

SARS-CoV-2 IgG/IgM Rapid Test Package Insert



Cat: RCD-422

Specimens: Whole Blood/Serum/Plasma

Version: 13-1

Effective Date: 2020-06

For professional *in vitro* diagnostic use only.

Read this package insert completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results. Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), coronavirus disease (COVID-19), and other Blood-borne Pathogens in Health-Care Settings.

INTENDED USE

The SARS-CoV-2 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 (SARS-CoV-2) in human whole blood, serum or plasma.

This test is intended to be used as an aid in the diagnosis of infection with Novel Coronavirus. Any reactive specimen with the SARS-CoV-2 IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

SUMMARY

The novel coronaviruses (SARS-CoV-2) belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

TEST PRINCIPLE

The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant SARS-CoV-2 antigen conjugated with colloid gold (SARS-CoV-2 conjugates) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (IgG and IgM bands) and a control band (C band). The IgG band is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-SARS-CoV-2, IgM band is pre-coated with reagents for the detection of IgM anti-SARS-CoV-2 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. SARS-CoV-2 IgM antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored IgM band, indicating SARS-CoV-2 IgM positive test result.

SARS-CoV-2 IgG antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored IgG band, indicating a SARS-CoV-2 IgG positive test result.

Absence of any test bands (IgG and IgM) 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.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Buffer
- Package insert

Materials Required But Not Provided

- Centrifuge (for plasma only)
- Timer
- Specimen collection containers

STORAGE AND STABILITY

- For professional *in vitro* diagnostic use only.
- Expiry date is 24 months after its manufacture date. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- Store unused tests unopened at 2°-27°C (36°-80°F). Do not open the Pouch until you are ready to perform a test. If stored refrigerated, ensure that the pouch is brought to operating

temperature (15°- 37°C, 59°- 99°F) before opening.

- After the aluminum foil pouch is opened, 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 on serum, plasma or whole blood specimen including plasma or whole blood samples prepared with 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; no longer 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.

Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 10 μ L) of whole blood, serum, plasma into the sample well, making sure that there are no air bubbles.

Then add 1-2 drops (about 70-100 μ L) of Sample Diluent immediately.

2. 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 IgG band is developed, the test indicates for the presence of SARS-CoV-2 IgG antibody. The result is positive.



In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of SARS-CoV-2 IgM antibody. The result is positive.



In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-SARS-CoV-2. 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 (IgG and IgM) indicates that no SARS-CoV-2 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. Clinical Performance

The clinical performance of the SARS-CoV-2 IgG/IgM Rapid Test was evaluated by testing a total of 306 clinical samples from individual patients. The samples were collected from patients at four countries in the world, concluding China, the United States, South Korea and Iran. All specimens were tested in the local laboratory.

1.1 Testing of RT-PCR positive clinical specimens

One hundred and seventy-three (173) positive samples collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection.

Table 1 Classification and statistical results of positive samples

| Infectious period(days) | Number | IgM | | IgG | |
|-------------------------|--------|-----|-----|-----|-----|
| | | Pos | Neg | Pos | Neg |
| 1-3 | 68 | 11 | 57 | 11 | 57 |
| 4-7 | 53 | 41 | 12 | 42 | 11 |
| ≥ 8 | 52 | 50 | 2 | 49 | 3 |

The positive rates of IgM and IgG were 16.2% and 16.2% respectively within 1-3 days. The positive rates of IgM and IgG were 77.4% and 79.2% respectively within 4-7 days. The positive rates of IgM and IgG were 96.2% and 94.2% respectively above 8 days.

1.2 Testing of RT-PCR negative clinical specimens

One hundred and thirty-three (133) negative samples collected from individuals who tested negative with a RT-PCR method for SARS-CoV-2 infection.

Table 2 Classification and statistical results of positive samples

| Number | IgM | | IgG | |
|--------|-----|-----|-----|-----|
| | Pos | Neg | Pos | Neg |
| 133 | 0 | 133 | 1 | 132 |

The negative rates of IgM and IgG were 100% and 99.2% respectively.

3. Cross Reactivity

Cross-reactivity of the SARS-CoV-2 IgG/IgM Rapid Test was evaluated using serum or plasma samples which contain antibodies to the pathogens listed below. No false positive was found with the following:

Table 3 Cross-reactivity Results

| Antibodies (Anti-IgM, Anti-IgG) | Number of specimens | | Cross reactivity |
|--|---------------------|---|------------------|
| a) Coronaviruses | | | |
| Human coronavirus 229E | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Human coronavirus OC43 | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Human coronavirus HKU1 | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Human coronavirus NL63 | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| b) High prevalence organisms relevant for differential diagnosis and others | | | |
| Adenovirus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Human Metapneumovirus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Parainfluenza virus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Influenza A virus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Influenza B virus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Haemophilus influenzae | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Rhinovirus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Respiratory syncytial virus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Epstein-Barr virus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |

| 3) Other organisms | | | |
|----------------------------|-----|---|---------|
| Enterovirus | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Chlamydia pneumoniae | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Legionella pneumophila | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Mycobacterium tuberculosis | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Streptococcus pneumoniae | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Streptococcus pyogenes | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Bordetella pertussis | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |
| Mycoplasma pneumoniae | IgM | 5 | 100%Neg |
| | IgG | 5 | 100%Neg |

4. Potential interfering substances

Low titer SARS-CoV-2 antibody positive serum samples and SARS-CoV-2 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positive or false negative was found with the following:

Table 4 Interference Results

| Substance | Concentration |
|---------------------------------------|---------------|
| Bilirubin Conjugated | 43umol/L |
| Bilirubin unconjugated | 24umol/L |
| Hemoglobin | 50mg/mL |
| Human Serum Albumin | 50g/L |
| Triglycerides | 500mg/dL |
| Cholesterol | 500mg/dL |
| Rheumatoid factors | 850 IU/mL |
| anti-saccharomces cerevisiae antibody | 60U/ml |
| Antinuclear antibody (ANA) titer | 1:1000 |
| Total IgM | 80mg/mL |
| Total IgG | 50mg/mL |

LIMITATIONS OF TEST

- The assay procedure and the assay result interpretation must strictly follow the package insert when testing. Failure to follow the procedure may give inaccurate results.
- 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.
- 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

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

be used for identification when necessary, and comprehensive judgment should be made based on the test results.

- It is only provided for use by clinical laboratories or to healthcare workers for point-of care testing, and not for at-home testing. The test package includes instructions for use along the following lines,
- It is only used as a supplementary test indicator for SARS-CoV-2 nucleic acid negative suspected cases or in conjunction with nucleic acid detection in the diagnosis of suspected cases. Not applicable to screening in the general population.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results should be confirmed by additional testing and clinical evaluation under the guidance of the physician.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus SARS-CoV, MERS-CoV.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- It is used to detect SARS-CoV-2 IgM and IgG antibodies in human blood samples. It is possible to get any results from other liquid samples, and the above results cannot be used as a judgment criterion.
- There are individual differences in the time of antibody production after SARS-CoV-2 infection, so the window period from SARS-CoV-2 infection to antibody detection is not consistent among different individuals.
- It is not for the screening of donated blood.

WARNINGS AND PRECAUTIONS

- 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.
- 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.
- Be careful to prevent the product from getting wet, and do not open the foil pouch before it is ready for testing; If the aluminum foil bag is damaged or the test card is damaged, it cannot be used.
- Do not replace the components in this kit with components in other kits.
- Hemolytic specimen should not be used for testing.
- Do not use cloudy polluted specimen for testing.
- Do not dilute the specimen, otherwise inaccurate results may be obtained.
- The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
- This kit is limited to qualitative detection of coronavirus antibodies in human serum, plasma or whole blood.
- 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.
- Specimen contained higher titers of heterophobic antibodies or rheumatoid factors may affect the expected results.
- When the assay procedure is completed, dispose the used components and samples in strict accordance with the laboratory practice for COVID-19.

REFERENCES

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- Gorbalenya AE (11 February 2020). "Severe acute respiratory syndrome-related coronavirus – The species and its viruses, a statement of the Coronavirus Study Group". Archived from the original on 11 February 2020. Retrieved 11 February 2020.
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- 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

 Zhuohai 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

 Prolinx GmbH
 Brehmstr. 56, 40239, Duesseldorf, Germany

US Distribution

Evanla, Inc.
 3015 S Archer Ave Front 1
 Chicago, IL 60608, USA
 Tel: (747) 333-8388
 E-Mail: cs@evanla.com
 Website: www.evanla.com

Important FDA guidance:

This test has not been reviewed by the FDA.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Not for the screening of donated blood

WARNINGS

For in vitro Diagnostic Use

- Read the package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
- Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), coronavirus disease (COVID-19), and other Blood-borne Pathogens in Health-Care Settings. Pathogens in Health-Care Settings.
- This test should be performed at temperatures in the range of (15°- 37°C, 59°- 99°F). If stored refrigerated, test is brought to operating temperature (15°- 37°C, 59°- 99°F) before performing testing.
- If the test kit is stored at temperatures outside of ambient temperature (2°- 27°C, 36°- 80°F), or used outside of the operating temperature (15°- 37°C, 59°- 99°F).
- Individuals undergoing preventive treatment for SARS-CoV-2 may produce false negative results.

PRECAUTIONS

Safety Precautions

- Handle blood specimens and materials contacting blood specimens as if capable of transmitting infectious agents.
- Do not drink, eat, or smoke in areas where specimens are being handled or testing is being performed.
- Wear disposable gloves while handling blood specimens and performing testing of blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
- Dispose of all test specimens and materials used in the test procedure in a biohazard waste container. Lancets and venipuncture materials should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**
- Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant. Bleach solutions should be made fresh each day.