Diagnostic Kit for IgM Antibody to Hepatitis E Virus

（Immunochromatography）

Product Name

Diagnostic Kit for IgM Antibody to Hepatitis E Virus（Immunochromatography）

Intended Use

The reagent is used to detect the Hepatitis E Virus IgM Antibody in serum / plasma qualitatively.

Hepatitis E is a kind of intestinal infectious disease caused by hepatitis E virus (HEV) with a worldwide distribution.HEV showed a spherical particles shape with 27~34 nm in diameter, icosahedral symmetry consisted of 20 shell particles, containing linear single-strand RNA. The incubation period of hepatitis E virus is 2 to 11 weeks, and on an average of 6 weeks. HEV is a disease with high mortality, mainly transmitted by digestive tract, and the clinical manifestations of which are similar to other acute hepatitis. All people are susceptible to the HEV. There are severe symptoms and high mortality of HEV. Hepatitis IgM is a specific antibody of hepatitis E virus, which can be detected early and disappear quickly. HEV IgM antibody can be detected in a short time later after infected, continue to rise very rapidly, decreasing significantly in 1-2 months, disappear in 5 months.

Detection of HEV-IgM antibody can diagnose HEV infection in early stage. Both the immunological detection and virus nucleic acid detection can be used as the basis for laboratory diagnosis of hepatitis E virus.

Test Principle

The test utilizes antibodies including a recombinant protein HEV-Ag and goat anti-mouse IgG antibody on the nitrocellulose membrane with colloidal gold marked mouse anti-human IgM as an mark tracer. The reagent is used to detect the HEV IgM antibody in serum / plasma according to the principle of double antibody sandwich method and gold immunochromatography assay.

The sample mixing up mouse anti-human IgM antibody –marker move along the membrane to the T line, and form the T line when the sample contains HEV-IgM antibody, which a positive result. Conversely, it is a negative result.

Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mouse anti-human IgM , nitrocellulose membrane coated with recombinant protein mixed HEV antigen (expression vector pBV220)，control line coated with goat anti-rabbit antibody (polyclonal antibody, goat-derived). The sample dilution is made of 20mM phosphate buffer (PBS).

Materials required but not provided: disposable pipette (depend on customer’s requirement)

Description: different components of different batches cannot be used at the same time to avoid erroneous results

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. The reagent can be used for the serum, plasma samples.

2. A serum / plasma sample must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants. 3. Samples may be stored at 2-8℃ for 1 week prior to assay, and at -20 ℃ for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times. Samples exhibiting visible precipitates, stink or muddy should not be used.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ the sample window of the cassette up.

2. Serum/Plasma: Drop 10μl serum/plasma vertically into the sample pad of strip/the sample hole of cassette. Add about 2 drops of (80μl-100μl) sample buffer into the sample pad of strip/the sample hole of cassette.

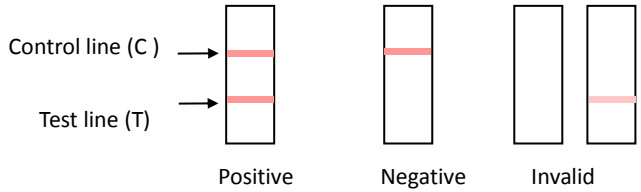
3. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Limitation

1. This reagent is designed for the qualitative screening test. Concentration of HEV-IgM cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Sensitivity can be lowered by the competition between high titers of HEV-IgG and HEV-IgM antibody to the antigen binding site. Results of this kind of samples should be analyzed cautiously.

4. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of HAV does not exist or the concentration is below detection limit. If HAV infection is still suspected, the sample should be collected 1-2 weeks later and carry the parallel detection with the first sample.

5. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.

6. Abnormal results may occur according to operator error or drug use. If HAV infection is still suspected, the sample should be collected later and carry the parallel detection with the first sample.

Performance Characteristics

1. Using internal and national quality control samples:

Negative specificity: The results should all be negative when detecting 20 kits of HEV-IgM negative quality control samples.

Positive specificity: The results should all be positive when detecting 12 kits of HEV-IgM positive quality control samples.

Limit of detection: The results should all be positive when detecting the internal quality control samples or the diluted national HEV-IgM positive quality control samples with the diluent rate at 1:8.

Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

A clinical evaluation was conducted on 1000 samples comparing the results obtained using the Diagnostic Kit for IgM Antibody to Hepatitis E Virus (Colloidal Gold) and other commercially available HAV tests. The results demonstrated a 98.56% positive agreement, 99.31% negative agreement, and a 99.10% overall agreement when compared to the other HEV-IgM test.

3. Analytical sensitivity: 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result. The reagent is not affected by the rheumatoid factor, antinuclear antibodies, anti-mitochondrial antibodies, non-specific IgG and IgM.

The addition of HBV, HAV, HCC, TP, HIV, toxoplasm, RV, RMV, HSV-Ⅰ, HSV-Ⅱ, HGV, EB and influenza A virus showed no cross-reactivity.

The detection results are negative after the destruction of HEV-IgM antibody, which indicated that the test kit has a strong specific for HEV-IgM.

4. Hook effect: the hook effect will not occur even the HEV-IgM diluents rate is 1:1024.

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. Patients used to receive monoclonal antibodies therapy may have human anti-mouse antibodies (HAMA) in blood, which does not apply to the detection of this reagent. Other detection method is suggested.

7. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.