Novel Coronavirus (SARS-COV-2) IgM/IgG Antibody Rapid Test Kit Instruction Manual

REF:C3049

【Product Name】

Novel Coronavirus (SARS-COV-2) IgM / IgG Antibody Rapid Test Kit

【Package】

Card:25/box

【Intended Use】

Novel Coronavirus (SARS-COV-2) IgM/IgG Antibody Rapid Test Kit is used to qualitatively detect novel Coronavirus (2019-NCOV) IgG/IgM antibody in human serum, plasma or whole blood (including fingertip blood). The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19).

The test provides preliminary test results. Negative results do not preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

For in vitro diagnostic use only.

【Summary】

The novel coronaviruses belong to the β genus.COVID-19 is an acute respiratory infectious disease caused by the novel coronaviruses. People are generally susceptible. Currently,the patients infected by 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 periodis 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.

【Principle】

The Novel Coronavirus (SARS-COV-2) IgM/IgG Antibody Rapid Test Kit consists of a nitrocellulose membrane coated with rat anti-human IgG antibody (T_1/G), rat anti-human IgM (T_2/M), Sheep anti-rat polyclonal antibody and a release pad coated with a novel coronavirus SARS-COV-2 specific antigen-latex microsphere complex and other reagents. The kit is a lateral flow immunochromatographic assay for the qualitative and differential detection of IgG and IgM antibody to 2019 novel Coronavirus in human serum, plasma and whole-blood. When a specimen is added to the sample well, if the SARS-CoV-2 IgM / IgG antibody level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T_1/G,T_2/M) of the device. This indicates a negative result. If the SARS-CoV-2 IgM / IgG antibody present and the concentration beyond the detection limit, antibody will bind to novel coronavirus SARS-COV-2 specific antigen-latex microsphere complex to form the antigen complex. This complex migrates through nitrocellulose membrane by capillary action. There is a visible colored band in the Test Region (T_1/G, T_2/M) of the device.The internal control (C band) should exhibit a red band regardless of the color development on any of the test bands in the test. Otherwise, the test result is invalid.

【Materials Supplied】

1） 25 Novel Coronavirus (SARS-COV-2) IgM/ IgG test cards

2） 25 Quantitative Sampling Needles and 25 Samplinng Tubes(Containing Buffer Solution)

3） An Introduction manual

【Storage and Stability】

1) Stored at 4～30 ℃ protect from light.

2) Do not freeze.

3) Properly stored kits are valid for 12 months.

4) See label for production date and validity.

5) The test cards should be used within 1 hour after taking out from the packaging bag.

【Specimen requirements】

1） This kit is only appropriate for human serum, plasma or whole blood(including fingertip blood) sample.

2） Fingertip blood and venous blood should be collected with standard clinical-laboratory procedure; avoid hemolysis during serum/plasma separated from whole blood.

3） The sample should be tested as soon as possible after collection, and should not be left for a long time at room temperature. If serum or plasma samples cannot be detected immediately, the sample can be stored at 2-8 ℃ for up to 3 days. For long term storage, specimens should be kept below -20 ℃. Whole blood collected by venipuncture should be stored at 2-8 ℃ if the test is to be run within 2 days after collection. Do not freeze whole blood specimens. Whole blood collected from fingertip should be tested immediately.

4） The sample must be returned to room temperature before testing.

【Test Procedure】

1） Please read the instruction manual carefully before operation.

2） Allow test card, buffer solution, and specimen to equilibrate to room temperature prior to test. After everything is ready, open the packaging bag, take out the card and place it on a level surface. Once opened, the test card must be used as soon as possible within 1 h.

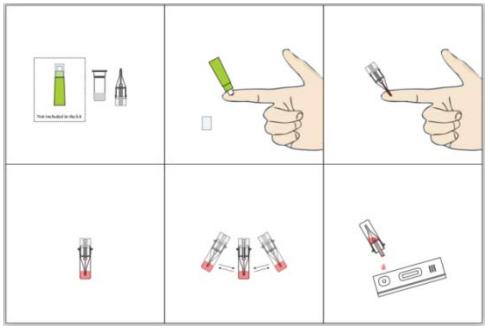
3） Suck up 10μL whole blood/plasma/serum sample with the quantitative sampling needle, insert the needle into the sampling tube containing buffer solution, shake the tube for several times and make sure that the sample is fully released in the buffer solution.

4） Take off the cap of the quantitative sampling needle, and squeeze the wall of the tube to add 2~3 drops (about 80ul) to sample well.

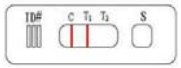
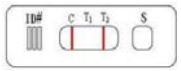
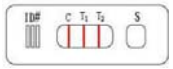
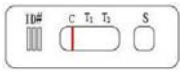
5） Read results: after adding sample, please read the result at 10~15min.

Do not interpret the result after 15 minutes.

Fingertip blood sample collection and test process



【Interpreting Test Results】

	**Novel Coronavirus (SARS-COV-2) IgG Positive:** the present of red band in control （ C）and T_1/G, indicating that SARS-COV-2 IgG antibody above detection limit in specimen.
	**Novel Coronavirus (SARS-COV-2) IgM Positive:** the present of red band in control （C） and T_2/M, indicating that SARS-COV-2 IgM antibody above detection limit in specimen.
	**Novel Coronavirus (SARS-COV-2) IgG and IgM Positive:** the present of red band in control (C), T_1/G and T_2/M)
	**Negative:** If only the control (C) band is present, the absence of red band in both testing position (T_1/G、T_2/M) indicates that no IgM and/or IgG antibody in specimen or IgM and/or IgG antibody below detection limit.
	**Invalid:** The absence of red band in control indicates that the operation is incorrect or reagent has spoiled. In any case, please retest; if the problem persists, stop using the product immediately and contact your local supplier.
Notes：The picture shows the appearance of a card-type. The interpretation method for the results of a strip-type is consistent with the card-type.	

【Quality Control】

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

【Limitations of the Procedure】

1. This product is only for qualitative test. It is not designed to confirm the concentration of SARS-CoV-2 antibodies.
2. It can only tell whether SARS-COV-2 IgM and / or IgG antibody present in specimen, and cannot be used as the only evidence for SARS-COV-2 infection. The diagnosis should be based on the latest version of the "Diagnosis and Treatment for Novel Coronavirus Pneumonia Infection."
3. Negative results may be caused by low concentration of the novel coronavirus IgM/IgG antibody in the sample and therefore cannot completely rule out the possibility of infection. Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation, and is not suitable for screening in the general population.
4. Inconsistent or incorrect results may occur due to improper technical or procedure manipulation, contaminated or hemolyzed samples or other drugs that may interfere with the test.
5. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:
   1) Improper sample collection, improper sample transfer or handling, the virus titer in the sample is too low;
   2) The level of SARS-CoV-2 antibodies is below the detection limit of the test.
   3) Variations in viral genes may cause changes in antibody determinants.

【Precautions】

1. Please read manual carefully before using this kit and strictly control the reaction time. Improper operation will lead to incorrect results. The interpretation of test methods and results must be carried out strictly accordance with the introduction.
2. Please test under standard laboratory conditions. All specimens and materials in the testing process should be handled in accordance with standard Lab procedure and biosafety guidelines.
3. Beware of moisture, do not open the packaging bag before it is ready for test; if the packaging bag is damaged or the test card is wet, please stop operating.
4. Do not use expired reagent kit. Do not replace the components of this product kit with those of other kits. Do not test the sample after dilution; otherwise you may get incorrect results.
5. Please equilibrate all reagents and samples to room temperature (15～30℃) before test.
6. This kit is limited to the qualitative detection of novel coronavirus antibody in human serum, plasma or whole blood.
7. Samples containing high concentration of heterophilic antibody or rheumatoid factors may affect the results.

【Index Of Symbol】

Attention, see instruction for use	Do not reuse
IVD For in vitro diagnostic use only	REF Catalog#
Store between 4~30℃	EC REP Authorized Representative
Tests per kit	Keep dry
Expiry Date	Caution
LOT Lot number	Keep away from sunlight
Manufacturer	

Beijing Jinwofu Bioengineering Technology Co.,Ltd.

Address:Room 206, 1st Building, No. 26, Jinyuan Road, Daxing District,102600， Beijing,P.R China.

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EC REP

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