www.bioneovan.com

Rapid test for IgM Antibody to Human Parvovirus B19 （Colloidal Gold）

Catalog No.: BG1401C

NAME AND INTENDED USE

Bioneovan Rapid test for IgM Antibody to Human Parvovirus B19（Colloidal Gold）is pre-determined for the qualitative detection of human parvovirus B19 IgM antibody in human whole blood, serum or plasma samples. It is used as an early infection of parvovirus in immunodiagnostics or hematological disease, hemolytic anemia patients, pregnant women, newborns, etc., serving as an auxiliary diagnostic reagents in clinical diagnosis.

SUMMARY

Human parvovirus (HPV B19) is the only pathogen of the genus Parvovirus that is pathogenic to humans. It belongs to the family of Parvoviridae and genus of erythropoiesis. Parvoviruses are mainly transmitted through the respiratory and bloodstream, with an incubation period of 6 to 8 days. For people with normal immunity, it does not cause symptoms or very mild symptoms, and it has lifelong immunity. Infection in patients with immunodeficiency or blood diseases can cause complications such as arthritis and vasculitis or secondary infections; patients with hemolytic anemia will develop temporary aplastic anemia; chronic inhibition of erythropoiesis presents symptoms of chronic anemia; early pregnancy can cause miscarriage, fetal malformation or stillbirth; in addition, parvovirus B19 is also the cause of infectious rash in children. After HPV B19 infects the body, symptoms usually appear within 3 days. At this time, 90% of patients can detect IgM antibodies; IgG antibodies appear after about 2 weeks; IgM usually disappears 2-3 months after the disease. There are many methods for detecting B19 infection, such as immunoelectron microscopy and receptor-mediated hemagglutination test, but the commonly used detection methods in the laboratory are still nucleic acid detection and serological detection.

PRINCIPLES OF THE ASSAY

The kit uses a colloidal gold immunochromatographic technique to qualitatively detect human parvovirus B19 IgM antibodies in whole blood, serum or plasma samples. The colloidal gold-labeled mouse anti-human IgM was coated on the gold standard pad, and the recombinant human parvovirus B19 antigen was coated on the nitrocellulose membrane. If it is a positive specimen, the human parvovirus B19 IgM antibody in the specimen can be labeled with colloidal gold. The mouse anti-human IgM binds to form an immune complex, due to the chromatographic complex and the sample flowing forward inside the nitrocellulose membrane. When the complex passes through the T line, it binds to the coated human parvovirus B19 antigen to form a complex and agglutinate color. The remaining colloidal gold-labeled mouse anti-human IgM binds to the C-line coated goat anti-mouse IgG antibody to agglutinate color; if it is a negative specimen, the sample does not contain human parvovirus B19 IgM antibody, resulting in the inability to form an immune complex, It can only be colored at the C line.

MATERIALS PROVIDED

1. Test card (T-line coated recombinant human parvovirus antigen (VP1), coated with goat anti-mouse IgG antibody in C-line, coating buffer: 0.05 M PBS pH 7.4): 1 test × 20.
2. Sample diluent: 1 bottle × 5 ml.
3. Manual: 1 copy

The components in different batches and different varieties of kits may not be mixed.

SAMPLE REQUIREMENT

1. Serum samples are collected by intravenous method according to the conventional method; plasma sample processing method: 1% heparin solution 100 μL anticoagulation 5-10 mL blood, 3.8% sodium citrate solution and blood anticoagulation in a ratio of 1:9, 15% 0.04 mL of disodium edetate (EDTA) solution was anticoagulated with 5 mL of blood.
2. Serum or plasma samples can be stored within 5 days after collection, and can be stored at 4 °C. For samples larger than 5 days, samples should be stored at -20 °C. The number of freeze-thaw cycles should not exceed 3 times. .
3. Whole blood samples are recommended to be tested within 3 days. The sample is stored at 2~8 °C. Do not freeze.
4. Hemolysis sample test results are invalid.

TEST PROCEDURE

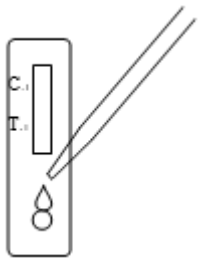
1. Preparation before testing: 1 μL of each of 10 μL, 50 μL and 100 μL micropipettes and a pair of tips or dropper (10 μL, 50 μL, 100 μL).
2. Inspection process: Place the test card on a dry horizontal work surface. Add 10 μL of serum or plasma sample (20 μL of whole blood) to each well of the test card using a micropipette, add 80 μL of the sample dilution, and observe the results within 15 to 20 minutes.
3. Precautions for the inspection process:

a. The test kit and the sample to be tested should be placed in a room temperature environment before being tested.

b. The test card is used within 30 minutes after the opening of the test card.

c. The observations are invalid after 20 minutes.

INTERPRETATION OF RESULTS



Positive Two pink lines appear in both C and T position
Negative Only one pink line appears in C position
Invalid: The control line next to the test line does not become visible after the addition of the sample.

Note: Invalid test results should be treated as infectious contaminants and samples should be re-acquired.

LIMITATION

1. The test results of this product are interpreted by human eyes and are subject to visual error or subjective judgment. Therefore, when the color of the strip is difficult to determine clearly, it is recommended to repeat the test.
2. This test card is one of the auxiliary means of diagnosis. The test results are for reference only and should not be used as the sole basis for clinical diagnosis and treatment. Positive results need to be further confirmed by other methods; limited by the sensitivity of the test, the negative result may be due to the antibody concentration being lower than the sensitivity of the product analysis. Clinical diagnosis should be combined with clinical examination, medical history and other tests.
3. In the early stage of infection, IgM is not produced or the titer is very low, which may lead to negative results. Patients should be reminded to review within 7~14 days. At the same time, the last collected specimens should be tested in parallel to confirm whether there is serological positive or significant titer. Raise.
4. Patients with impaired immune function or immunosuppressive therapy have limited reference values for serological antibody testing.
5. IgM antibody positive not only occurs in the primary infection, but also in the secondary infection IgM response.
6. This reagent is a qualitative test and cannot be used to determine the antibody content.
7. This reagent is for the detection of individual whole blood, serum or plasma samples. Do not use it for the detection of saliva, urine or other body fluids.

PRECAUTIONS

1. The positive results detected by the kit need to be further confirmed by other methods.
2. The kit should be sealed and protected from moisture. When the humidity is 60% or less, it is used within 1 hour of opening. And the humidity is 60% or more, please avoid it being placed in the air for too long, causing moisture and affecting the test results.
3. The depth of the color of the test line is not necessarily related to the titer of the antibody in the sample. The result of the interpretation after 20 minutes is invalid.
4. When the human parvovirus B19IgM antibody is extremely high in the specimen, the C-line band may be weakened, which is normal.
5. The kit components and the waste generated by the test are treated as infectious contaminants.
6. This reagent is for in vitro diagnosis only, and the sample to be tested is limited to human whole blood, serum or plasma.

STORAGE AND STABILITY

Store at 4~30°C in the dark. When the humidity is 60% or less, it is used within 1 hour after opening. And when the humidity is 60% or more, it is used promptly after opening.

EXPIRATION

The shelf life is 24 months. Do not use the kit beyond its expiration date.