Novel Coronavirus(COVID-19)IgG/IgM

Rapid Test Device

Clinical Trial Test Report

Product Name: Novel Coronavirus(COVID-19)IgG/IgM Rapid Test Device

Package Specification: 25 tests/kit

Experimental Institution: The Fifth Affiliated Hospital of Sun Yat-Sen University

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1. Introduction

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. The α and β gene are only pathogenic to mammals. The γ gene mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also some evident that it can be transmitted through the fecal-oral route.

So far, there are 7 types of human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and Novel Coronavirus(COVID-19) (2019) , it's an important pathogen of human respiratory infections. Among them, the COVID-19 was discovered in 2019 from Wuhan virus pneumonia outbreak. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea and so on. These manifestations can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome(ARDS), septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

IgM is the primary antibody to appear in the human immune system soon after infected. The detection of SARS-CoV-2 specific IgM during acute infection has the advantages of high sensitivity, early diagnosis, and ability to determine whether the suspected person is infected, etc. Therefore, the detection of Coronavirus (SARS-CoV-2) IgM antibody has important clinical significance, which is of great significance to effective control of the large-scale spread of SARS-CoV-2.

IgM antibody produces after several days of virus infection, and can be detected as early as one week or even 3 days, the time it appears varies from individual to individual . IgG antibody generally begins to produce 7-14 days after virus infected, maintain time is longer, some cases can maintain lifetime even.

Zhuhai Encode Medical Engineering Co.,Ltd (hereinafter referred to as Encode) combined with international, domestic and foreign research results of Coronavirus,

developed Novel Coronavirus(COVID-19)IgG/IgM Rapid Test Device (hereinafter referred to as Kit), the kit is to use the antigen-antibody reaction and the immune chromatography detection principle and development of rapid diagnostic kit, with strong specificity, high sensitivity, rapid, simple, no special instrument characteristics, It is a aid for medical and health institutions to diagnosis Coronavirus (COVID-19).

2.Test Principle and Characteristics

2.1 Test Principle

Coronavirus(COVID-19)IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant *COVID-19* antigen conjugated with colloid gold (*COVID-19* conjugates) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-*COVID-19*, T2 band is pre-coated with reagents for the detection of IgM anti-*COVID-19* and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. *COVID-19* IgM antibodies if present in the specimen will bind to the *COVID-19* conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored T2 band, indicating *COVID-19* IgM positive test result.

COVID-19 IgG antibodies if present in the specimen will bind to the *COVID-19* conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored T1 band, indicating a *COVID-19* IgG positive test result.

Absence of any test bands (T1 and T2) suggests a negative result. The test card also contains a quality control band C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. The quality control

band is a color band of the quality control antibody immune complex. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

2. 2 Characteristics

The Novel Coronavirus(COVID-19) IgG/IgM Rapid Test is developed by Zhuhai Encode Medical Engineering Co.,Ltd using the principles of antigen-antibody specific binding and immunochromatography, the kit for qualitative detection of IgG and IgM antibodies of Coronavirus (COVID-19) in human serum, plasma or whole blood has been developed with the following characteristics:

High sensitivity: The clinical positive detection rate is higher than 90%

Convenient: Easy to use, simple , fast,without instrument and result into 15 minutes,it suitable for mass screening, Significantly reduce workload and risk of individual infected in hospitals.

Storage and Validity: Long shelf life, store at 2-30℃， room temperature storage

Low Inter-assay difference : Strict quality control and process optimization, guarantee stable and high quality

3. Intended Use

The Novel Coronavirus(COVID-19) IgG/IgM Rapid Test is used for the qualitative detection of IgG and IgM antibodies in human serum, plasma or whole blood.

4. Trial Test Evaluation and Purpose

4.1 Purpose

The project is an clinic evaluation, in order to study the clinical positive and negative detection rate of COVID-19 by the novel Coronavirus (COVID-19)IgG/IgM Rapid

which manufactured by Zhuhai Encode Medical Engineering Co.,Ltd

4.2 Project Content

- IgM diagnostic coincidence rate
- IgG diagnostic coincidence rate
- Negative coincidence rate

5. Test Design

5.1 Test Method

5.1.1 Sample source and quantity： Collect serum,plasma and whole blood from 49 cases positive Novel Coronavirus infection patient, include 10 cases serum, plasma or whole blood samples from convalescent patients, and 32 cases from clinically confirmed negative for Novel coronavirus infection paitents

5.1.2 Specimen collection and preparation: follow the product inserts strictly **.**

5.1.3 Test Procedure:

Operation method: Operate strictly in accordance with the package insert, handle the specimen according to specimen collection and preparation guideline, and read the results according to interpretation of results in the package insert.

5.2 Validation project

5.2.1 Positive coincidence rate: Novel Coronavirus infection positive coincidence rate includes positive detection rate of IgM antibody from the novel coronavirus infected patients and IgG positive detection rate of convalescent patients who was infected by novel coronavirus, in their serum, plasma or whole blood samples

5.2.2 Negative coincidence rate: Negative coincidence rate of patients who were not infected by Novel Coronavirus

6. Test implementation and result statistics

6.1 Batch No. of Test kit : 202001301

6.2 Statistics of test results

Collected 81 cases clinical specimen from Novel Coronavirus infected patients, include 49 cases blood specimen from confirmed Positive Novel Coronavirus infected patients and 32 cases from confirmed negative Novel Coronavirus infected patients

6.3 Statistics of Positive Specimen

When the human body attacked by foreign antigens, the first responding antibody is IgM, which is secreted directly by the receptor on the surface of B cells. The B cells produce IgM entering the lymph nodes, receive stimulation from T cells and antigen-presenting cells in the center of occurrence and further mature, differentiate into plasma cells, and produce large amount of IgG. IgM is usually produced 3-7 days after infected.

According to the characteristics of novel coronavirus antibody produced in human body , we classified the positive samples from the positive diagnosis based on sampling time as Table1shows.

Table 1 Test results of positive specimens

		IgM		IgG	
Specimen Positive Time	**Number of specimens**	**Positive**	**Negative**	**Positive**	**Negative**
1 Day	15	2	13	2	13
2 Days	9	2	7	2	7
3 Days	1	0	1	0	1
4 Days	5	4	1	5	0
5 Days	3	3	0	3	0
6 Days	4	3	1	3	1
7 Days	2	2	0	2	0
8 Days	3	2	1	2	1
9 Days	2	2	0	2	0
10 Days	3	3	0	3	0
12 Days	2	2	0	2	0

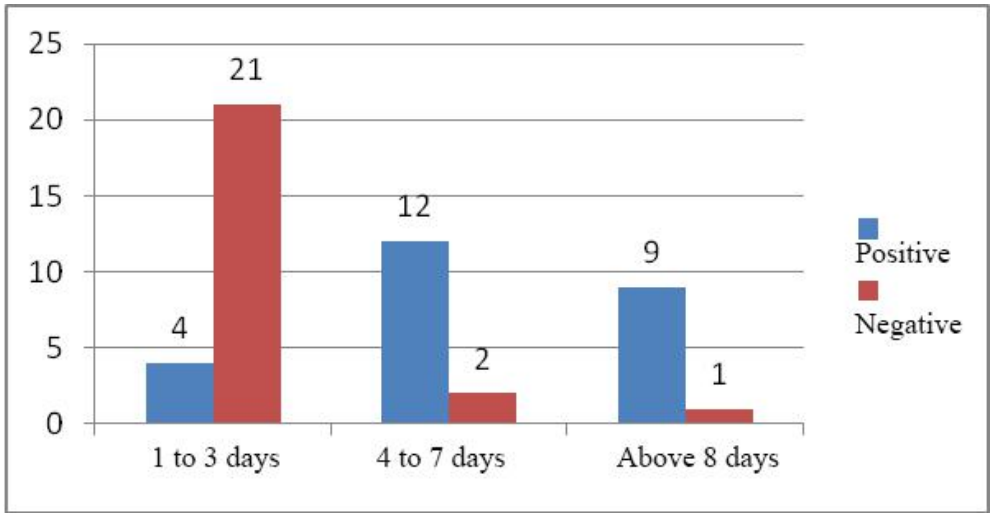
The 49 positive specimens were further classified according to the time when

the specimens were taken. Divided into samples taken 1-3 days after the positive diagnosis, samples taken 4-7 days after the positive diagnosis, and samples taken more than 8 days after the positive diagnosis.

Table 2 Classification and statistical results of positive specimens

		IgM		IgG	
Specimen Positive Time	**Number of specimens**	**Positive**	**Negative**	**Positive**	**Negative**
1-3 Days	25	4	21	4	21
4-7 Days	14	12	2	13	1
Above 8 Days	10	9	1	9	1

Chart 1 Classification statistics of positive test results



6.3.1 Classification and analysis of positive specimen from clinical positive confirmed to sampling date:

A total of 24 specimens were tested from 1 to 3 days, the IgM positive rate was 16% and the IgG positive rate was 16%;

A total of 14 specimens were tested from 4 to 7 days, the IgM positive rate was 85.7% and the IgG positive rate was 92.8%;

A total of 10 specimens were tested in the range of more than 8 days, the IgM positive rate was 90% and the IgG positive rate was 90%.

6.3.2 Statistical analysis of confirmed negative specimens

31 cases confirmed negative specimens were tested, statistics are shown in the table below.

Table 3 Confirmed negative specimen test results

	IgM		IgG	
Number of specimens	Positive	Negative	Positive	Negative
31	0	31	0	31

31 cases confirmed negative specimens were tested, and the negative coincidence rate was 100%.