COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)

Clinical Study Report

Name of in vitro diagnostic reagents used in the test: COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)

Specifications: 25 Tests/Box

Start and end time of the test: August 21th, 2020- September 23th, 2020

Applicant: New Gene (Hangzhou) Bioengineering Co., Ltd.

Address: Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

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Summary

The COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold) developed by New Gene (Hangzhou) Bioengineering Co., Ltd. can quickly and qualitatively detect the IgM and IgG antibody in human blood/serum/plasma samples. It can be used as a supplementary test for COVID-19 diagnosis.

According to the clinical trial plan, the COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold) or "test reagent", is to test plasma samples from confirmed COVID-19 patients and healthy donors. The sensitivity, specificity, and total accuracy are used to evaluate the reliability of test reagent in clinical applications.

Method: A collection of clinical samples are examined by the test reagent to calculate the clinical sensitivity, clinical specificity, and total accuracy of the test reagent.

Standard of criteria for a qualified test reagent: Clinical sensitivity ≥90%, clinical specificity ≥90%, and total accuracy ≥90%.

Results: The sensitivity, specificity, and accuracy of test reagent are 94.9% (95% CI: 88.5% - 98.3%), 99.0% (95% CI: 94.8% - 100.0%;), and 97.0% (95% CI: 93.7% - 98.9%) for IgM detection, and 97.9% (95% CI: 92.8% - 99.7%), 99.0% (95% CI: 94.8% - 100.0%;), and 98.5% (95% CI: 95.7% - 99.7%) for IgG detection, respectively.

Conclusion: The test reagent has reliable performance in diagnosing COVID-19 cases.

Acronyms

Test reagent: The COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold) developed by New Gene (Hangzhou) Bioengineering Co., Ltd.

SARS-COV-2: Novel Corona Virus 2019

Main contents

Introduction

The novel coronavirus SARS-COV-2 is the causative pathogen for the global pandemic of COVID-19. It is contagious in humans, either symptomatically or asymptomatically. Based on current epidemic knowledge, the asymptomatic infection may last for 1 day to 14 days, mainly 3 days to 7 days. Symptoms of COVID-19 include fever, fatigue, and cough. Some patients also complains about nasal obstruction, runny nose, score throat, muscle aches, and diarrhea.

In response to the emergent market needs, New Gene (Hangzhou) Bioengineering Co., Ltd. has developed the COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold). It identifies potential patients that infected by SARS-COV-2, by detecting the virus induced IgM/IgG antibody in human blood/serum/plasma samples.

Production of the COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold) is implemented in Class 100,000 cleanrooms, by proficient operators. Multiple quality

control processes are included in the manufacture procedures to examine the quality of raw materials, semi-finished products, and finished products. The construction of cleanrooms, personnel training, and manufacture practices are implemented under relevant laws and regulations.

To evaluate the clinical performance of the COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold), the current clinical trial is jointly carried out by the applicant and a clinical site. The applicant is responsible for providing test reagents and training relevant personnel with the operating procedures and technical principles to minimize operational bias. The clinical site is responsible for the collection and storage of clinical trial samples, the implementation of clinical trials, the compilation of clinical trial records, and the composing of clinical trial reports.

Trial objective

The objective of current trial is to evaluate the performance of test reagent in clinical applications, using samples from confirmed COVID-19 patients and healthy donors.

Trial design

Clinical samples for the current trial are collected by the clinical site, and tested by both the test reagent. The clinical sensitivity, clinical specificity, and total accuracy of test reagent are calculated based on the test results.

Results and analysis

Determining the sample size.

Considering the uncertainty of obtaining positive samples, the number of samples for this clinical trial shall be no less than 60, of which the number of positive samples shall not be less than 30.

Sample collection, storage, and transportation.

Blood samples are collected from confirmed COVID-19 patients and healthy donors, and preserved in anti-coagulation tubes. Plasma is isolated within 6 hours post blood collection, and kept frozen at -70°C until used.

Information of the test reagent.

Test reagent	COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)		
Specification	25 Tests/Box	Lot No.	20200724-01
Period of Validity	1 year	Storage	2°C~30°C
Manufacturer	New Gene (Hangzhou) Bioengineering Co., Ltd.		

Quality control methods

The clinical trial is strictly implemented in accordance with the corresponding instruction

manual.

Statistical analysis method of clinical trial data

		Clinical Diagnosis		Total
		Positive	Negative	
Test reagent	Positive	a	b	a + b
	Negative	c	d	c + d
Total		a + c	b + d	a + b + c + d

Clinical sensitivity (%) = [a / (a + c)] ×100%

Clinical specificity (%) = [d / (b + d)] ×100%

Total accuracy (%) = [(a + d) / (a + b + c + d)] ×100%

The confidence intervals are calculated following the binomial distribution.

Clinical trial results and analysis

Sample characterization

A collection of 203 plasma samples have been tested with Test Reagent. These samples are taken from 98 confirmed COVID-19 patients and 105 healthy donors. Out of the 98 confirmed COVID-19 patients, 43 (43.9%) are female and 55 (56.1%) are male. Their ages range from 24 to 69 years old, and are 49 years old on average. The sampling times are between Day 21 to Day 28 post symptom onset, mainly on Day 23 (23.4%).

Result analysis

IgM Antibody Test Results

The Test Reagent finds out 94 positive results, of which 93 samples are from COVID-19 patients. One sample from a healthy donor is reported positive by Test Reagent, and another 5 samples from COVID-19 patients are reported negative by Test Reagent. The other 104 samples from healthy donors are reported negative by Test Reagent.

IgM		Clinical Diagnosis		Total
		Positive	Negative	
Test reagent	Positive	93	1	94
	Negative	5	104	109
Total		98	105	203

Clinical sensitivity (%) = [93 / (93 + 5)] ×100% = 94.9%;

95% confidence interval: 88.5% - 98.3%;

Clinical specificity (%) = [104 / (1 + 104)] ×100% = 99.0%;

95% confidence interval: 94.8% - 100.0%;

Total accuracy (%) = [(93 + 104) / (93 + 1 + 5 + 104)] ×100% = 97.0%;

95% confidence interval: 93.7% - 98.9%.

IgG Antibody Test Results

The Test Reagent finds out 97 positive results, of which 96 samples are from COVID-19 patients. One sample from a healthy donor is reported positive by Test Reagent, and another 2 samples from COVID-19 patients are reported negative by Test Reagent. The other 104 samples from healthy donors are reported negative by Test Reagent.

IgG		Clinical Diagnosis		Total
		Positive	Negative	
Test reagent	Positive	96	1	97
	Negative	2	104	106
Total		98	105	203

Clinical sensitivity (%) = [96 / (96 + 2)] ×100% = 97.9%;

95% confidence interval: 92.8% - 99.7%;

Clinical specificity (%) = [104 / (1 + 104)] ×100% = 99.0%;

95% confidence interval: 94.8% - 100.0%;

Total accuracy (%) = [(96 + 104) / (96 + 1 + 2 + 104)] ×100% = 98.5%;

95% confidence interval: 95.7% - 99.7%.

Discussion and conclusion

In this clinic trial, performance of the test reagent “COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)” is evaluated on a collection of 203 clinical samples.The test reagent have shown sensitivity, specificity, and accuracy of 94.9% (95% CI: 88.5% - 98.3%), 99.0% (95% CI: 94.8% - 100.0%;), and 97.0% (95% CI: 93.7% - 98.9%) for IgM detection, and 97.9% (95% CI: 92.8% - 99.7%), 99.0% (95% CI: 94.8% - 100.0%;), and 98.5% (95% CI: 95.7% - 99.7%) for IgG detection, respectively, which implies a promising future in clinical applications.

Although the nucleic acid test is considered as the most accurate method for COVID-19 diagnosis, sampling bias in clinical applications has shown non-negligible impacts on testing results. Similar problem is also reported in antigen tests. In simple words, the viral particles are only detectable when they are picked up by sampling tools like swabs. If the users fail to pick up any viral particles, a false negative result will be reported. Compared to nucleic acid tests and antigen tests, the antibody tests are not affected by sampling bias because the antibodies are considered evenly distributed in blood system. Therefore, the application of antibody test can be used as a supplementary test to assist nucleic acid tests and antigen tests.

In summary, the current clinical trial has proven the reliable performance of COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold). This product is promising to assist the diagnosis of COVID-19 cases in large scales.