SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit

(Colloidal Gold)

Clinical Evaluation Report

Product name：SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit (Colloidal Gold)

Packing specification：10 tests/box

Clinical evaluation category：Comparison with CFDA-certified reagent

Clinical evaluation place： The First Hospital of Changsha, Hunan province, China

Start date: February 21, 2020

Completion date : February 29, 2020

Operator (signature)：

Statistics (signature)：

Application company（seal）：Shenzhen Heto Medical Tech Co.,Ltd.

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1. Overview

1.1 Abstract

Objective:

To evaluate the detection capability of SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit (Colloidal Gold) produced by Shenzhen Heto Medical Tech Co.,Ltd. is equivalent to that of similar products on the market when used for qualitative detection of IgG/IgM antibody in human serum, plasma and whole blood samples in vitro.

Methods:

Synchronous blind test and methodological comparison design.

Results:

In this test, a total of 250 serum samples were enrolled for the consistency comparison of experimental reagent and reference reagent, and no duplicate samples were selected. The sex ratio was distributed among 141 males (56.40%) and 109 females (43.60%). The age of enrolled patients ranged from 5.00 to 83.00 years. There were 135 cases with negative IgG antibody, accounting for 54.00% and 115 positive samples, accounting for 46.00%. There were 132 cases with negative IgM antibody, accounting for 52.80% and 118 positive samples, accounting for 47.20%. According to the consistency analysis of 250 samples, the IgG antibody detection sensitivity was 96.52%, meeting the clinical requirements of no less than 85%, and the specificity was 98.52%, meeting the clinical requirements of no less than 90%. The IgM antibody detection sensitivity was 94.07%, meeting the clinical requirements of no less than 85%, and the specificity was 97.73%, meeting the clinical requirements of no less than 90%.

This test examined the consistency of homologous serum and plasma using experimental reagent in a total of 250 samples, and no duplicate samples were selected. The sex ratio was distributed among 141 males (56.40%) and 109 females (43.60%). The age of enrolled patients ranged from 5.00 to 83.00 years. There were 137 cases with negative IgG antibody, accounting for 54.80% and 113 positive samples, accounting for 45.20%. There were 136 cases with negative IgM antibody, accounting for 54.40% and 114 positive samples, accounting for 45.60%. According to the consistency analysis of 250 samples, the IgG antibody detection sensitivity was 96.46%,

meeting the clinical requirements of no less than 85%, and the specificity was 98.54%, meeting the clinical requirements of no less than 90%. The IgM antibody detection sensitivity was 96.49%, meeting the clinical requirements of no less than 85%, and the specificity was 97.79%, meeting the clinical requirements of no less than 90%.

This test examined the consistency of homologous serum and whole blood using experimental reagent in a total of 250 samples, and no duplicate samples were selected. The sex ratio was distributed among 141 males (56.40%) and 109 females (43.60%). The age of enrolled patients ranged from 5.00 to 83.00 years. There were 137 cases with negative IgG antibody, accounting for 54.80% and 113 positive samples, accounting for 45.20%.There were 136 cases with negative IgM antibody, accounting for 54.40% and 114 positive samples, accounting for 45.60%. According to the consistency analysis of 250 samples, the IgG antibody detection sensitivity was 96.46%, meeting the clinical requirements of no less than 85%, and the specificity was 97.08%, meeting the clinical requirements of no less than 90%. The IgM antibody detection sensitivity was 97.37%, meeting the clinical requirements of no less than 85%, and the specificity was 97.79%, meeting the clinical requirements of no less than 90%.

Conclusion:

This clinical trial has performed a full analysis of the experimental reagents through methodological comparisons, and the results all meet the criteria for clinical evaluation. It has been verified that there is no difference between the experimental reagent‘s serum detection ability and clinical diagnostic criteria.The results of serum, plasma and whole blood samples were well consistent. All the results are accurate, stable and reliable which meet the needs of clinical testing.

1.2 Abbreviation

Severe Acute Respiratory Syndrome Coronavirus 2：SARS-CoV-2

2. Main Content

2.1 Basic Content

2.1.1 Introduction

The novel coronavirus (SARS-CoV-2) belongs to beta coronavirus, has an envelope, and the particles are round or elliptic, often polymorphic, with a diameter of 60-140nm. Its genetic characteristics are significantly different from SARAr-CoV and MERSr-CoV. When isolated and cultured in vitro, SARS-CoV-2 can be found in human respiratory epithelial cells in about 96 hours, while it takes 6 days to isolate and culture in Vero E6 and Huh-7 cell lines. It can be transmitted through respiratory droplets and contact, and the population is generally susceptible. The incubation period is 1-14 days, mostly 3-7 days. Main symptoms are fever, fatigue, and dry cough. A few patients have symptoms such as nasal congestion, runny nose, sore throat, and diarrhea. Severe patients often have dyspnea, septic shock, difficult to correct metabolic acidosis, and coagulation dysfunction after one week of onset.The elderly and those with chronic underlying disease have a poor prognosis, and children are relatively mild. Most of the SARS-CoV-2 IgM antibodies began to show positive after 3-5 days of onset, and the recovery period of IgG antibody titers increased by 4 times or more compared with the acute phase. Two consecutive negative nucleic acid tests for SARS-CoV-2 in suspected cases (Sampling time shall be at least 24 hours apart) and still negative IgG and IgM of SARS-CoV-2 specific antibodies 7 days after onset can rule out the diagnosis of suspected cases.

The SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit (Colloidal Gold) produced by Shenzhen Heto Medical Tech Co.,Ltd. is used to qualitatively detect the SARS-CoV-2 antibody in human blood (serum, plasma, whole blood) in vitro with the characteristics of simple operation and rapid detection.

2.1.2 Research purpose

To evaluate the detection capability of SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit (Colloidal Gold) produced by Shenzhen Heto Medical Tech Co.,Ltd. is equivalent to that of similar

products on the market when used for qualitative detection of IgG/IgM antibody in human serum, plasma and whole blood samples in vitro.

2.1.3 Testing management

This clinical trial was conducted by Shenzhen Heto Medical Tech Co.,Ltd. in accordance with “Technical Guidelines for Clinical Trials of Diagnostic Reagents in Vitro” and “Technical Review Points for Registration of SARS-CoV-2 Antigen/Antibody Detection Reagents (Trial)” and supervised the implementation of the entire clinical evaluation trial.

During the trial, the main investigator is responsible for the coordination and management of the entire clinical trial, and the main participants are responsible for the main trial work. During the clinical trial, the main researcher supervises the quality control of the testing laboratory. Any problems found in the test must be contacted with the main researcher in time and appropriate measures should be taken. The final test results are statistically analyzed by the person in charge of statistics (SPSS16.0 statistical software was used), and the main investigator confirmed and wrote the report. Finally, Shenzhen Heto Medical Tech Co.,Ltd. issued a clinical trial report in accordance with the requirements of exempting clinical trials.

2.1.4 Research design

2.1.4.1 General design

This test uses synchronous blind test and methodological comparison design.

In order to eliminate the possible impact of the subjective biases and personal preferences of researchers on the test results during the clinical trial process, this test uses a blind test. That is, the test personnel in this test do not know the specific information of the sample, and the clinical information of the sample may not be released until the end of the test. After the samples were enrolled, the samples were coded by the blind editor authorized by the clinical trial, in which the blind editor authorized by the clinical trial was not involved in the test operation of the clinical trial. Testing personnel shall test the coded sample according to the reagent test specification. In the process of test operation, clinical test researchers should strictly follow the requirements of the product specification for test operation and interpretation check, and the results obtained in the test process should be truthfully recorded in the data collection table.

For the detection of serum samples, the test operator divided each sample into two parts after the completion of sample enrollment, each sample was randomly coded, one part was included in the experimental reagent serum group, and one part was included in the reference reagent detection group. Another test operator synchronously tested the blind samples once according to the requirements of their respective instructions, and recorded the test results. Finally, based on the test results, reveal the blind and compare the data.

For the detection of plasma and whole blood samples, the test operator randomly coded the plasma and whole blood of the same subject after sample enrollment. Among them, plasma was included in the experimental reagent plasma group and whole blood was included in the experimental reagent whole blood group.Another test operator synchronously tested the blind samples once according to the requirements of their respective instructions, and recorded the test results. Finally, based on the test results, reveal the blind and compare the data.

2.1.4.2 Measures to reduce and avoid bias

1) Subjects were screened strictly according to the inclusion and exclusion criteria of the clinical trial protocol to reduce the selection bias.

2) Prior to the start of the trial, the sponsor shall train the participants in the clinical trial protocol and the use of the research reagent, ensure the consistency of the clinical trial protocol and the operation of the research reagent, and promote communication among the clinical trial investigators during the clinical trial.

3) Prior to the start of the trial, the clinical trial personnel shall maintain and calibrate or quality control all the equipment to be used. The applicant shall conduct the pre-test of the clinical trial with the clinical trial researcher, so as to make the applicant familiar with and master the operation method, technical performance, etc. of the product, and control the trial operation error to the maximum extent.

4) In the process of the test, the clinical test researcher must do the quality control work according to the requirements of the reagent specification and operate in strict accordance with the test plan. The clinical trial supervisor shall supervise the work to ensure that the clinical trial researchers operate and implement the test plan strictly.

5) When the clinical trial is completed, the data shall be kept and sorted out. When problems

are found in the data, the researcher shall check and confirm the data to avoid recording errors.

2.1.4.3 Clinical sample selection

2.1.4.3.1 Inclusion criteria

As this kit is an in vitro qualitative test kit, it can only be used for the auxiliary diagnosis of pneumonia caused by SARS-CoV-2 in clinic, and it cannot identify the clinical disease. Therefore, the positive and negative samples are mainly differentiated in clinical practice, and the samples included are from suspected cases of pneumonia caused by SARS-CoV-2.

Using the results of reference group as the classification basis, the subjects of this clinical study were divided into positive group and negative group. In the consistency comparison of experimental reagent and reference reagent, the result of reference reagent test was used as the classification basis. The consistency comparison among different sample types was based on the detection results of serum samples.

1) Sample inclusion criteria: the sample should be a sample with sufficient margin and clearly recorded source, including different age, gender and other factors. The collection and treatment of samples are in accordance with the reagent specification or relevant regulations, and the plasma (whole blood) samples should be anticoagulant with EDTA-2K anticoagulant. Sample information should be complete, including age, sex, sample collection date, clinical diagnosis such as confirmation or exclusion of SARS-CoV-2 infection.

2) Inclusion criteria for the positive group: clinically confirmed cases were collected, and the samples met the requirements of 1).

3) Inclusion criteria for the negative group: clinical excluded cases were collected, and the samples met the requirements of 1).

2.1.4.3.2 Exclusion criteria

1) The time of sample collection or case information is not clear.

2) The sample size is not enough to complete the test.

3) Before the test operation, it was found that the sample preservation process was polluted, resulting in turbidity.

4) Plasma (whole blood) samples were not anticoagulant with EDTA-2K anticoagulant.

5) The researchers believe that the sample does not meet the test requirements.

2.1.4.3.3 Rejection criteria

1) Samples that are unable to complete the test process due to instrument or human factors (sample contamination during operation).

2) The sample test results are from the samples that are not stored and tested according to the instructions of the test reagent / reference reagent.

2.1.4.4 Samples distribution

According to “Technical Review Points for Registration of SARS-CoV-2 Antigen/Antibody Detection Reagents (Trial)” and “Technical Guidelines for Clinical Trials of Diagnostic Reagents in Vitro”, specific requirements for clinical sample size are as follows:

The clinical sensitivity is expected to be 85%, the number of confirmed cases should be no less than 70 based on the sampling accuracy formula. The clinical specificity is expected to be 95%. The target value of specificity was set at 90% based on the clinical requirements on the specificity of this kind of detection reagent, and the excluded cases are recommended to be no less than 100 based on the formula of target value method.

2.1.4.5 Sample collection, storage and transportation methods

As the remaining samples of the hospital are used, no separate collection is involved.

2.1.4.6 Reagents and instruments for clinical research

1) The information of reagents for test is shown in Table 1:

Table 1 Reagent Information

Reagent Name	SARS-CoV-2 IgG/IgM Ab Diagnostic Test Kit (Colloidal gold)	2019-nCoV Ab Diagnostic Test Kit (Colloidal gold)
Specification	10 tests/box	10 tests/box
Company	Shenzhen Heto Medical Tech Co.,Ltd.	Innote (Tangshan) Biotechnology Co., Ltd.
Lot Number	20020300	XXX
Expiration	20210211	XXX
Preservation Condition	10~30□	10~30□
Registration Number	/	20203400177

2.1.4.7 Quality control

1） Definition

Quality control is defined as the operation of techniques and activities, such as monitoring, under the quality assurance system to verify that the research quality meets the requirements. Quality control must be applied at every stage of data processing to ensure that all data is trusted and properly located.

2） Study monitoring

During the outbreak, authorized and qualified inspectors will conduct regular remote primary data checks according to the monitoring plan to verify compliance with protocols and regulations and assist investigators.

3） Laboratory quality control

The laboratory of the testing shall establish a unified test index, standard operating procedures and quality control procedures.

4） Quality control of reagent testing process

In each test, the quality control line shall have red strip (qualified quality control). If the quality control line does not have red strip (unqualified quality control), the cause shall be found out and retested until the quality control result is qualified, so as to ensure the reliability and stability of the system.

5） Qualification of researchers

The researchers participating in the clinical trial must have the specialty, qualification and ability of the clinical trial, and pass the qualification examination. The personnel requirements should be relatively fixed.

6） Training for researchers before the experiment

Shenzhen Heto Medical Tech Co.,Ltd. is responsible for the training of researchers before the start of the trial to help clinical researchers fully understand the overall situation, scheme, CRF, etc. of the trial.

2.1.4.8 Statistical analysis method of clinical trial data

Use SPSS16.0 statistical software or the following formula for statistical analysis.

Table 2 Consistency data analysis

Experimental Reagent Group	Reference Reagent Group		Sum
	Positive	Negative	
Positive	a	b	a+b
Negative	c	d	c+d
Sum	a+c	b+d	a+b+c+d
Sensitivity		a/(a+c)	
Specificity		d/(b+d)	

2.2 Clinical Trial Results and Analysis

2.2.1 Overall distribution of samples

In this test, a total of 250 cases of serum samples were enrolled in the consistency comparison test of experimental reagent and reference reagent, and 0 cases of repeated samples were excluded for statistical analysis, including 135 IgG negative samples (54.00%), 115 IgG positive samples (46.00%), 132 IgM negative samples (52.80%) and 118 IgM positive samples (47.20%).

A total of 250 samples were enrolled in the consistency comparison test of homologous serum and plasma using experimental reagent, and 0 duplicate samples were removed, including 137 (54.80%) IgG antibody negative samples, 113 (45.20%) IgG antibody positive samples, 136 (54.40%) IgM antibody negative samples, and 114 (45.60%) IgM antibody positive samples.

A total of 250 samples were enrolled in the consistency comparison test of homologous serum and whole blood using experimental reagent, and 0 duplicate samples were removed, including 137 (54.80%) IgG antibody negative samples, 113 (45.20%) IgG antibody positive samples, 136 (54.40%) IgM antibody negative samples, and 114 (45.60%) IgM antibody positive samples. See table 3 below for details.

Table 3 Proportion and concentration distribution of clinical trials

Sample Type	Number of total cases	IgG Ab				IgM Ab			
		Negative		Positive		Negative		Positive	
		Number of cases	Ratio	Number of cases	Ratio	Number of cases	Ratio	Number of cases	Ratio
Serum	250	135	54.00%	115	46.00%	132	52.80%	118	47.20%
Plasma	250	137	54.80%	113	45.20%	136	54.40%	114	45.60%
Whole Blood	250	137	54.80%	113	45.20%	136	54.40%	114	45.60%

2.2.2 Sex and age distribution of samples

A total of 250 serum samples were enrolled in the consistency comparison test of experimental reagent and reference reagent,, including 141 males and 109 females.

A total of 250 samples were enrolled in the consistency comparison test of homologous serum and plasma using experimental reagent, including 141 males and 109 females.

A total of 250 samples were enrolled in the consistency comparison test of homologous serum and whole blood using experimental reagent, including 141 males and 109 females.

The specific distribution of samples is shown in the following table:

Table 4 Sex and age distribution

Index	Sample distribution	Serum	Plasma	Whole blood
Sex	Total	250	250	250
	Male（N,%）	141 (56.40%)	141 (56.40%)	141 (56.40%)
	Female（N,%）	109 (43.60%)	109 (43.60%)	109 (43.60%)
Age（y）	Total	250	250	250
	X±SD	35.63 ±15.71	35.63 ±15.71	35.63 ±15.71
	Mean（q1，q3）	34.00	34.00	34.00
	Min-Max	5.00~83.00	5.00~83.00	5.00~83.00

2.2.3 Consistency analysis of test results

2.3.3.1 Consistency comparison of experimental reagent and reference reagent

In this test, 250 serum samples were enrolled in the consistency comparison test of experimental reagent and reference reagent. The consistency data of the IgG antibody test results were analyzed, and a total of 111 samples were tested positive by experimental reagent and

reference reagent. There were 2 samples in which the experimental reagent was positive and the reference reagent was negative, and 4 samples in which the experimental reagent was negative and the reference reagent was positive. There were 133 samples with negative test results of experimental reagent and reference reagent. Hence, the sensitivity and specificity were 96.52% and 98.52% respectively.

Table 5 Consistency analysis of IgG antibody measurement by experimental reagent and reference reagent

Experimental reagent for serum IgG	Reference reagent for serum IgG		Sum
	Positive	Negative	
Positive	111	2	113
Negative	4	133	137
Sum	115	135	250
Sensitivity		96.52%	
Specificity		98.52%	

In this test, 250 serum samples were enrolled in the consistency comparison test of experimental reagent and reference reagent. The consistency data of the IgM antibody test results were analyzed, and a total of 111 samples were tested positive by experimental reagent and reference reagent. There were 3 samples in which the experimental reagent was positive and the reference reagent was negative, and 7 samples in which the experimental reagent was negative and the reference reagent was positive. There were 129 samples with negative test results of experimental reagent and reference reagent. Hence, the sensitivity and specificity were 94.07% and 97.73% respectively.

Table 6 Consistency analysis of IgM antibody measurement by experimental reagent and reference reagent

Experimental reagent for serum IgM	Reference reagent for serum IgM		Sum
	Positive	Negative	
Positive	111	3	114
Negative	7	129	136
Sum	118	132	250
Sensitivity		94.07%	
Specificity		97.73%	

2.3.3.2 Consistency comparison of homologous serum and plasma by experimental reagent

In this test, 250 samples were enrolled in the consistency comparison test of homologous serum and plasma using experimental reagent。The consistency data of the IgG antibody test results were analyzed, and a total of 109 samples were tested positive for both serum and homologous plasma. There were 2 samples with positive serum test results and negative homologous plasma test results, and 4 samples with negative serum test results and positive homologous plasma test results. There were 135 samples with negative test results of both serum and homologous plasma. Hence, the sensitivity and specificity were 96.46% and 98.54% respectively.

Table 7 Consistency analysis of homologous serum and plasma IgG antibody measurement by experimental reagent

Serum IgG	Plasma IgG		Sum
	Positive	Negative	
Positive	109	2	111
Negative	4	135	139
Sum	113	137	250
Sensitivity		96.46%	
Specificity		98.54%	

In this test, 250 samples were enrolled in the consistency comparison test of homologous serum and plasma using experimental reagent。The consistency data of the IgM antibody test results were analyzed, and a total of 110 samples were tested positive for both serum and homologous plasma. There were 4 samples with positive serum test results and negative homologous plasma test results, and 5 samples with negative serum test results and positive homologous plasma test results. There were 133 samples with negative test results of both serum and homologous plasma. Hence, the sensitivity and specificity were 96.49% and 97.79% respectively.

Table 8 Consistency analysis of homologous serum and plasma IgM antibody measurement by experimental reagent

Serum IgM	Plasma IgM		Sum
	Positive	Negative	
Positive	110	3	113
Negative	4	133	137
Sum	114	136	250
Sensitivity		96.49%	
Specificity		97.79%	

2.3.3.3 Consistency comparison of homologous serum and whole blood by experimental reagent

In this test, 250 samples were enrolled in the consistency comparison test of homologous serum and whole blood using experimental reagent。The consistency data of the IgG antibody test results were analyzed, and a total of 109 samples were tested positive for both serum and homologous plasma. There were 4 samples with positive serum test results and negative homologous plasma test results, and 4 samples with negative serum test results and positive homologous plasma test results. There were 133 samples with negative test results of both serum and homologous plasma. Hence, the sensitivity and specificity were 96.46% and 97.08% respectively.

Table 9 Consistency analysis of homologous serum and whole blood IgG antibody measurement by experimental reagent

Serum IgG	Whole blood IgG		Sum
	Positive	Negative	
Positive	109	4	113
Negative	4	133	137
Sum	113	137	250
Sensitivity		96.46%	
Specificity		97.08%	

In this test, 250 samples were enrolled in the consistency comparison test of homologous serum and whole blood using experimental reagent。The consistency data of the IgM antibody test results were analyzed, and a total of 111 samples were tested positive for both serum and

homologous plasma. There were 3 samples with positive serum test results and negative homologous plasma test results, and 3 samples with negative serum test results and positive homologous plasma test results. There were 133 samples with negative test results of both serum and homologous plasma. Hence, the sensitivity and specificity were 97.37% and 97.79% respectively.

Table 10 Consistency analysis of homologous serum and whole blood IgM antibody measurement by experimental reagent

Serum IgM	Whole blood IgM		Sum
	Positive	Negative	
Positive	111	3	114
Negative	3	133	136
Sum	114	136	250
Sensitivity		97.37%	
Specificity		97.79%	

2.3 Test Reliability

1) The collection and preservation methods of all test samples are reliable.

2) The operators have received special training throughout the test process to ensure the reliability of the test results.

3) When conducting clinical trials, the tests shall be conducted in strict accordance with the requirements of laboratory quality control and clinical trial program in clinical hospitals. The results were analyzed by experienced researchers to ensure the reliability of clinical trials.

2.4 Discussion and Conclusion

In this test, a total of 250 serum samples were enrolled for the consistency comparison of experimental reagent and reference reagent, and no duplicate samples were selected. The sex ratio was distributed among 141 males (56.40%) and 109 females (43.60%). The age of enrolled patients ranged from 5.00 to 83.00 years. There were 135 cases with negative IgG antibody, accounting for 54.00% and 115 positive samples, accounting for 46.00%. There were 132 cases with negative IgM antibody, accounting for 52.80% and 118 positive samples, accounting for 47.20%. According to the consistency analysis of 250 samples, the IgG antibody detection

sensitivity was 96.52%, meeting the clinical requirements of no less than 85%, and the specificity was 98.52%, meeting the clinical requirements of no less than 90%. The IgM antibody detection sensitivity was 94.07%, meeting the clinical requirements of no less than 85%, and the specificity was 97.73%, meeting the clinical requirements of no less than 90%.

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Conclusion:

This clinical trial has performed a full analysis of the experimental reagents through methodological comparisons, and the results all meet the criteria for clinical evaluation. It has been verified that there is no difference between the experimental reagent‘s serum detection ability and

clinical diagnostic criteria.The results of serum, plasma and whole blood samples were well consistent. All the results are accurate, stable and reliable which meet the needs of clinical testing.

2.5 Explanation of Special Circumstances in Clinical Trial

No.

2.6 Appendix

1） Instructions for Use (IFU)
2） Clinical Evaluation Data