Novel Coronavirus(COVID-19)IgG/IgM Rapid Test Device Package Insert

CE

Cat: RCD-422 **Specimens:** Whole Blood/Serum/Plasma

Version:02 **Effective Date:** 2020-03

For professional *in vitro* diagnostic use only.

INTENDED USE

The Novel Coronavirus(COVID-19)IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus(COVID-19) in human wholeblood,serum or plasma.

This test is intended to be used as a screening test and as an aid in the diagnosis of infection with Novel Coronavirus. Any reactive specimen with the Novel Coronavirus(COVID-19)IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

SUMMARY AND EXPLANATION OF THE TEST

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 evidence 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, a COVID-19 was discovered in 2019 due to Wuhan virus pneumonia cases. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea and so on. Can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

TEST PRINCIPLE

The The Novel 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.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Disposable pipettes	For adding specimens use
5ml Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Alcohol Pad (for home test package only)
- Centrifuge (for plasma only)
- Specimen collection containers
- Lancets (for home test package only)
- Timer

STORAGE AND STABILITY

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- The kit should be stored at 2 ~ 30°C in cool and dry place, protected from light.
- After open the aluminum foil pouch, the test card will become invalid due to moisture absorption. Please use it within 1 hour.

SPECIMEN COLLECTION AND PREPARATION

- The kit can be performed used on Serum , Plasma or Whole Blood specimen, include plasma or whole blood samples prepared from commonly used anticoagulants (EDTA, heparin, sodium citrate).
- Testing should be performed immediately after specimen collection. If it cannot be detected immediately, the serum and plasma specimen to be tested can be stored at 2 ~ 8 ° C for 5 days. For long-term storage, store at -20 ° C. Avoid repeated freeze-thaw specimens. Anticoagulated whole blood specimens should not be stored for more than 72 hours at room temperature; not more than 7 days at 2-8 ° C.
- Before testing, slowly return the refrigerated or frozen specimens to room temperature and mix them carefully. When clearly visible particulate matter is present in the specimen, it should be centrifuged to remove sediment before testing.
- If the specimen contains a large amount of lipid, hemolysis or turbidity, please do not use it, so as not to affect the result judgment.

ASSAY PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Place the test device on a clean, flat surface and label specimen number
2. Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 10 μL) of whole blood (include finger blood),serum, plasma into the sample well,making sure that there are no air bubbles. Then add 1-2drops (about 70-100 μL) of Sample Diluent immediately.
3. Set up timer. Results can be read in 15 minutes. ***Don't read result after 15 minutes.***

INTERPRETATION OF ASSAY RESULT

POSITIVE RESULT:

In addition to the presence of C band, if only T1 band is developed, the test indicates for the presence of *COVID-19* IgG antibody. The result is positive.

In addition to the presence of C band, if only T2 band is developed, the test indicates for the presence of *COVID-19* IgM antibody. The result is positive.

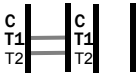
In addition to the presence of C band, both T1 and T2 bands are developed, the test indicates for the presence of both IgG and IgM anti- *COVID-19,* The result is also positive.

***NOTE:** Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

NEGATIVE RESULT:

If only the C band is present, the absence of any burgundy color in the both test bands (T1 and T2) indicates that no *COVID-19* antibody is detected in the specimen. The result is negative.

INVALID RESULT:



If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Positive Coincidence Rate: The test results of positive quality control are all positive

2. Negative Coincidence Rate: The test results of negative quality control are all negative

3. Analytical Specificity: The test results of specimen from non- infected by novel coronavirus should be negative

4. Analytical Sensitivity: The detection result is positive when detection of a novel coronavirus IgG strongly positive serum 1:50 dilution sensitivity reference : The detection result is positive when detection of a novel coronavirus IgM strongly positive serum 1:50 dilution sensitivity reference

5. Intra-Assay: There is no different test results of the same quality control in the same batch;

6. Inter-Assay: There is no different test results of the same quality control from different batch.

LIMITATIONS OF TEST

1. The Assay Procedure and the Assay Result Interpretation must be followed strictly the inserts when testing. Failure to follow the procedure may give inaccurate results.
2. This kit is only used for in vitro diagnosis and is only used for qualitative detection of Coronavirus IgG and/or IgM antibodies in blood samples, and cannot be quantitative detection.
3. Positive and negative results indicate the presence of IgG and/or IgM antibodies with/without detectable concentrations of Coronavirus in blood samples, but cannot be used as the sole criterion for the determination of Coronavirus infection. Other methods (such as nucleic acid testing) should be used for identification when necessary, and comprehensive judgment should be made based on the test results.

WARNINGS AND PRECAUTIONS

1.Before using the kit, please read the instructions carefully and control the reaction time strictly. If you do not follow the instruction, you will get inaccurate results.

2. The specimen should be tested in the laboratory with certain conditions.All samples and materials in the testing process shall be handled in accordance with the laboratory practice for infectious diseases.

3. Be careful to prevent the product from getting wet, and do not open the aluminum bag before it is ready for testing;If the aluminum foil bag is damaged or the test card is damage, it cannot be used.

4. Do not replace the components in this kit with components in other kits.

5. Hemolytic specimen should not be used for testing.

6. Do not use cloudy pollution specimen for testing.

7. Do not dilute the specimen for testing, otherwise inaccurate results may be obtained.

8. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.

9. This kit is limited to qualitative detection of Coronavirus antibodies in human serum, plasma or whole blood.

10. The kit will produce negative results under the following conditions: when the titer of the Coronavirus antibody in the specimen is less than the minimum detection limit of the kit, or the Coronavirus antibody does not exist at the time of specimen.

11.Specimen contained higher titers of heterophobic antibodies or rheumatoid factors may affect the expected results.

12.When the assay procedure is completed, in accordance with local regulations dispose the test kit and tube

REFERENCES

1.Catharine I. Paules, MD; Hilary D. Marston, MD, MPH; Anthony. S. Fauci, MD. Coronavirus Infections—More Than Just the Common Cold. JAMA. 2020;323(8):707-708 .

2.C Huang, Y Wang, X Li, L Ren, J Zhao, Y Hu, L Zhang. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet, Volume 395, Issue 10223, 15 – 21 February 2020, Pages 497-506.

3.Prof Nanshan Chen MD, Prof Min Zhou MD, Xuan Dong PhD, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. The Lancet,Available online 30 January 2020.

4.Prof Roujian Lu MSc, Xiang Zhao MD, Juan Li PhD, et al.Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. The Lancet, Volume 395, Issue 10224, 22 – 28 February 2020, Pages 565-574.

5.B.Coutard, C.Valle, X.de Lamballerie, et al. The spike glycoprotein of the new coronavirus 2019-nCoV contains a furin-like cleavage site absent in CoV of the same clade. Antiviral Research, Volume 176, April 2020.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		

Zhuhai Encode Medical Engineering Co.,Ltd

NO.020, Honghui 2nd Road, Hongqi Industrial Zone, Jinwan District, Zhuhai,P.R. China 519090

Tel: (0086)756-3981528 Fax: (0086)756-3983809

E-mail: encode01@hotmail.com itd@encode.com.cn

Website: http//www.encode.com.cn

EC REP Prolinx GmbH

Brehmstr. 56, 40239, Duesseldorf, Germany