Clinical Report

Coronavirus-19 (COVID-19) Antibody (IgM/IgG) Rapid Test Kit (Colloidal gold immunochromatography)

Wuhan UNscience Biotechnology Co., Ltd.

CONTENTS

Abstract

Product Name:

Coronavirus-19 (COVID-19) Antibody (IgG/IgM) Rapid Test Kit (Colloidal gold immunochromatography)

Research objective:

The purpose of this experiment is to take clinical test to the COVID-19 IgG/IgM Rapid Test Kit (Colloidal gold immunochromatography) produced by Wuhan UN Biotechnology Co., Ltd. according to the requirements of *Technical Guidelines for Clinical Trials of in vitro Diagnostic Reagents*, to evaluate whether the test reagent is equivalent to the clinical application performance of the listed reference reagent.

Test description:

The sample types studied in this experiment were serum, plasma and whole blood. Serum was selected as the main sample study type, and the test was compared with gold standard clinical and data analysis, to analyze whether the results were equivalent or not. The samples of serum and plasma homology were determined by the test reagent, and the results of serum and plasma were evaluated to analyze whether the results were identical or not.

With the approval of the Ethics Committee, from March 2020, there were 1585 selected case specimens, of which 421 were clinically diagnosed patients with Coronavirus infection, 1164 were clinically excluded cases, no cases were found that did not conform to the program selected, and no cases of laboratory operation deviation were found.

In 1585 cases, the sensitivity and specificity of the method were calculated by statistical analysis, and 203 serum/plasma and homologous whole blood samples were measured with the test reagent to evaluate whether the results of serum/plasma and homologous whole blood were consistent, and the following results and conclusions were obtained:

1. The clinical sensitivity of the product was 98.81% (95% CI: 97.25%, 99.61%) and the specificity was 98.02% (95% CI : 97.05%, 98.74%) in 1585 clinical samples (421 positive and 1164 negative).

2. The homologous serum/plasma, whole blood samples (125 positive and 78 negative) of 203 subjects were compared. According to the results of serum/plasma test, the results of whole blood test were consistent :96.85%(95% CI：95.87%~97.60%).

The results indicate a high degree of consistency between this product and clinical diagnosis results.

Abbreviation

COVID-19   2019 novel coronavirus

1 Basic content

1.1 Introduction

2019 novel coronavirus (COVID-19) was found due to the case of viral pneumonia in Wuhan in 2019, and it was named by the World Health Organization on January 12, 2020. The most common symptoms of patients infected with COVID-19 are respiratory symptoms, fever, cough, shortness of breath and dyspnea. In more serious cases, infection can lead to pneumonia, severe acute respiratory syndrome, renal failure, and even death. There is no specific treatment for COVID-19 induced diseases. In view of the current trend of the virus in the world, the rapid differentiation of patients and healthy people is the focus of epidemic prevention.

The on-sale detection products mainly include 3 categories: RT-PCR Method, chemiluminescence analysis method and colloidal gold Immunochromatographic Method. Among them, the RT-PCR Method mainly determined the viral nucleic acid, while the chemiluminescence analysis method Method and colloidal gold Immunochromatographic Method mainly determined the antibody produced in the patient's body.

COVID-19 IgG/IgM Rapid Test Kit (Colloidal gold immunochromatography) produced by UN is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma.

This kit adopts colloidal gold immunochromatography principle to detect the IgG and IgM antibodies to COVID-19. The nitrocellulose membrane was coated with mouse anti-human IgM monoclonal antibody, mouse anti-human IgG monoclonal antibody and sheep anti-mouse IgG antibody respectively, and colloidal gold labeled recombinant novel coronavirus (COVID-19) antigen and mouse lgG antibody were used as tracers, respectively.

During testing, sample was added into the sample well. If the sample contains IgM antibodies to COVID-19, it can bind to the colloidal gold labeled recombinant novel coronavirus (COVID-19) antigen and form a complex substance, which is captured at the coated mouse anti-human IgM antibody, and binds to the mouse anti-human IgM antibody to form a complex, showing purplish red band. If the sample contains IgG antibodies to COVID-19, it can bind to the colloidal gold labeled recombinant novel coronavirus (COVID-19) antigen and form a complex substance, which is captured at the coated mouse anti-human IgG antibody, and binds to the mouse anti-human IgG antibody to form a complex, showing purplish red band. The colloidal gold labeled IgG antibody binds to the coated goat anti-mouse IgG antibody and presents purplish red bands as the quality control line.

The purpose of this experiment is to take clinical test to the COVID-19 IgG/IgM Rapid Test Kit (Colloidal gold immunochromatography) produced by Wuhan UN Biotechnology Co., Ltd. according to the requirements of *Technical Guidelines for Clinical Trials of in vitro Diagnostic Reagents*, to evaluate whether the test reagent is equivalent to the clinical diagnosis standard of new coronavirus pneumonia.

1.2 Research objective

According to the requirement of the Guidance for Clinical Trials of IVD Reagents, we proceed the clinic validation test of the COVID-19 IgG/IgM Rapid Test Kit developed by UN science to evaluate whether the kit is equivalent to the clinical diagnostic criteria of novel coronavirus pneumonia.

1.3 Experimental management

1.3.1 Quality control in clinical studies

1.3.1.1 Personnel training

At the kick-off meeting of this clinical research, the main investigator of the leading unit trained the co-investigators and related researchers of each center in clinical schemes, case report forms (CRF) and related regulations; before the formal selection of subjects, the technicians in UN science come to the central laboratories to train the inspectors responsible for product operation. After the training is qualified, the clinicians can formally select the subjects. During the clinical trial, the inspectors sent by the sponsor will conduct regular inspections.

1.3.1.2 Quality control of products for clinical research

The clinical research product should be manufactured in the applicant's lab in accordance to the requirement of IVD reagents production enforcement regulation.

1.3.1.3 Quality control of clinical case diagnosis

The Confirmed cases and excluded cases are determined by the Treatment of Novel Coronavirus Pneumonia(Trial Edition 7), issued by National Health Commission on

March 3, 2020.

1.3.1.4 Laboratory quality control

The quality control of the Tuberculosis diagnostic laboratory is carried out according to the requirement of laboratory quality control regulated in the Clinical Technical Operation (fascicule Tuberculosis) compiled by Chinese Medical Association.

The quality control of the laboratory for testing products for clinical research shall comply with the specific requirements of basic laboratory operation specifications and product specifications, including basic temperature and humidity control, calibration of measuring instruments and equipment, etc. If the quality control conditions that do not meet the requirements of the product specification appear during the test, the re-inspection shall be required, and the qualified quality control data can be used only after passing the test.

Before and during the study, the applicant provided positive and negative reference materials to review and verify the specimen testing personnel and laboratory conditions.

1.3.2 Biosafety

Laboratory operations and specimen handling are conducted in accordance with the operating specifications of grade Ⅱ (and above) bio-safety laboratories. The experimenter performs three levels of bio-safety protection.

1.3.3 Clinical observing

During the clinical study, the applicant shall assign clinical supervisors to track the progress of the trial, coordinate the solution to problems in the trial, and monitor the laboratory quality control, reagent operation and recording, reagent storage conditions and improvement of CRF, etc. to ensure that the requirements of the clinical study protocol are strictly followed.

1.3.4 Clinical data management and statistical analysis

The double-blind method was adopted in this clinical study. The study specimens of the selected cases were indicated serial number by clinical examiner, and sent to

laboratory for testing. The case information and test data during the study were kept separately by clinicians and inspectors. At the end of the study, case information and test data were collected in the department of the main investigator to uncover the blindness, and the results were judged and analyzed.

The person in charge of the laboratory appoints special test personnel and review personnel to be responsible for testing and recording the test data of each case.

1.4 Experimental design

1.4.1 Overall design and project of the test

In this study, the clinical diagnostic performance of the product to be registered was comprehensively evaluated by comparing the selected virus with the gold standard and the assessment results by referring to the Novel Coronavirus Pneumonia Diagnosis and Treatment Program (Trial Seventh Edition).

1.4.2 Test project and test method selection

1.4.2.1 Basis for sample size and determination of sample size

According to the "Technical Guiding Principles for Clinical Research of In Vitro Diagnostic Reagents", the total number of samples in the third category of clinical research is at least 1,000.

The minimum sample size for the case group and the control group in this study was determined according to the general sample size estimation formula for clinical epidemiological diagnostic test research, namely:

$$n1 = \frac{Z^2_\alpha Sen(1 - Sen)}{\delta^2} \;, \qquad n2 = \frac{Z^2_\alpha Spe(1 - Spe)}{\delta^2}$$

Set α=0.05，Zα=1.96 (both sides), sensitivity (Sen) = 0.80, specificity (Spe) = 0.85, assuming δ = 0.05, then n1 = 246, n2 = 196, that is, the case group needs at least 246 cases And the control group needs at least 196 cases to be statistically significant.

According to the unified clinical research plan of the product to be registered, this test requires no less than 600 cases in the sample group.

1.4.2.2 Determination of gold standards

Novel coronavirus diagnostic gold standard:

Suspected cases identified through epidemiological investigations and clinical symptoms can be diagnosed as confirmed cases when having either pathogenic or serological evidence.

1. Real-time fluorescent RT-PCR detection of novel coronavirus nucleic acid is positive;

2. By viral gene sequencing, the sequence is highly homologous to known novel coronavirus;

3. Serum IgM and IgG which are specific to novel coronavirus are positive; Serum IgG which is specific to novel coronavirus changes from negative to positive, or increases by 4 times or more in the recovery period than that in the acute phase.

Gold standard for excluding cases: If the test result of the novel coronavirus nucleic acid detection is negative by two consecutive times (sampling time interval of at least 24 hours), and meanwhile the novel coronavirus-specific antibodies IgM and IgG remain negative for 7 days after onset illness, then the suspected cases determined through epidemiological investigation and clinical symptoms can be excluded.

1.4.2.3 Sample inclusion criteria and exclusion criteria

The samples were selected according to the requirements of the diagnosis and treatment specifications for confirmed and excluded cases, and the hospital issued a diagnosis and exclusion opinion on the cases.

1.4.3 Collection, preservation and transport of samples

Serum (or plasma) or whole blood samples are collected by conventional methods.

The collected whole blood samples can be stored at 2℃~8℃ for 3 days, and DON'T BE FROZEN. Venous whole blood samples can use conventional heparin (9.8-28 IU / mL), sodium citrate (3.8%, equivalent to 129mmol), and ethylenediamine tetraacetic acid (EDTA) (4.55 mmol / mL ±0.85 mmol / L) Anticoagulation.

The collected serum/plasma samples can be stored at 2℃~8℃ for 7 days, and

tentatively stored at ≤-20℃ for 6 months. Don't freeze and thaw the serum samples repeatedly for more than 8 times. Serum samples were best tested on the same day of collection.

During the collection and storage of samples, please pay attention to aseptic operation.

1.4.4 Information on products used in this clinical trial

Name: COVID-19 IgG/IgM Rapid Test Kit (colloidal gold immunochromatography)
Specification: 40T/box
Manufacturer: WUHAN UNSCIENCE BIOTECHNOLOGY CO., LTD,
Batch NO.20200226

1.4.5 Quality control methods for product testing

The enterprise minimum detection limit reference product S1 should be negative, S2A, S2B and S3 should be positive;

1.4.6 Judgement of result

Observe for 10 minutes and record the results.

Invalid: When there is no red line in the quality control area (C), the test is invalid. It is recommended to retest with a new rapid test strip. Pay attention to sampling sufficiently.

IgM antibody positive: A clear purple-red band appears at the T and C lines of the IgM antibody detection reagent reading window, which is considered to be positive for the novel coronavirus lgM antibody.

IgG antibody positive: A clear purple-red band appears at the T and C lines of the IgG antibody detection reagent reading window, which is considered to be positive for a novel coronavirus IgG antibody.

Negative: The reading window of IgM antibody and IgG antibody only show a clear purple-red band at the position of C line, which is judged as negative for novel coronavirus lgM antibody and IgG antibody.

1.4.7 Statistical analysis

Statistical analysis is performed by MEDCALC software. The diagnostic performance indicators such as sensitivity, specificity, positive consistency, negative consistency, and overall consistency report the percentage and calculate 95% confidence intervals.

1.4.8 Modification of the project during the test

No scheme modification in this experiment

1.5 Clinical trial results and analysis

1.5.1 Results of comparison test

There were selected 1585 clinical samples, including 421 samples from clinically diagnostic patients with new coronavirus infection, 1164 samples from clinically excluded patients, and no cases did not meet the scheme, no cases were with laboratory operation deviation. The results were statistically analyzed after detecting 1585 cases, then the sensitivity and specificity of the method were calculated.

Table 1 Clinical trial results

NO.	Hospital confirmed results	Result of UNCOV-40		
		IgM	IgG	Determination
1	+	+	-	+
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	+	-	+	+
6	+	-	+	+
7	-	-	-	-
8	-	-	-	-
9	+	+	-	+
10	-	-	-	-
11	-	-	-	-
12	-	-	-	-
13	-	-	-	-
14	+	-	+	+
15	+	+	-	+
16	+	+	-	+
17	-	-	-	-

18	+	+	-	+
19	+	-	+	+
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403	+	+	-	+
404	+	+	-	+
405	+	-	+	+
406	+	-	+	+
407	+	+	-	+
408	+	+	-	+
409	+	+	-	+
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411	+	-	+	+
412	+	-	+	+
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1188	-	-	-	-
1189	+	-	+	+
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1197	-	-	-	-
1198	+	-	+	+
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1403	-	-	-	-

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1406	-	-	-	-
1407	+	-	+	+
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1420	-	-	-	-
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1422	-	-	-	-
1423	-	-	-	-
1424	+	-	+	+
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1433	-	-	-	-
1434	+	-	+	+
1435	-	-	-	-
1436	-	-	-	-
1437	-	-	-	-
1438	-	-	-	-
1439	+	-	+	+
1440	-	-	-	-
1441	-	-	-	-
1442	-	-	-	-
1443	-	-	-	-
1444	+	+	+	+
1445	-	-	-	-

1446	-	-	-	-
1447	-	-	-	-
1448	+	-	+	+
1449	-	-	-	-
1450	-	-	-	-
1451	-	-	-	-
1452	-	-	-	-
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1573	-	-	-	-
1574	-	-	-	-
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1578	-	-	-	-
1579	-	-	-	-
1580	-	-	-	-
1581	-	-	-	-
1582	-	-	-	-
1583	-	-	-	-
1584	-	-	-	-
1585	-	-	-	-

1.5.2 Sensitivity and specificity

1585 samples were counted by medcalc software, of which 421 were clinically confirmed and 1164 were excluded. 439 were tested to be positive and 1146 were negative. The clinical sensitivity of the product was 98.81% (95% CI: 97.25%, 99.61%) and the specificity was 98.02% (95% CI: 97.05%, 98.74%).

Table 2. Sensitivity and specificity

Sensitivity	98.81%	97.25%~99.61%
Specificity	98.02%	97.05%~98.74%
AUC	0.98	0.98~0.99
Positive probability ratio	50.01	33.36~74.96
Negative probability ratio	0.01	0.01~0.03
Epidemicity of diseases	26.56%	24.40%~28.81%
Positive predictive value	94.76%	92.24%~96.65%
Negative predictive value	99.56%	98.98%~99.86%

1.5.3 Homology results

203 serum/plasma and homologous whole blood samples were measured with the test reagent to evaluate the consistency between serum/plasma and homologous whole

blood. The results are as follows:

Table 3. Homology results

NO.	Serum results			Plasma results			Whole blood results		
	IgM	IgG	Determination	IgM	IgG	Determination	IgM	IgG	Determination
1	-	+	+	-	+	+	-	+	+
2	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-
4	-	+	+	-	+	+	-	+	+
5	-	-	-	-	-	-	-	-	-
6	+	-	+	+	-	+	+	-	+
7	-	+	+	-	+	+	-	+	+
8	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-
11	+	-	+	+	-	+	+	-	+
12	-	-	-	-	-	-	-	-	-
13	-	+	+	-	+	+	-	+	+
14	+	-	+	+	-	+	+	-	+
15	+	-	+	+	-	+	+	-	+
16	-	+	+	-	+	+	-	+	+
17	+	-	+	+	-	+	+	-	+
18	+	-	+	+	-	+	+	-	+
19	+	-	+	+	-	+	+	-	+
20	-	+	+	-	+	+	-	+	+
21	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-
23	+	-	+	+	-	+	+	-	+
24	+	-	+	+	-	+	+	-	+
25	-	+	+	-	+	+	-	+	+
26	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-
28	+	-	+	+	-	+	+	-	+
29	+	-	+	+	-	+	+	-	+
30	+	-	+	+	-	+	+	-	+
31	-	-	-	-	-	-	-	-	-
32	-	+	+	-	+	+	-	+	+
33	+	-	+	+	-	+	+	-	+
34	+	-	+	+	-	+	+	-	+
35	-	-	-	-	-	-	-	-	-
36	-	+	+	-	+	+	-	+	+

37	-	-	-	-	-	-	-	-	-
38	+	-	+	+	-	+	+	-	+
39	-	+	+	-	+	+	-	+	+
40	-	+	+	-	+	+	-	+	+
41	-	+	+	-	+	+	-	+	+
42	-	-	-	-	-	-	-	-	-
43	+	-	+	+	-	+	+	-	+
44	+	-	+	+	-	+	+	-	+
45	+	-	+	+	-	+	+	-	+
46	+	-	+	+	-	+	+	-	+
47	-	+	+	-	+	+	-	+	+
48	+	-	+	+	-	+	+	-	+
49	-	+	+	-	+	+	-	+	+
50	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	+	-	+
52	-	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-	-
54	-	+	+	-	+	+	-	+	+
55	-	+	+	-	+	+	-	+	+
56	-	+	+	-	+	+	-	+	+
57	+	-	+	+	-	+	+	-	+
58	+	-	+	+	-	+	+	-	+
59	-	-	-	-	-	-	-	-	-
60	-	+	+	-	+	+	-	+	+
61	+	-	+	+	-	+	+	-	+
62	-	+	+	-	+	+	-	+	+
63	-	+	+	-	+	+	-	+	+
64	+	-	+	+	-	+	+	-	+
65	-	+	+	-	+	+	-	+	+
66	-	-	-	-	-	-	-	-	-
67	-	-	-	-	-	-	-	-	-
68	-	-	-	-	-	-	-	-	-
69	-	+	+	-	+	+	-	+	+
70	-	+	+	-	+	+	-	+	+
71	+	-	+	+	-	+	+	-	+
72	+	-	+	+	-	+	+	-	+
73	-	-	-	-	-	-	-	-	-
74	+	-	+	+	-	+	+	-	+
75	-	-	-	-	-	-	-	-	-
76	+	-	+	+	-	+	+	-	+
77	+	-	+	+	-	+	+	-	+
78	-	+	+	-	+	+	-	+	+

79	-	-	-	-	-	-	-	-	-
80	-	+	+	-	+	+	-	+	+
81	-	-	-	-	-	-	-	-	-
82	-	+	+	-	+	+	-	+	+
83	-	+	+	-	+	+	-	+	+
84	-	-	-	-	-	-	-	-	-
85	-	-	-	-	-	-	+	-	+
86	+	-	+	+	-	+	+	-	+
87	+	-	+	+	-	+	+	-	+
88	-	-	-	-	-	-	-	-	-
89	-	-	-	-	-	-	-	-	-
90	+	-	-	-	-	-	-	-	-
91	-	-	-	-	-	-	-	-	-
92	-	-	-	-	-	-	-	-	-
93	-	+	+	-	+	+	-	+	+
94	-	-	-	-	-	-	-	-	-
95	-	-	-	-	-	-	-	-	-
96	-	-	-	-	-	-	-	-	-
97	+	-	+	+	-	+	+	-	+
98	+	-	+	+	-	+	+	-	+
99	-	-	-	-	-	-	-	-	-
100	-	+	+	-	+	+	-	+	+
101	-	-	-	-	-	-	-	-	-
102	-	+	+	-	+	+	-	+	+
103	-	-	-	-	-	-	-	-	-
104	-	-	-	-	-	-	-	-	-
105	-	-	-	-	-	-	-	-	-
106	-	+	+	-	+	+	-	+	+
107	-	-	-	-	-	-	-	-	-
108	+	-	+	+	-	+	+	-	+
109	-	-	-	-	-	-	-	-	-
110	-	-	-	-	-	-	-	-	-
111	-	-	-	-	-	-	-	-	-
112	+	-	+	+	-	+	+	-	+
113	-	-	-	-	-	-	-	-	-
114	-	+	+	-	+	+	-	+	+
115	-	-	-	-	-	-	-	-	-
116	-	+	+	-	+	+	-	+	+
117	-	+	+	-	+	+	-	+	+
118	-	+	+	-	+	+	-	+	+
119	-	+	+	-	+	+	-	+	+
120	-	-	-	-	-	-	-	-	-

121	-	-	-	-	-	-	-	-	-
122	+	-	+	+	-	+	+	-	+
123	-	-	-	-	-	-	-	-	-
124	-	+	+	-	+	+	-	+	+
125	-	+	+	-	+	+	-	+	+
126	+	-	+	+	-	+	+	-	+
127	-	+	+	-	+	+	-	+	+
128	-	-	-	-	-	-	-	-	-
129	-	+	+	-	+	+	-	+	+
130	-	+	+	-	+	+	-	+	+
131	-	-	-	-	-	-	-	-	-
132	+	-	+	+	-	+	+	-	+
133	-	-	-	-	-	-	-	-	-
134	-	-	-	-	-	-	-	-	-
135	-	+	+	-	+	+	-	+	+
136	-	+	+	-	+	+	-	+	+
137	-	-	-	-	-	-	-	-	-
138	-	-	-	-	-	-	-	-	-
139	+	-	+	+	-	+	+	-	+
140	-	-	-	-	-	-	-	-	-
141	-	-	-	-	-	-	-	-	-
142	+	-	+	+	-	+	+	-	+
143	-	+	+	-	+	+	-	+	+
144	-	-	-	-	-	-	-	-	-
145	+	-	+	+	-	+	+	-	+
146	-	+	+	-	+	+	-	+	+
147	-	+	+	-	+	+	-	+	+
148	+	-	+	+	-	+	+	-	+
149	-	+	+	-	+	+	-	+	+
150	-	+	+	-	+	+	-	+	+
151	+	-	+	+	-	+	+	-	+
152	-	+	+	-	+	+	-	+	+
153	-	-	-	-	-	-	-	-	-
154	-	-	-	-	-	-	-	-	-
155	-	-	-	-	-	-	-	-	-
156	-	-	-	-	-	-	+	-	+
157	-	+	+	-	+	+	-	+	+
158	+	-	+	+	-	+	+	-	+
159	+	-	+	+	-	+	+	-	+
160	+	-	+	+	-	+	+	-	+
161	+	-	+	+	-	+	+	-	+
162	+	-	+	+	-	+	+	-	+

163	+	-	+	+	-	+	+	-	+
164	-	-	-	-	-	-	-	-	-
165	-	+	+	-	+	+	-	+	+
166	+	-	+	+	-	+	+	-	+
167	-	-	-	-	-	-	-	-	-
168	-	-	-	-	-	-	-	-	-
169	-	-	-	-	-	-	-	-	-
170	-	-	-	-	-	-	-	-	-
171	-	+	+	-	+	+	-	+	+
172	-	+	+	-	+	+	-	+	+
173	-	+	+	-	+	+	-	+	+
174	-	-	-	-	-	-	-	-	-
175	+	-	+	+	-	+	+	-	+
176	-	+	+	-	+	+	-	+	+
177	-	+	+	-	+	+	-	+	+
178	+	-	+	+	-	+	+	-	+
179	-	+	+	-	+	+	-	+	+
180	-	-	-	-	-	-	-	-	-
181	-	-	-	-	-	-	-	-	-
182	+	-	+	+	-	+	+	-	+
183	-	+	+	-	+	+	-	+	+
184	-	-	-	-	-	-	-	-	-
185	+	-	+	+	-	+	+	-	+
186	+	-	+	+	-	+	+	-	+
187	-	+	+	-	+	+	-	+	+
188	-	+	+	-	+	+	-	+	+
189	-	+	+	-	+	+	-	+	+
190	-	-	-	-	-	-	-	-	-
191	-	-	-	-	-	-	-	-	-
192	+	-	+	+	-	+	+	-	+
193	-	+	+	-	+	+	-	+	+
194	-	-	-	-	-	-	-	-	-
195	+	-	+	+	-	+	+	-	+
196	+	-	+	+	-	+	+	-	+
197	+	-	+	+	-	+	+	-	+
198	-	-	-	-	-	-	-	-	-
199	-	+	+	-	+	+	-	+	+
200	-	+	+	-	+	+	-	+	+
201	-	+	+	-	+	+	-	+	+
202	-	+	+	-	+	+	-	+	+
203	-	-	-	-	-	-	-	-	-

1.5.4 Homologous consistency

Take homology consistency analysis of 203 serum/plasma and homologous whole blood with a 95% confidence interval of 95.87%–97.60%.

Variable quantity Y	Serum
Variable quantity X	Plasma

Number of samples	203
Coherent correlation coefficient	1.0000
95% confidence interval	-1.000 - -1.0000
Pearson ρ (Precision)	1.0000
Deviation correction factor C_b (Accuracy)	1.0000

Variable quantity Y	Whole blood
Variable quantity X	Serum/ plasma

Number of samples	203
Coherent correlation coefficient	0.9685
95% confidence interval	0.9587 - 0.9760
Pearson ρ (Precision)	0.9690
Deviation correction factor C_b (Accuracy)	0.9995

1.6 Discuss and conclusion

There were 1585 selected case specimens, of which 421 were clinically diagnosed patients with Coronavirus infection, 1164 were clinically excluded cases, no cases were found that did not conform to the program selected, and no cases of laboratory operation deviation were found.

In 1585 cases, the sensitivity and specificity of the method were calculated by statistical analysis, and 203 serum/plasma and homologous whole blood samples were measured with the test reagent to evaluate whether the results of serum/plasma and homologous whole blood were consistent, and the following results and conclusions were obtained:

1. The clinical sensitivity of the product was 98.81% (95% CI: 97.25%, 99.61%) and the specificity was 98.02% (95% CI: 97.05%, 98.74%) in 1585 clinical samples

(421 positive and 1164 negative).

2. The homologous serum/plasma, whole blood samples (125 positive and 78 negative) of 203 subjects were compared. According to the results of serum/plasma test, the results of whole blood test were consistent :96.85%（95% CI：95.87%~97.60%）.

The results indicate a high degree of consistency between this product and clinical diagnosis results.

2 Description of special circumstances in clinical studies

None.

3 Main references

Ming Wang, Qing Wu, Wanzhou Xu, *et.al.* Clinical diagnosis of 8274 samples with 2019-novel coronavirus in Wuhan . *MedRxiv*，2020，Feb. 18.