Enterovirus 71 (EV71)-IgM antibody

Catalog No.: BG1201C

Packing specification

40 test cards/box

Intended Use

This kit is used to qualitatively detect the EV71- IgM antibody in human blood, serum or plasma samples. It is a diagnosis reagent of EV early infection in clinical diagnosis. Enterovirus type 71 is one of the Picornaviridae virus (enterovirus, EV) genus, group A. It has obvious properties of dermatotropic and neurotropic. Being infected by EV71 can cause hand-foot-mouth disease, Herpes pharyngitis, Aseptic meningitis and encephalitis, encephalitis and the paralysis of poliomyelitis and recessive infection in more cases. Human being is the only known natural host of EV71. The EV71 is mainly infected by the fecal - oral transmission. EV71 has a world-wide distribution. Its epidemic season is summer and autumn, but it can infect during all year. Human is the generally susceptible of EV71, while the infants and young children are more dangerous.

Principles of the Tests

This kit is applying the technology of colloidal gold immunochromatography to qualitative test the EV71- IgM antibody of whole blood, serum or plasma samples. The EV71-IgM antibodies in positive sample can combine with colloidal gold labeled mouse anti human IgM immobilized on conjugate pad to form immune complex, and move along the membrane strip by chromatography. Some of the complex is caught by recombinant EV71-Ag pre-coated on T line to form "gold labeled mouse anti human IgM- EV71 IgM Ab- EV71 Ag" and develop color. The remaining free complex will be caught by the goat anti-mouse IgG antibody coated on the C line to develop color. As for negative samples, in which have no EV71- IgM antibodies, cannot form immune complexes and develop color on the T line, and colorate on C line only.

Main Constituent

1. Test Card (Coating the recombinant EV71 VP1-VP3 antigen on T-line, the goat anti-mouse IgG antibody on C-line. 40 test cards/box
2. The sample diluent: 1 bottle (5 ml)
3. Product instruction: 1

Storage conditions and the period of validity

Store at 4～30℃, dry places for 24 months. Use test card within 1 hour once open to atmosphere when the humidity is below 60%, or use it immediately if the humidity is higher.

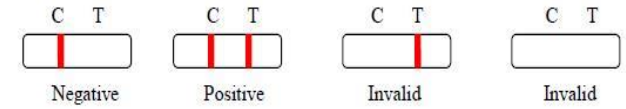
Sample Request

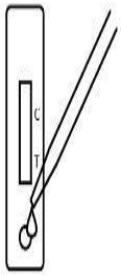
1. Serum samples were collected from the venous blood by conventional method. Plasma sample: add 100ul heparin solution (1%) to 5 ~ 10ml blood; or sodium citrate solution (3.8%) to plasma according to the proportion of 1:9; or EDTA solution (15%) 0.04ml to 5ml plasma.
2. Serum and plasma samples can be stored at 4 ℃ if tests will be done within 5 days, otherwise stored at -20 ℃. No more than 3 times of freeze-thaw.
3. Whole blood samples should be stored at 2-8℃ and tested within 3 days, and cannot be frozen.
4. The test result is invalid for hemolysis sample

Test Procedure

1. Test preparation: 10μL, 50μL, 100μL micropipettes and matched tips
2. Test process: The temperature of the kit and the test sample should be the same with room temperature before test. Place the test card on a dry horizontal work surface. Add 10μL serum or plasma sample into the sample well (or 50μL whole blood), then add 100 μL of sample dilution immediately. Observe the result in 15-20 minutes after the serum or plasma samples added. The observation is invalid after 20 minutes.

Test results explain





To develop color on C line only: negative; To develop color on both C line and T line: positive; To develop color on T line only: invalid; Not to develop color on both C line and T line: invalid.
Note: Re-detection if the detection result is invalid. The invalid test cards should be dealt as infectious pollutants. The temperature of the kit and the test sample should be the same with room temperature before pre-detection.

Limitation

1. It was vulnerable to the visual error or subjective judgment factors. Duplicating detection when a stripe color is not obvious.
2. The detection card is one of the assistant diagnostic methods. Its test results are only for reference and should not be the sole basis for clinical diagnosis and treatment. The positive results should be further verified by other methods. Due to the limit of detection sensitivity, the negative results may be observed because the concentration of antibodies is lower than the analysis sensitivity. The clinical diagnosis should combine with the clinical diagnosis, medical history and other detection methods.
3. During early stage of infection, IgM may not be generated or in low titer. It might cause negative results. Suggest the patients to review in 7-14 days and do parallel detection to the old samples

at the same times to confirm whether serological positive or titer increased significantly.
4. The results are unreliable to the patients with impaired immune function or immunosuppressive treatment.
5. Positive is not only occurs in the primary infection, but also in secondary infection.
6. This kit is a qualitative test and cannot used to determine antibody levels.
7. For the test of human blood, serum or plasma samples only, not for saliva, urine or other body fluids testing.

Product performance indicators

Positive coincidence rate: to internal reference (+/+) =12/12; Negative coincidence rate (-/-) =12/12; Precision (n=10): positive for all tests, and develop color equably; Minimum detection limit: positive end point is not less than 1:8 or 1:16 dilution of positive reference L1. The result must be negative to reference L2. The samples which is positive with toxoplasma IgM antibody (S/C value: ≤ 13.65), rubella virus IgM antibody (S/C value: ≤ 11.42), cytomegalovirus IgM antibody (S/C value: ≤ 13.41), herpes simplex virus II IgM antibody (S/C value: ≤ 12.53), Toxoplasma IgG antibody (S/C value: ≤ 13.45), rubella virus IgG antibody (S/C value: ≤ 10.39), cytomegalovirus IgG antibody (S/C value: ≤ 13.15), herpes simplex virus II IgG antibody (S/C value: ≤ 14.28), hepatitis B virus surface antigen (S/C value: ≤ 13.57), hepatitis C virus surface antigen positive (S/C value: ≤ 14.75), CVA16 antibody (S/C value: ≤ 14.28), HIV (S/C values: ≤ 11.37), HEV-IgM (S/C values: ≤ 12.15), rheumatoid factor (≤ 54IU/ml), antinuclear antibody (≤ 1:640), Vibrio cholera, Salmonella etc. cannot affect results. There is impact in test when the lipid content of the sample is higher than 6mmol / L and the bilirubin level is higher than 40μmol / L

Precautions

1. It needs other methods to confirmation when the kit test result is positive.
2. To avoid the test card exposing in the air long time since it can absorb moisture and affect the test results. Use test card within 1 hour once open to atmosphere when the humidity is below 60%, or use it immediately if the humidity is higher.
3. The degree of coloration on the test line do not inherently connected to the antibody titers in test sample.
4. The color of C line is likely to abate when the content of the virus antibodies is extremely high in the sample. It is a normal phenomenon.
5. Be attention to the potential biological risks. Wearing necessary protective equipments, and dealing with waste as infectious material.