SARS-CoV-2 IgM Antibody ELISA Kit

Catalog No. BSKV0002 (96 wells)

For use with human or animal serum.

For Research Use Only. Not for use in diagnostic procedures.

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INTRODUCTIONS

The new coronavirus belongs to the beta coronavirus of the genus β, which has an envelope, the particles are round or oval, often polymorphic, and the diameter is 60-140nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SLCOVZC45).

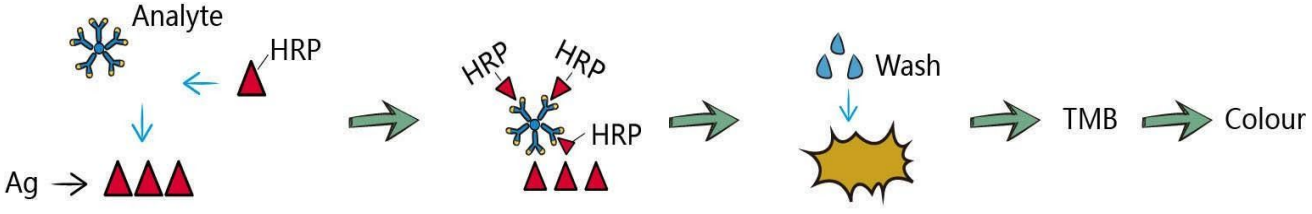
In vitro isolation and culture, 2019-nCoV can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to isolate and culture in Vero E6 and Huh-7 cell lines. Based on current epidemiological investigations, the incubation period is generally 7 days, with a maximum of 14 days. Main symptoms are fever, fatigue, and dry cough. A few patients have symptoms such as nasal congestion, runny nose, and diarrhea. In severe cases, dyspnea occurs more than a week later. In severe cases, acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, and coagulation dysfunction develop rapidly. It is worth noting that in the course of severe and critically ill patients, there may be moderate to low fever, even without obvious fever. Some patients showed only low fever, mild fatigue, and no pneumonia and recovered after 1 week. In the early stages of the disease, the total number of white blood cells in the peripheral blood was normal or decreased, the lymphocyte count decreased, and some patients had increased liver enzymes, muscle enzymes, and myoglobin. Most patients have elevated C-reactive protein (CRP) and erythrocyte sedimentation rate and normal procalcitonin. In severe cases, D-dimer increases and peripheral blood lymphocytes progressively decrease. New coronavirus nucleic acids can be detected in throat swabs, sputum, lower respiratory tract secretions, and blood.

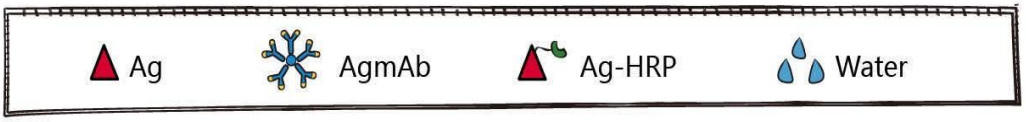
PRINCIPLE OF THE ASSAY

The kit uses enzyme-linked immunoassay. According to the structural characteristics of IgM antibody, the same protein antigen was selected to be coated with microporous plate and labeled with horseradish peroxidase (HRP). The kit design is as follows:

The recombinant SARS-CoV-2-n protein was coated with a 96-well microporous plate (solid phase antigen); Labeled SARS-CoV-2-n recombinant protein (labeled antigen) with horseradish peroxidase (HRP); When the positive sample to be tested (IgM) and the labeled antigen are added to the microplate, the pattern and product of (solid antigen +IgMAb+ labeled antigen) → (solid antigen -igmab-4 labeled antigen) will be formed. Absorbance was measured at 450nm wavelength by an microplate reader .

The concentration of IgM antibody in the sample was directly proportional to the absorbance (OD value).





S-ELISA

KIT FEATURES:

1. This kit is: qualitative detection of IgM antibody in human or animal serum after SARS -CoV-2 virus infection.
2. The samples used in this kit are: human or animal serum samples.
3. No pretreatment or dilution is required for the test sample.
4. Short detection time.
5. Use generic; the open microplate reader is convenient for primary medical institutions to use.
6. It can be connected with the automatic ELISA system for automatic large-scale detection.

INTENDED USE:

1. Detect the infected people in the window period.
2. Track and monitor IgM antibody levels in infected people.
3. Assessment of prognosis and recovery.
4. Detect the source of blood donation and guide immunotherapy.
5. Used for monitoring IgM antibody after vaccination to evaluate the effect of immunization.
6. For animal immunity test and antibody monitoring after animal infection.
7. The product of this kit has a complementary relationship with the nucleic acid detection kit of the immunochromatography rapid detection kit.
8. This kit product is an auxiliary diagnostic product used in the window period of virus infection.

MATERIALS SUPPLIED

1. SARS-CoV-2-n antigen microporous plate coated with SARS-CoV-2-n recombinant protein antigen. specification: 96-well / plate.
2. IgM antibody negative reference: 1 bottle, specification : 0.8ml/ bottle.
3. IgM antibody positive reference: 1 bottle, specification : 0.8ml/ bottle.
4. Enzyme conjugate: SARS-CoV-2-n antigen with HRP labeled : 1 bottle, specification : 10.5ml/ bottle.
5. Color rendering solution A, the main component is H_2O_2. 1 bottle, specification : 5.0ml/ bottle.
6. Color rendering solution B, the main component is TMB. 1 bottle, specification : 5.0ml/ bottle.
7. Termination liquid, mainly containing dilute H_2SO_4. 1 bottle, specification : 5.0ml/ bottle.
8. Concentrated washing solution, 10 times concentrated washing solution, diluted before use. 1 bottle, Specification: 50.0ml/ bottle.
9. Operating instructions.

STORAGE

2~8 refrigerated storage period of 6 months.

MATERIALS NEEDED BUT NOT SUPPLIED

1. Microplate reader (containing Wavelength: 450nm & 630nm).
2. Automatic microplate reader.
3. 37℃ water bath.
4. Micropipette.
5. Centrifuge.

SAMPLE COLLECTION:

1. The sample is suitable for fresh serum within 2-8℃ 7 days.
2. The patient is on an empty stomach; Collecting venous blood aseptically; And separate the serum.
3. No pretreatment is required for the sample.
4. There is no need to add any anticoagulant to the sample.
5. Hemolysis sample; High-fat samples; Microbiological contaminated samples; It belongs to unqualified sample.

OPERATION METHOD:

1. Preparation of washing solution: the concentrated washing solution is diluted with distilled water or deionized water at a ratio of 1:10.
2. After the kit is balanced to room temperature, take out the required microporous strips and fix them on the rack, and make them in good order.
3. For each reaction hole, add: Negative reference product; Positive reference product; Serum samples to be tested: 100ul.
4. For each reaction hole, add 100ul enzyme conjugate.
5. Incubate for 3 hour at 37 ℃.
6. Wash board, 4- 5 times, pat dry.
7. For each reaction hole, 50ul of Color rendering solution A and B were added respectively. (or mix chromogenic solution A and chromogenic solution B 1:1 before use. Then, in each reaction hole, the colored liquid after mixing is added respectively 100ul).
8. Keep out of the light for 15 minutes.
9. Add termination solution. Add 50ul of termination solution to each well as soon as possible and mix thoroughly.
10. The wavelength of 450nm was selected by using the microplate reader. The reference wavelength was 630nm, and the absorbance of each detection hole was detected (OD value).
11. Quality control:
[Absorbance (OD value) of IgM antibody positive reference] / [Absorbance (OD value) of IgM negative reference] ≧ 2.5, test results were valid.

12. Result calculation:
P/N≧ 2.5 is positive
※ P: absorbance value (OD) of the sample.
N: absorbance value (OD) of IgM antibody negative reference.

DATA ANALYSIS ASSISTANCE

We have partnered with **MyAssays** to offer you an easy to use and versatile tool to analyze the data you receive using our ELISA Kit. Use the link below to be directed to the data analysis tool provided by **MyAssays** specifically for **bskv0002**. You can also search **"bskv0002"** on the **MyAssays.com** website to access the data analysis tool.

https://www.myassays.com/bioss-sars-cov-2-igm-antibody-elisa-kit.assay

EXPLAIN FOR RESULTS:

1. The IgM antibody concentration in the sample is directly proportional to the absorbance (OD value), that is, the larger the OD value, the higher the IgM antibody concentration.
2. When a person is first infected with a novel coronavirus (SARS-CoV-2), the human immune system immunizes against the virus. Epidemic prevention, production of specific antibodies, 1 week after infection began to produce IgM antibodies. IgM antibody is the first antibody to appear in the human immune system. The detection of IgM antibody indicates the recent occurrence of infection, which can be used for the early diagnosis of infection.
3. With the extension of the infection period, IgM antibody levels were normally distributed in the serum. For IgM resistance in serum. Quantitative detection of the body can distinguish between virus infection and vaccination.
4. It is suggested that each laboratory should establish its own reference range according to the actual situation.

TEST THE LIMITATIONS OF THE METHOD:

1. This kit is only used to detect human or animal serum.
2. Collect human or animal venous blood correctly and separate the serum as soon as possible due to improper sampling; Improper sample storage; Repeated freeze-thaw; Will affect the test results.
3. This kit can qualitatively detect IgM antibody of SARS-CoV-2 virus through human or animal serum.
4. The test results of this kit are only for clinical reference and cannot be used as the only basis for clinical diagnosis.
5. If no IgM antibody is detected. In addition to the reexamination, it is recommended to pass nucleic acid testing or other related tests. Review and confirmation.
6. Possibility of no IgM antibody detected:
   a. no IgM antibody is produced.
   b. Unreasonable sample collection; Unreasonable transportation and storage; Repeated freezing and thawing.
   c. virus mutation.

PRODUCT PERFORMANCE INDEX:

1. Positive reference products: the compliance rate of the positive reference products of the enterprise; 100%.
2. Negative reference products: the compliance rate of the negative reference products of the enterprise; 100%.
3. Repeatability: test the positive reference products of the enterprise; Repeat detection for 10 times; All the results were positive.
4. Specificity: after the destruction test of 2-mercapto ethanol in this kit, it is verified that the detected antibody is IgM type antibody.

NOTES:

1. This product is for external diagnostic use only.
2. Do not mix products from other manufacturers.
3. The already used enzyme-labeled slats shall not be used again.
4. Pay attention to keep the bottom of the plate clean and bright when removing the strip, so as not to affect the reading; If the bottom of the board is dirty, please dip the mirror paper in the alcohol before reading the board.
5. After fixing and adding the sample, please avoid disassembling, so as to avoid affecting the reading value due to the spillage of the sample.
6. Unseal the remaining unused enzyme label strips, seal them with a self-sealing bag, and store them at 2 - 8℃.
7. When preparing the mixture of Color rendering solution A and Color rendering solution B, clean containers should be used instead of containers that were fixed and not cleaned adequately before use.
8. If a small amount of crystallization is found in the washing solution, which is the low-temperature crystallization of phosphate, please balance it and dissolve it at room temperature, without any influence on the product performance. Please feel free to use it.
9. Before operation, read this instruction carefully and follow the operation strictly. Avoid false detection results.
10. Please store the reagent in strict accordance with the storage conditions of each component of the kit and avoid exposing the reagent to bright light. All reagent bottles must be tightly capped to prevent evaporation.
11. When adding samples, the interval between the first hole and the last hole is too long, resulting in different pre-incubation times, which may affect the accuracy and repeatability of the measured values.
12. The termination solution contains sulfuric acid. Necessary chemical protection should be carried out during operation.
13. Serum samples are considered potentially infectious and should be handled with necessary biosecurity precautions.
14. Waste samples and waste liquids shall be disposed of in accordance with the corresponding biosafety and toxic and hazardous substances management regulations.