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

Product Number: RPT0011

Shipping and Storage

The Hantavirus IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be stored at any temperature between 4-30°C. Avoid light. The stability of the kit under these storage conditions is 12 months. When humidity is below 60%, use up the reagents within 1 hour after the kit is unpacked. When humidity is above 60%, use it immediately after opening.

Component

Component	RPT0011
Test Cassette	25T/Kit
Buffer (0.01M PBS)	1 bottle

Description

Hantaviruses belong to the genus Hantaviruses of the Bunyaviridae family, including pathogens that can cause Hemorrhagic Fever with Renal Syndrome (HFRS) of varying severity, Hantavirus pulmonary syndrome (HPS) and some pathogens that have not yet been reported to cause human diseases. Hantavirus has at least 8 virus types with distinct antigenic genotypes. The Hantaviruses prevalent in our country are mainly serotype I (HTN) and serotype II (SEO). Hantavirus is transmitted from animal to animal or to human through respiratory tract, digestive tract and skin. Aerosol is the main way of transmission. In most cases, IgM antibodies can be detected within 2 to 8 days after the onset of illness. Almost all patients are positive for IgM antibodies within 5 to 15 days, and IgM antibodies disappear after 2 to 5 months of illness, which provides a basis for the clinical diagnosis and early diagnosis of hantavirus infection. Clinical or laboratory methods for diagnosing Hantavirus infection include ELISA, immunofluorescence (IF), PRNT, hemagglutination inhibition test (HI) PCR technology and virus isolation, among which virus isolation is the "gold standard" for the diagnosis of viral diseases. This kit is used as an auxiliary diagnostic reagent for early Hantavirus infection in clinical diagnosis.

Application

The Hantavirus IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid immunochromatographic assay intended for the qualitative detection of IgM antibodies to Hantavirus in human whole blood, serum, or plasma. This test is intended to be used as an aid in the rapid differential diagnosis of Hantavirus infection, including Hemorrhagic Fever with Renal Syndrome (HFRS), in individuals with clinical signs and symptoms consistent with the disease. It is intended for professional in vitro diagnostic use only. It is not intended for use in blood banks, blood donations, or organ/tissue transplantation screening. It is not intended to be used as the sole basis for diagnosis or treatment decisions. Positive or reactive result should be confirmed by a confirmatory method (e.g., PCR, ELISA). Negative results do not rule out Hantavirus infection and should be interpreted together with clinical findings.

Principle

The kit uses colloidal gold immunochromatography to qualitatively detect Hantavirus IgM antibodies in whole blood, serum or plasma samples. Coat the gold-labeled pad with colloidal gold-labeled mouse anti-human IgM (u chain) monoclonal antibody, and coat the recombinant Hantavirus antigen on the nitrocellulose membrane at the same time. If it is a positive specimen, the Hantavirus IgM antibody in the specimen can be combined with colloidal gold-labeled mouse anti-human IgM (u chain) monoclonal antibody to form an immune complex. The complex and the sample flow forward inside the nitrocellulose membrane due to chromatography. When the complex passes through the T line, it combines with the coated recombinant Hantavirus antigen to form "Au-mouse anti-human IgM (u chain) monoclonal antibody-HV-lgM-recombinant HV-Ag" and then agglutinates and develops color. The remaining colloidal gold-labeled mouse anti-human IgM (u chain) monoclonal antibody binds to the goat anti-mouse IgG polyclonal antibody coated at the C line to agglutinate and develop color. If it is a negative specimen, the specimen does not contain Hantavirus

IgM antibodies,so that the immune complex cannot be formed, and the color can only be developed at the C line.

Required materials not provided

1. Timer or clock
2. Micropipette of 10μL, 50μL and 100μL
3. Pipette tips or droppers of 1μL, 50μL and 100μL)

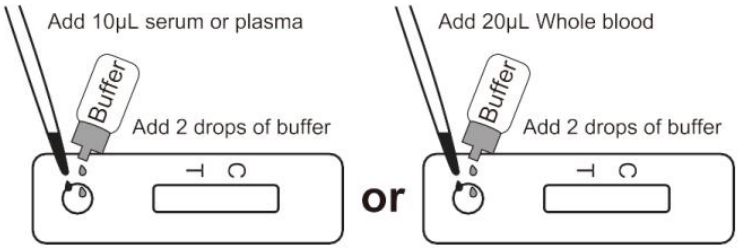
Specimen collection

1. Serum samples are collected via venous blood according to conventional methods: methods of handling plasma samples: 100μL of 1% heparin solution, anticoagulant 5~10mL blood, 3.8% sodium citrate solution and blood is anticoagulated at a ratio of 1:9, 15% disodium ethylenediamine tetraacetate (EDTA) solution 0.04mL anticoagulant 5mL blood can be used.
2. The collected serum or plasma samples are tested within 5 days. The samples can be stored at 2-8°C. For more than 5 days storage they must be kept frozen at -20°C, which can be stored for 3 years. The number of freezing and thawing of sample should not exceed 3 times.
3. Whole blood samples are recommended to be tested within 3 days. Samples are stored at2-8°C. Do not freeze whole blood specimens.
4. The result of the hemolyzed sample test is invalid.

Protocol

1. Preparation: 10μL, 50μL and 100μL micropipette for each, and a few matched suction heads or droppers (10μL, 50μL, 100μL).
2. Process: Place the test cassette flat on a dry surface, use the micropipette to add 10μL serum or plasma to the sample well or add 20μL whole blood to the sample well, and then add 2 drops of buffer (approximately 80μL) to the sample well.
3. Start timer. Read results between 15-20 minutes. Do not read before 15 minutes or after20 minutes.

   Note: Place the kit and the sample to be tested at a room temperature before testing; Use the test cassette within 30 minutes after opening; The result is invalid after 20 minutes.



Result analysis

1. Positive: Two distinct red lines appear. One line presents at Control Line (C), and the other line presents at Test Line (T). Note: Look closely! Even if you see a very faint pink 'T' Line and a pink 'C' Line, you should report the result as POSITIVE.
2. Negative: Only One red line appears in the Control Line (C). No line appears in the Test Line(T)
3. Invalid: No line appears in the Control Line (C), even if a line appears in the Test Line (T), indicates the result is invalid. STOP! If the test is invalid, repeat the test procedure using a new test. Read and follow the test instructions carefully. If the new test still fails, please contact the distributor or the store, where you bought the product, with the lot number.
4. Note: Samples with invalid test results should be treated as infectious pollutants and a new sample should be collected.

Limitation

1. The test results of this kit read by human eyes are easily affected by the visual error or subjective judgment and other factors. When the line color is not easy to determine. Repeat test is recommended.
2. This test cassette is used as one of the assistances means of diagnosis. The test result is for reference only. Should not be used as the sole basis for clinical diagnosis. Positive results should be confirmed by other methods. Limited by the sensitivity of detection,negative results may be due to the antibody concentration below the analytical sensitivity of the product. Clinical diagnosis should be combined with clinical examination, medical history and other tests.
3. In the initial stage of infection, the uncreated or low titer IgM will lead to negative result. The patients should be prompted to review within 7-14 days. At the time of reexamination,the samples collected last time were tested in parallel to confirm the presence of seroconversion or significant increase in titer.
4. Serological antibody testing in immunocompromised or immunosuppressive therapy patients has limited reference values.
5. IgM antibody positivity not only occurs in primary infection, but also in secondary infection.
6. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result.
7. This product has not been clinically validated for neonates and infants.
8. This test is to detect individual serum or plasma samples. Do not use it for the detection of saliva, urine or other body fluids.

Performance

1. The following standards are met when using enterprise internal control standard products for inspection: positive coincidence rate (+/+) = 10/10; negative coincidence rate (-1-) =10/10. The minimum detection limit (LOD) standard (S1~S5) is not less than 3/5. S1~S3 is positive. S5 is negative. The precision (n=10) results are all positive, and the color rendering is uniform.
2. Toxoplasma gondi 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 type II IgM antibody (S/C value: <12.53), dengue virus IgM antibody (S/C value: s12.34),Crimean-Congo hemorrhagic fever virus IgM antibody (S/C value: $14.08), hepatitis B Virus surface antigen positive (S/C value: S13.57), hepatitis C virus antibody positive (S/C value: $14.75), HEV-IgM (S/C value: $13.24), high concentration of hantavirus IgG antibody (S/C value: $15.20), rheumatoid factor (54 IU/mL), antinuclear antibody ($1:640)positive samples and high-concentration non-specific lgM samples (S4.02 g/L) will not affect this kit. When the blood lipid content in the sample is higher than 6mmol/L and the bilirubin content is higher than 40μmol/L, the detection may be missed.
3. IgM antibody destruction test: HV-IgM positive internal control standards are all positive before the IgM antibody is destroyed, and all the tests are negative after the IgM antibody is destroyed. The samples should be processed according to "Specimen Collection".
4. HOOK effect: high concentrations of strong positive samples can be detected clinically, but the results are not negative. After the strong positive samples are diluted, the HV-lgM antibody positivity is weakened, and the HOOK effect does not appear.
5. The kit can detect Hantan-type and Seoul-type IgM antibodies of Hantavirus.

Note

1. The positive results obtained by this kit should be further confirmed by other methods.
2. The kit should be sealed to prevent moisture. When the humidity is below 60%, use it within 1 hour after opening. When the humidity is above 60%, use it immediately after opening. Avoid placing it in the air for a long time, which may get damp and affect the test results.
3. The depth of the color of the detection line is not necessarily related to the titer of the antibody in the sample. The result to be read after 20 minutes is invalid.
4. When the content of Hantavirus IgM antibody in the sample is extremely high, the C line band may be weakened, which is a normal phenomenon.
5. Kit components and waste generated by testing are treated as infectious pollutants.6. The kit is only used for in vitro diagnosis,

and the tested samples are limited to human whole blood, serum or plasma.