EV71 IgM Rapid Test

Cat. No.:DTS779
Pkg.Size:10 tests

Intended use

This test is a single use, rapid device intended for qualitative detection of IgM-class antibodies to human Enterovirus 71 (EV71) in serum, plasma or whole blood samples. It is intended to be used in clinical laboratories for early diagnosis and management of patients related to infection with EV71.

General Description

Human Enterovirus 71 (EV71), the newest member of Enterovirudae, is notable for its etiological role in epidemics of severe neurological diseases in children. It appears to be emerging as an important virulent neurotropic enterovirus in the upcoming era of poliomyelitis eradication. The illness usually peaks in June or July. EV71 infection may be asymptomatic or may cause diarrhea and rashes. EV71 one of the major causative agents for hand, foot and mouth disease (HFMD), is sometimes associated with severe central nervous system diseases.
Direct detection of virus is the mainstay of diagnosis. EV71 can be isolated from throat and stool specimens, as well as from skin vesicle fluid. PCR testing provides generally greater sensitivity than culture for throat and stool specimens, and viral RNA has also been detected in vesicular fluid, blood and urine. EV71 specifc serological assays, including tests specific for IgM antibody, have also been developed to assist for early and easier diagnosis of the disease.

Principle Of The Test

This test employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to EV71 antigens are dry-immobilized at the end of nitrocellulose membrane strip. Anti-human IgM (anti-μ chain) are bond at the Test Zone (T) and goat anti-mouse IgG antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, EV71 IgM antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-human IgM (anti-μ chain) generating a visible red line. If there are no EV71 IgM antibodies in sample, no red line is formed in the Test Zone (T). The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the goat anti-mouse IgG antibodies aggregating in a red line, which indicates the validity of the test.

Reagents And Materials Provided

1. 10 EV71 IgM colloidal gold rapid test strips, each placed in white plastic cassette and packed in foil pouch
2. Instructions for Use
3. 1.5ml×10 tubes for sample dilution
4. 10 sample droppers

Materials Required But Not Supplied

1. safety lancet
2. alcohol prep-pad
3. disposable pipette
4. clock or timer

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5. specimen collection container
6. centrifuge
7. biohazard waste container.

Storage

This test can be stored at room temperature (2-30℃, do not freeze!) for 18 months from the date of manufacture (see label on strip pouch). Use immediately after opening.

Specimen Collection And Preparation

Wash your hands with soap and warm water. Choose a puncture site on the fingertip. Clean the fingertip with Alcohol Prep Pad. Place a Safety Lancet on a selected puncture site. Forcefully press the tip of the Safety Lance against your fingertip. Wipe away the first drop of blood with sterile gauze or cotton. Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood.

Assay Procedure

Allow the test cassette to reach room temperature (appropriately 30minutes). Add one drop (about 15μl) serum/plasma sample or two drops (about 30μl) whole blood sample into the sample dilution tube by using the sample dropper and mix completely. Open the pouch and pipette 80μl diluted sample into the sample window (S). Avoid dropping sample in the observation window. Do not allow the sample to overflow. Place the cassette on flat surface and read the results within 30 minutes. A positive test line may appear after 30minutes-this is a False Positive Result- do not read the results after 30 minutes.

Interpretation of Results

Quality Control: One red line will always appear next to the Control Zone(C) indicating the validity of the test. If no red line appears, the test is invalid - discard the test and repeat with new sample and new cassette.
Positive Results: One red line next to the Test Zone (T) indicates that IgM antibodies to EV71 have been detected using this EV71 IgM Rapid Test.
Negative Results: No red line appears within 30 minutes next to the Test Zone (T) indicating that no IgM antibodies to EV71 have been detected with this EV71 IgM Rapid Test. However, this does not exclude the possibility from infection with EV71.
The positive result obtained with this EV71 IgM Rapid Test alone cannot be the final diagnosis of EV71. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of any positive samples with other analytical system (e.g. ELISA, WB) is required to confirm any positive result.

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Performance Data

In total 212 clinical samples were tested including 26 EV71 PCR positive samples, 186 non-EV71 hand, foot and mouth diseases samples. The test demonstrated sensitivity of 88.5% (23/26) and specificity of 95.2% (177/186).

Warnings and Precautions

FOR PROFESSIONAL USE ONLY

• All the waste and sample should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.

• Once taking the cassette out of the pouch, carry out your testing as early as possible (no more than 60 minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.

• The performance characteristics of the test depend on sample quality and preparation. For strong reactive samples, the red line (corresponding to the Test Zone (T) may appear in 3-5 minutes after sample loading, but for weak reactive samples, the red line may appear in 15 minutes. To obtain accurate assay results, the test results must be read within 30 minutes. Results obtained after 30 minutes can lead to incorrect interpretation

• Make sure that the test is within the indicated validity.

• If automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.

• Do not modify the test procedure.

• Do not reuse the test cassettes. Autoclave before disposal.

• A test giving an invalid result should be repeated.

• Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.

Limitations

• Negative results do not exclude the possibility of EV71 exposure or infection. Infection through recent exposure (seroconversion) to EV71 may not be detectable. For positive results, line intensity cannot be used to evaluate the EV71 IgM antibody levels. A test giving an invalid result should be repeated.

• If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the

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test to humidity. For more information contact Beijing Wantai technical support for further assistance.

• This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.

• This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

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