of Trial Completion

Serum/plasma, homologous whole blood samples of 70 exclusion cases and 102 confirmed cases were included from 3 clinical trial institutions in specimen type consistency test. Therefore, a total of 172 samples were included in specimen type consistency test for statistics. Details were shown in Table 6.

Table 6. The number of samples actually entered into the group and the tests

completed for the specimen types consistency test of each institution

Name of institution	Case Number of Actual Entered into the Group		Total
	Excluded case	Confirmed case	
Nanchang No.3 Hospital	24	0	24
Jiangmen Wuyi Chinese Medicine Hospital	46	3	49
Guangzhou No.8 People's Hospital	0	99	99
Total	70	102	172

4.2.2 Analysis of Results of Serum/Plasma, Homologous Whole Blood of Test Reagent

According to the test results of serum/plasma sample, grouped the samples as negative and positive groups, comparative evaluation was used for results of serum/plasma samples and those of whole blood samples, and the results were shown in Table 6.

4.2.2.1 Coincidence Rate Analysis of Test Reagent Results Between Serum/Plasma and Whole Blood

Table 2. Contingency Table of Results of Specimen Type Consistency Test

Serum/Plasma Samples			
Whole blood samples	Positive	Negative	Total
Positive	85	0	85
Negative	6	81	87
Total	91	81	172
Positive coincidence rate	93.41%	95%CI:	86.35%-96.94%
Negative coincidence rate	100.00%	95%CI:	95.47%-100.00%
Overall coincidence rate	96.51%	95%CI:	92.60%-98.39%

A total of 166 samples were of consistent results between serum/plasma samples and homologous whole blood samples. Among them, 85 were detected positive simultaneously, 81 were detected negative simultaneously.

A total of 6 samples were of inconsistent results between serum/plasma samples

and homologous whole blood samples. 6 serum/plasma positive were detected as whole blood negative, and these 6 cases were all confirmed cases.

5. Discussion and Conclusion

The selected samples in this trial included human serum, plasma and whole blood samples. A total of 768 samples were entered into group in this trial (including 248 serum samples, 257 plasma samples, 263 whole blood samples), with no excluded samples, and 768 samples were included for statistics.

1. Analysis of Comparative Test Result

(1) Analysis of Results between Test Reagent and Confirmed Cases

In the comparative test, serum, plasma and whole blood samples of 235 excluded cases and 361 confirmed cases (including 101 cases of early patients) were collected from 6 clinical institutions, therefore 596 samples were totally included for statistics.

There were 546 samples in which test reagent's result for the detection of SARS-CoV-2 antibody were consistent with diagnostic result. 312 confirmed cases were detected as SARS-CoV-2 antibody positive (the detection rate for early period confirmed cases is 84/101=83.17%). 234 excluded cases were detected as SARS-CoV-2 antibody negative.

There were 50 samples in which test reagent's result for the detection of SARS-CoV-2 antibody were inconsistent with diagnostic result. 49 confirmed cases were detected as SARS-CoV-2 antibody negative (17 cases of early onset), 1 excluded case was tested as SARS-CoV-2 antibody positive.

Through statistical analysis, comparing with clinical diagnostic results, the sensitivity of test reagent was 86.43% (95% CI: 82.51%, 89.58%), the specificity was 99.57% (95% CI: 97.63%, 99.92%), overall coincidence rate is 91.61% (95% CI: 89.10%, 93.58%). This demonstrated that the detection results of test reagent and clinically confirmed results were mostly consistent. The detection rate of early period

confirmed patient was 83.17%.

(2) Statistical Analysis between Test Reagent Results and Marketed Nuclear Acid Detection Reagent PCR Results

For 596 samples included in statistics, 335 of them had PCR detection results tested by marketed SARS-CoV-2 nuclear acid detection reagent.

There were 318 samples in which test reagent's result were consistent with marketed nuclear acid detection reagent's PCR result. 221 cases with PCR result positive were tested as SARS-CoV-2 antibody positive. 97 cases with PCR result negative were tested as SARS-CoV-2 antibody negative.

There were 17 samples in which the test reagent's result for the detection of SARS-CoV-2 antibody were inconsistent with PCR results. 1 case with PCR negative was tested as SARS-CoV-2 antibody positive, while 16 cases with PCR positive were tested as SARS-CoV-2 antibody negative.

Through statistical analysis, comparing with PCR result of marketed nuclear acid detection reagent, the test reagent's positive coincidence rate was 93.25% (95% CI: 89.32%, 95.80%), negative coincidence rate was 98.98% (95% CI: 94.44%, 99.82%), overall coincidence rate was 94.93% (95% CI: 92.02%, 96.81%). These suggested that the detection results of test reagent were mostly consistent with results of marketed nuclear acid detection reagent.

2. Analysis of Specimen Type Consistency Test Result

Compared with homologous serum/plasma sample results, whole blood samples' positive coincidence rate was 93.41% (95% CI: 86.35%, 96.94%), negative coincidence rate was 100.00% (95% CI: 92.60%, 98.39%). These suggested that detection results of whole blood samples were consistent with those of homologous serum/plasma samples.

Conclusion:

SARS-CoV-2 Antibody Test (Lateral Flow Method) manufactured by Guangzhou Wondfo Biotech Co., Ltd can meet clinical intended application.