www.bioneovan.com

Rapid test for IgM Antibody to Mumps virus（Colloidal Gold）

Catalog No.: BG2001C

NAME AND INTENDED USE

Bioneovan Rapid test for IgM Antibody to Mumps virus （Colloidal Gold） is an in vitro immunoassay for the qualitative determination of the detection of mumps virus IgM antibodies in human whole blood, serum or plasma samples, and is used as an auxiliary diagnostic reagent for early infection of mumps virus in clinical diagnosis.

SUMMARY

Mumps Virus (Mu) is a pathogen of mumps, belonging to the Paramyxoviridae family. It was first discovered in 1935 and proved to be the main cause of mumps. The popularity of MuV is peaked in winter and spring, and is limited to humans. MuV is the only source of infection for infected people. The main routes of transmission are saliva, saliva-contaminated foods and articles, and airborne droplets. Children and adolescents are susceptible to mumps. Clinical take parotid gland enlargement as main characteristic, common complication has virus meningitis and encephalitis, orchitis, epididymis inflammation, still have ovarian inflammation, pancreatitis, myocarditis to wait in addition, it is the male infertile disease and child acquired sex deaf most common reason, serious person can bring about disable or death. Mumps virus IgM antibody appeared shortly after the onset (2 ~ 3 days), and reached a peak within 2 weeks, and then decreased gradually, which could be kept for several months, and was an important basis for early diagnosis of MuV infection.At present, the main methods to diagnose MuV infection in clinic or laboratory include virus isolation and culture, serological detection (complement binding test, neutralization test, etc.), immunological detection (enzyme-linked immunoassay, indirect immunofluorescence detection, etc.) and molecular biological methods such as rt-pcr.

PRINCIPLES OF THE ASSAY

The kit was used for qualitative detection of mumps virus IgM antibody in whole blood, serum or plasma samples using colloidal gold immunochromatography. The colloidal gold-labeled mouse anti-human IgM is coated on the gold standard pad, and the recombinant mumps virus antigen is coated on the nitrocellulose membrane. If the sample is a positive specimen, the mumps virus IgM antibody in the specimen can be combined with the colloidal gold-labeled mouse. The anti-human IgM binds to form an immune complex, and the complex and the sample flow forward inside the nitrocellulose membrane due to the chromatography. When the complex passes through the T line, it binds to the encapsulated mumps virus antigen to form the complex and agglomerate and display color. The remaining colloid gold labeled mouse anti-human IgM and the anti-mouse IgG antibody in the c-line were bound and agglutinated for color development. If the sample is negative, the sample does not contain mumps virus IgM antibody, resulting in the inability to form an immune complex, only in the C line color.

MATERIALS PROVIDED

20 x1 tests (Cassette) Mumps virus test Cassette

Each box contains as below:

1. Test card (T-line coated with recombinant mumps virus antigen (NP), coated with goat anti-mouse IgG antibody on 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.

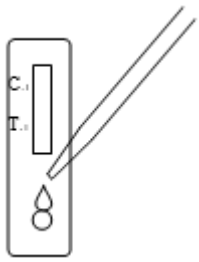
SAMPLE REQUIREMENT

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. This reagent is a qualitative test and cannot be used to determine the antibody content.
6. 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 mumps virus IgM antibody content in the specimen is extremely high, 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.