SARS-CoV-2 Total Antibody ELISA Kit

Catalog No. BSKV0003 (96 wells)

For use with human or animal serum.

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

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INTRODUCTIONS

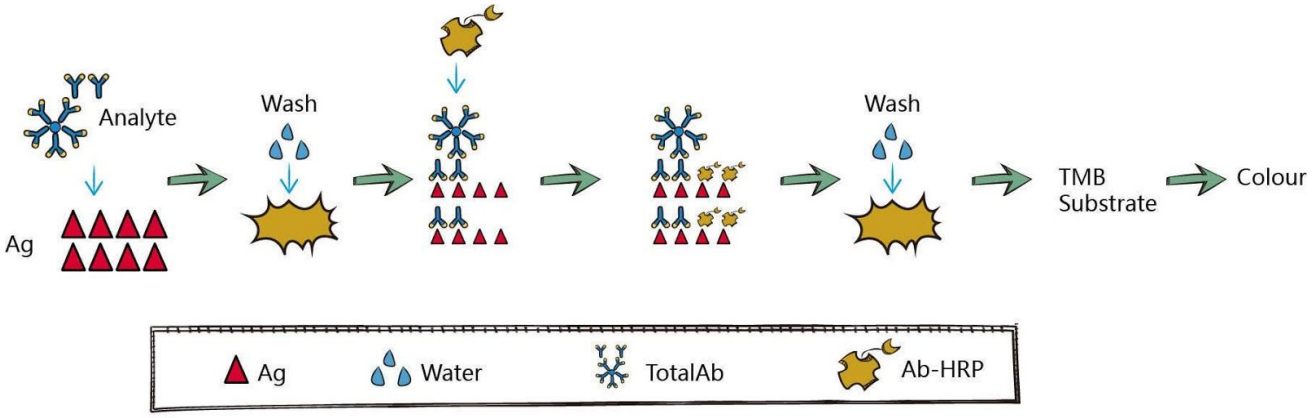
Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure and death.
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 Novel Coronavirus, formerly known as 2019-nCoV and now known as SARS-COV-2, is a new strain of coronavirus that was first identified during an outbreak in Wuhan, China which started in December 2019.

PRINCIPLE OF THE ASSAY

The kit uses enzyme-linked immunoassay, According to the principle of antibody blocking, the following design is made:

The recombinant protein of SARS-CoV-2-N was used as coating antigen and was coated with 96-well reaction plate. When the positive sample is added and within a certain reaction time, the (solid phase antigen-antibody) complex is formed. Wash the plate; Get rid of the substance that didn't participate in the reaction. HRP anti-SARS- CoV-2-n antibody was added as a tracer. Antigenic reaction with no binding antibody on the reaction plate; Formation of (Solid phase antigen - HRP antibody) complexes. Absorbance was measured 450nm using an microplate reader.

The concentration of specific total antibody in the sample was inversely proportional to the absorbance (OD value).



b-ELISA

KIT FEATURES:

1. This kit is: semi-quantitative detection of total antibody against SARS-CoV-2 virus in human or animal serum.
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 infected people.
2. Track and monitor antibody levels in infected people.
3. Assessment of disease prognosis and recovery.
4. Detect the source of blood donation and guide immunotherapy.
5. Used for antibody monitoring after vaccination to assess the effect of immunization. (i.e., to assess the success of vaccination, whether there is immune protection, etc.).
6. Used 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 a product used in the process of diagnosis and treatment.

MATERIALS SUPPLIED

1. SARS-CoV-2-n antigen microplate coated with SARS-CoV-2-n recombinant protein antigen. Specification: 96-well plate.
2. Negative reference; 1 bottle. Specification: 0.8ml / bottle.
3. Positive reference product; 1 bottle. Specification: 0.8ml / bottle.
4. Enzyme Conjugate, anti-SARS-CoV-2-n monoclonal antibody with HRP marker: 1 bottle. Specification: 10.5ml / bottle.
5. Color rendering solution A, mainly composed of H_2O_2; 1 bottle; Specification: 5.0ml / bottle.
6. Color rendering solution B, mainly composed of which is TMB. 1 bottle; Specification: 5.0ml / bottle.
7. Termination solution, 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 instruction

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 serum.
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 in 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. Incubate for 45 min at 37 ℃.
5. Washboard, 4- 5 times, pat dry.
6. For each reaction hole, add 100ul enzyme conjugate.
7. Incubate for 30 min at 37 ℃.
8. Washboard, 4- 5 times, pat dry.
9. 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).
10. Keep out of the light for 15 minutes.
11. Add termination solution. Add 50ul of termination solution to each well as soon as possible and mix thoroughly.
12. 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).
13. Quality control: if the absorbance of the negative reference is; OD ≥ 0.8, the test result was effective.
14. Result calculation:

    Blocking rate = [(OD value of negative reference - OD value of sample)/OD value of negative reference] × 100%

RESULTS OF EVALUATION:

Blocking rate < 20%, Negative

Blocking rate : 20%-30% Suspected positive

Blocking rate ≥ 30%, Positive.

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 **bskv0003**. You can also search **"bskv0003"** on the **MyAssays.com** website to access the data analysis tool.

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

EXPLAIN FOR RESULTS:

1. The specific total antibody concentration in the sample is inversely proportional to the absorbance (OD value). Namely, OD value is greater than small, the higher the concentration of the total specific antibody.
2. The specific total antibody concentration in the sample was directly proportional to the blocking rate, That is: the greater the blocking rate, specific the higher the concentration of total sexual antibodies.
3. It is suggested that each laboratory should establish its own reference range according to the actual situation.

LABORATORY QUALITY CONTROL REQUIREMENTS:

If, the absorbance (OD value) of the negative reference is < 0.8; The test results should be retested.

TEST THE LIMITATIONS OF THE METHOD:

1. This kit is only used to detect human or animal serum.
2. Collect human vein blood correctly and separate the serum as soon as possible. Improper sampling; improper sample storage; the after freezing and thawing; will affect the test results.
3. This kit can detect the total antibody of SARS-CoV-2 virus through human or animal serum and calculate the blocking rate. Semi-quantitatively assess antibody levels in samples. But it is not possible to distinguish between IgM and IgG antibodies.
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 the test is negative. In addition to the reexamination, it is recommended to pass the nucleic acid test or other related tests, for the complex nuclear and confirmation.
6. Possibility of negative results：

a. True negative, no antibody is produced.

b. Unreasonable sample collection; Unreasonable transportation and storage; Repeated freeze-thaw.

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. Minimum detection limit: 130ng/ml.

4. Repeatability: Test the positive reference products of the enterprise; Repeat detection for 10 times; All the results were positive.

5. Specificity:

5.1. This kit does not cross-react with the following antibodies

a. Antibodies to influenza a virus.

b. Influenza b virus antibody.

c. Parainfluenza virus antibody.

d. Antibodies to chlamydia pneumoniae.

e. Mycoplasma pneumoniae antibody.

f. Antibody to respiratory syncytial virus.

g. Treponema pallidum antibody.

h. Hepatitis b surface antibody.

i. Antibody to hepatitis c virus.

j. Adenovirus antibody.

k. Epstein barr virus antibody.

l. Measles virus antibody.

m. Cytomegalovirus antibody.

n. Antibodies to mumps virus.

o. Human immunodeficiency virus antibody.

p. Enterovirus 71 antibody.

q. Positive samples of varicella zoster virus.

5.2. The test results of this kit are not disturbed by the following substances:

a. Hemoglobin ≤ 250 μmol/L

b. Hemoglobin ≤ 9 g/L.

c. Triglyceride ≦ 15 mmol/L.

d. Rheumatoid factor ≤ 80 IU/ml.

e. Anti-nuclear antibody titer ≤ 1:240.

f. Anti-mitochondrial antibody is ≤80 IU/ml.

g. Mouse IgG ≤ 1000ug/ml.

h. Histamine hydrochloride.

i. A-interferon.

j. Zanamivir

k. Ribavirin

l. Oseltamivir

m. Palmer peramivir

n. Lopinavir

o. Ritonavir

p. Abidol

q. Levofloxacin

r. O song called

s. ceftriaxone

t. Meropenem

u. Tobramycin

6. Hook effect:

When the concentration of the antibody reference substance reached 2.5mg/ml, the blocking rate of the antibody reference substance ≥ 94.0 ± 4.2 %, and no hook effect was observed.

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.