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Hantavirus IgG &IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

Product Number: RPT0013

Shipping and Storage

1. Dry and store in the dark at 4-30℃, with a shelf life of 12 months.
2. During the long-term stability experiment, under general conditions, the product performance indicators can still be met within 14 months, fully meeting the requirement of a product shelf life of 12 months; During the accelerated stability experiment, under the condition of 37℃, the test results after 16 days (equivalent to 14 months) still meet the product performance requirements. For product transportation, it is sufficient to meet the conditions of dry and dark storage at 4-30℃. When the humidity is below 60% at room temperature, use within 1 hour after opening; When the humidity is above 60%, use immediately after opening.
3. Production date, expiration date until see label.

Component

Component	RPT0013
Detection card or Detection strip	1T/pack, 20pcs/box
Sample diluent	1 bottle

1. The detection card consists of a sample pad, a gold label pad, nitrocellulose film, and absorbent paper.
2. The detection line on nitrocellulose membrane is coated with mouse anti human IgG monoclonal antibody (immune source: normal human IgG), mouse anti human IgM monoclonal antibody (immune source: normal human IgM), the quality control line is coated with rabbit anti Hantavirus polyclonal antibody (immune source: Hantavirus recombinant antigen), and the gold conjugate pad is fixed with colloidal gold labeled Hantavirus recombinant antigen (expression vector: pET-30a).
3. The sample diluent is composed of 20mM phosphate buffer solution.

Description

This reagent kit adopts the principle of colloidal gold immunochromatography. Two detection lines, mouse anti human IgG monoclonal antibody and mouse anti human IgM monoclonal antibody, are respectively coated at the corresponding positions of the detection line on nitrocellulose membrane. Rabbit anti Hantavirus polyclonal antibody is coated at the quality control line, and colloidal gold labeled Hantavirus recombinant antigen is coated on the gold label pad. When detecting positive samples, the Hantavirus (IgG or IgM) antibody in the sample binds to the colloidal gold labeled Hantavirus recombinant antigen to form an immune complex. Due to the chromatography effect, the complex flows forward inside the nitrocellulose membrane and binds to the coated mouse anti human IgG monoclonal antibody or mouse anti human IgM monoclonal antibody when passing through the detection line, forming "Au Hantavirus recombinant antigen Hantavirus IgG antibody mouse anti human IgG monoclonal antibody" or "Au Hantavirus recombinant antigen Hantavirus IgM antibody mouse anti human IgM monoclonal antibody" and agglomerating. The remaining colloidal gold labeled Hantavirus recombinant antigen and the rabbit anti Hantavirus polyclonal antibody coated at the quality control line agglutinate and color. Combine and aggregate to produce color. When detecting negative samples, if the sample does not contain antibodies against Hantavirus, which prevents the formation of immune complexes, it can only be colored at the quality control line.

Application

This kit is used for in vitro qualitative detection of IgM/IgG antibodies against Hantavirus in human venous whole blood or serum (plasma) samples.

Hemorrhagic fever with renal syndrome, also known as epidemic hemorrhagic fever, is an acute, endemic, and naturally

occurring infectious disease caused by Hantavirus. The condition is critical, with many complications and a high mortality rate. Hanta virus (HTV) belongs to the Hanta virus genus of the Bunyaviridae family. Hantavirus is a single stranded negative stranded RNA virus, with a circular or oval shape, a double layered envelope, and spikes on the outer membrane. The average diameter is 120nm, and its gene RNA can be divided into three fragments: L, M, and S, with molecular weights of 2.7×10^6, 1.2×10^6, and 0.6×10^6, respectively. Fingerprint analysis shows that the three fragments of viral RNA are unique and vary among different virus strains. The S gene contains 1696 nucleotides and encodes nucleocapsid protein (including nucleoprotein NP); The M gene contains 3616 nucleotides and encodes envelope glycoproteins, which can be divided into G1 and G2; the L gene encodes polymerase, which contains 6533 nucleotides. Nucleocapsid protein (including nucleoprotein NP) is one of the main structural proteins of viruses, which encapsulates various gene fragments of the virus. G1 and G2 glycoproteins form the envelope of the virus. The virus is sensitive to ultraviolet radiation, ethanol, and iodine, and is relatively stable at temperatures ranging from 4 to 20℃. It can be inactivated at 56 ℃ for 30 minutes or 100℃ for 1 minute.

The host animals of HTV are mainly rodents, but recent studies have found that other animals (such as cows, cats, dogs, etc.) can also become hosts of HTV. HTV can cause its host to carry the virus for life and present as asymptomatic persistent infection. The main routes of infection include inhalation of aerosols formed from excrement (such as feces, urine, saliva, etc.), ingestion of contaminated food, and contact with wounds, which are also the main ways of infecting humans. The incubation period of Hantavirus infection in the human body lasts about 2 weeks, usually 2-3 days after virus infection. IgM antibodies can be detected in the serum, reaching their peak in 7-10 days, which can be used as an early diagnostic indicator; IgG antibodies appear 2 weeks after infection. Virus specific IgG can exist in the body for a long time, and there may be a delay in IgG response. Therefore, IgM positive Hantavirus infected individuals may have negative IgG. Therefore, IgM testing is an important method for diagnosing acute infections, especially for detecting secondary infections.

The commonly used serum detection methods include immunofluorescence test, enzyme-linked immunosorbent assay, immunoblotting test, hemagglutination inhibition test, etc. The widely used diagnostic techniques for Hantavirus both domestically and internationally mainly include IgM antibody immunocapture assay, indirect enzyme-linked immunosorbent assay, immunofluorescence assay, RT-PCR, and virus isolation.

Specimen collection

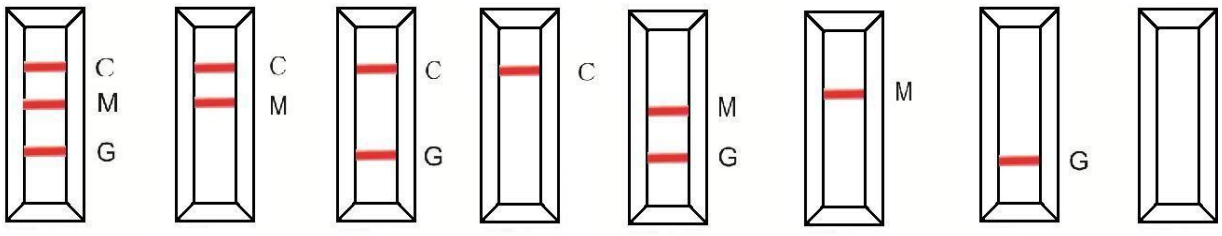
Whole blood is venous whole blood. Whole blood samples are collected and used immediately without storage. Serum samples are collected intravenously using conventional methods. Plasma samples can be treated with heparin, sodium citrate, and EDTA. Serum or plasma samples measured within 5 days can be stored at 4℃. The sample can be stored at -20℃ for at least 3 months. The sample should avoid hemolysis or repeated freeze-thaw cycles (no more than 8 freeze-thaw cycles). Samples that are turbid or have sediment should be centrifuged or filtered to clarify before testing.

Protocol

Before conducting the test, it is necessary to read the user manual in its entirety.

Please restore the reagents and samples to room temperature before testing. The experimental humidity should be less than 60%, and the experimental temperature should be between 18-30℃. When the reagent kit and sample have not returned to room temperature and the experimental temperature and humidity have not met the requirements, experimental operations cannot be carried out to avoid affecting the accuracy of the experimental results.

1. The detection method for the detection card is as follows, and the results are shown in the following figure:



1.1. Take out the detection card from the aluminum foil bag,

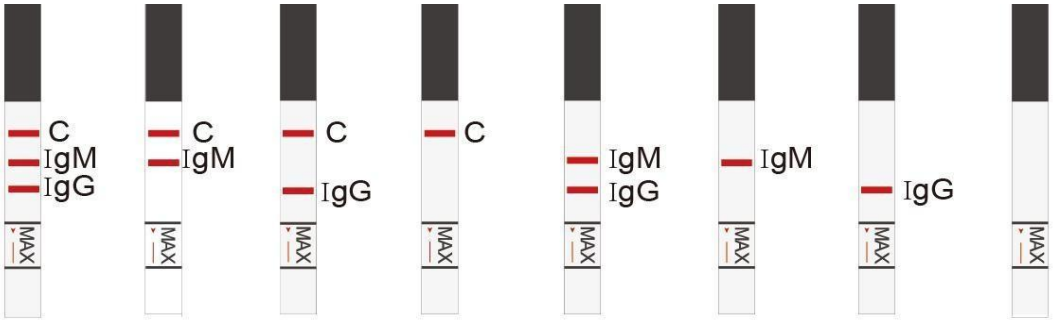
1.2. Place it flat on a horizontal workbench and mark the sample properly.

1.3. Take 10μL of serum and plasma or 20μL of whole blood sample and directly add it to the sample well, then add 100μL (about 2-3 drops) of sample diluent.

1.4. Read the results within 10-15 minutes, and the test results will be invalid after 20 minutes.

1.5. On the diagram, from left to right, they respectively represent: IgG and IgM are both positive; IgM positive; IgG positive; negative; invalid; invalid; invalid; invalid.

2. The detection method for the detection strip is as follows, and the results are shown in the following figure:



2.1. Take out the test strip from the original aluminum foil bag and place it flat on the table.

2.2. Use a micropipette to take 10μL of serum or plasma sample or 20μL of whole blood sample, add it to the sample addition point indicated by the arrow at the bottom of the detection strip, and then add 100μL of sample diluent (about 2-3 drops).

2.3. Read the results within 10-15 minutes, and the test results will be invalid after 20 minutes.

2.4. On the diagram, from left to right, they respectively represent: IgG and IgM are both positive; IgM positive; IgG positive; negative; invalid; invalid; invalid; invalid

Interpretation of Inspection Results

1. IgG positive: Two red lines appear at the IgG detection line and quality control line.
2. IgM positive: Two red lines appear at the IgM detection line and quality control line.
3. IgG and IgM are both positive: Three red lines appear at the IgG detection line, IgM detection line, and quality control line.
4. Negative: Only one red quality control line appears in the detection window.
5. Invalid: No red quality control line appears in the detection window.
6. Invalid results should be retested strictly according to the instructions. If the retest results are still invalid, contact the local supplier or our customer service for technical consultation to determine if there is a problem with the product.

Limitation

1. This reagent is for qualitative testing and cannot be used to determine antibody content.
2. This reagent is used for the detection of personal whole blood, serum, or plasma samples, and should not be used for the detection of saliva, urine, or other bodily fluids.
3. Like all diagnostic reagents, the test results must be combined with other clinical symptoms obtained by the physician for diagnosis.
4. The examination results of this product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered based on their symptoms/signs, medical history, other laboratory tests, treatment response, and epidemiological information.
5. In the early stage of infection, the absence or low titer of virus specific IgM antibodies can lead to negative results. If there is suspicion of virus infection, patients should be advised to have a follow-up examination within 7-14 days, and a second sample should be taken and tested simultaneously with the first sample under the same conditions to determine whether there is a significant increase in serum conversion or virus specific IgG or IgM antibody titer from the initial infection.
6. High titer virus specific IgG and IgM antibodies may reduce the sensitivity of detection, and the detection results of IgG and IgM may show false low values or negative results. Especially for newborn samples suspected of congenital viral infection,

their serum may contain high levels of virus specific IgG antibodies from the mother and relatively low levels of virus specific IgM antibodies produced by the fetus. Therefore, negative results for such samples should be analyzed with caution.

7. Due to the possibility of maternal derived virus specific IgM antibodies (placental leakage) in umbilical cord blood, it is recommended to test subsequent samples of infants 5 days after birth to confirm positive results for virus specific IgM antibodies in umbilical cord blood samples. We strongly recommend parallel testing of serum samples from newborns and mothers. If it is a congenital infection of the fetus, the IgM antibody level (as well as IgG antibody level) will continue to exist or show an upward trend. Conversely, if the antibody comes from the mother, the antibody level of the infant will gradually decrease or disappear in parallel testing.
8. Due to the inability of laboratory tests on pregnant women to reliably identify the risk of fetal illness, it is not recommended to use this reagent for screening asymptomatic maternal infections, and the results of this reagent should not be used alone as a basis for terminating pregnancy.
9. Patients with impaired immune function or receiving immunosuppressive therapy, such as those infected with human immunodeficiency (HIV) or those receiving immunosuppressive therapy after organ transplantation, have limited reference value for serological IgM antibody testing, which may lead to erroneous medical interpretations.
10. The analysis of positive test results for individuals who have received blood transfusions or other blood product treatments in the past few months should be approached with caution.
11. Virus specific IgM antibodies may not only appear in primary infections, but also in secondary and recurrent infections.
12. When the prevalence of a disease decreases, the positive predictive value decreases, and the interpretation of positive results in low-risk populations should be cautious. The population is generally susceptible, and the younger the age, the higher the susceptibility and the more severe the clinical manifestations. Older children and adults are mostly asymptomatic infections.
13. The interpretation of positive results should be further determined in conjunction with clinical symptoms and other pathogenic methods.
14. A negative result indicates that no IgM/IgG antibodies against Hantavirus were detected, but if the content of IgM/IgG antibodies against Hantavirus in the sample is below the minimum detection limit of the kit, a negative result may also be obtained.
15. Due to the lack of relevant validation on infant and toddler samples during the clinical trial process of this product, the interpretation of positive results should be cautious when testing infant and toddler samples, and should also be judged based on clinical symptoms of the samples.

Performance Parameters

1. The positive conformity rate, repeatability, negative conformity rate, and minimum detection limit of this product all meet the quality standard requirements, and the product quality is stable within the validity period.
2. Analysis specificity: The results of cross reactivity with other pathogens and endogenous interferent tests are as follows:
   - 2.1. Cross reaction: Rheumatoid factor, anti nuclear antibody, anti double stranded DNA antibody, anti mitochondrial antibody, hepatitis B virus surface antigen antibody, hepatitis C virus antibody, syphilis antibody, HIV antibody, mycoplasma pneumoniae IgG antibody, chlamydia pneumoniae IgG antibody, parainfluenza virus IgG antibody, influenza A virus antigen, influenza B virus antigen and dengue virus antigen positive sample antibody will not interfere with this product.
   - 2.2. Interference substances: Triglyceride content higher than 8mmol/L, bilirubin content higher than 30μmol/L, and hemoglobin content greater than 4.0g/L in the sample will all affect the experimental results.
   - 2.3. Drug impact: Commonly used antiviral drugs such as ribavirin and interferon alpha have no effect on the detection of this kit.
3. When the concentration of high concentration non-specific IgG antibodies is higher than 15g/L, sample detection will weaken the color result of the test strip IgG. It is recommended to choose other methods for detection of such samples. When the concentration of high concentration non-specific IgM antibody is higher than 6g/L, sample detection will weaken the IgM color result of the test strip. It is recommended to choose other methods for detection of such samples.
4. High concentrations of specific IgG antibodies can weaken the color results of IgM positive samples. When detecting such

samples, it is necessary to combine clinical symptoms for comprehensive judgment to avoid missed diagnosis.

5. When the concentration of high concentration specific IgM antibody is higher than 6g/L, it will weaken the color results of IgG positive samples. When detecting such samples, it is necessary to combine clinical symptoms for comprehensive judgment to avoid missed diagnosis.
6. In the experiment, 0.2mol/L 2-mercaptoethanol was mixed with 10 IgM antibody positive samples of equal volume, and after being treated at 37 ℃ for 1 hour, the IgM antibody detection results of the 10 samples were all negative. 2-mercaptoethanol can destroy specific IgM antibodies, leading to the appearance of false negative samples.
7. HOOK effect: When the concentration of Hantavirus IgM and IgG antibodies is too high, HOOK effect will occur, and the detection line band will weaken. It is recommended to dilute the sample 10 times and retest.
8. Comparative experimental study: A clinical comparative study was conducted on 1050 clinical specimens with similar marketed test kits, and the total conformity rate of this test kit with similar test kits was 95.9%; The single item conformity rate of Hantavirus IgM was 98%, the positive conformity rate was 94.0%, and the negative conformity rate was 98.8%; The single item conformity rate of Hantavirus IgG was 97.9%, the positive conformity rate was 94.2%, and the negative conformity rate was 98.6%. There was no significant difference in the detection results between this kit and similar kits.
9. Serum samples from acute phase patients were isolated from Hantavirus using Vero cells and classified using RT-PCR with type specific PCR primers. In the experiment, 9 acute phase samples were used for typing detection, of which 2 samples failed to isolate the virus, resulting in 4 Hantaan type samples and 3 Seoul type samples. Our company's developed reagent kit can detect all of the above different types of samples.

Note

1. The positive samples obtained by using this reagent kit need to be further confirmed by other methods.
2. The reagent kit should be sealed and stored to prevent moisture. After removing the test strip from the packaging, it should be tested as soon as possible to avoid being left in the air for too long, which may cause moisture.
3. The depth of the color of the detection line is not necessarily related to the titer of antibodies in the sample, and the result obtained after 20 minutes is invalid.
4. When the content of Hantavirus IgM and IgG antibodies in the sample is extremely high, the C-line band may weaken, which is a normal phenomenon.
5. The test results of this type of reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment.
6. Abandoned samples and reagents should be treated as potential infectious substances.
7. Only used for in vitro diagnostics.