Hantavirus IgG/IgM Antibody Rapid Test Kit
Instructions for use

CE IVD

REF RNPT96027-01/RNPT96027-02/RNPT96027-05/RNPT96027-20/RNPT96027-25 EN

FOR PROFESSIONAL USE ONLY

Intended Use

This kit is used for qualitative detection of Hantavirus IgG antibody and IgM antibody in human serum, plasma and whole blood samples in vitro, which plays an important role in the early diagnosis and treatment of Hantavirus infection, and can assist in the diagnosis of Hantavirus infection in clinical practice.

Principle

The Hantavirus IgM/IgG Antibody Rapid Test Kit uses the specific antigen of Hantavirus for tracer labeling, and uses anti-human IgM and anti-human IgG monoclonal antibodies for coating as the detection line. If there is a certain concentration of Hantavirus antibody (IgM/IgG) in the test sample, the tested antibody binds to the specific antigen of Hantavirus labeled by the tracer to form a complex. Under the action of chromatography, the complex moves to the detection line and is captured by the coated antibody, thus showing a red band. When the sample to be tested does not contain Hantavirus antibody, the antibody-antigen labeling complex does not form, and it is not captured by the assay line to produce a red band. Whether the sample contains the antibody to be tested or not, a red band should appear at the C of the quality control line as an internal control standard for whether the chromatographic process is normal and whether the reagent fails.

Storage and Stability

• Store the test kit between 2°C~30°C in a place out of direct sunlight, product expiration date 24 months.
• After the foil pouch is opened, the test card should be used as soon as possible within 1 hour.

Components

•Test Card • Sample Diluent Buffer Sterile Lancets • Dropper • Alcohol Pad
• Instructions for Use

Precautions

• This kit is a disposable in vitro diagnostic reagent, please do not reuse, and do not use expired products.
• The aluminum foil pouch contains a desiccant and should not be taken internally.
• Fresh samples are recommended.
• Components in different lot kits should not be cross-used to avoid erroneous results.
• The temperature of the experimental environment should be avoided from being too high, and the test card should be restored to room temperature before opening it to avoid moisture absorption.
• After the test, the used test card, sample diluent, straw, etc. will be disposed of as biomedical waste.
• Please pay attention to safety measures during operation, such as wearing protective clothing and gloves.
• As with all diagnostic reagents, the final diagnosis should be made by the physician after taking into account the various test indicators and clinical symptoms.

Sample Collection and Preparation

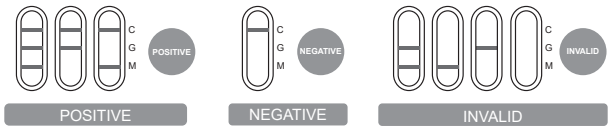
1.Whole blood samples collection: Fingertip or venous blood was collected using anticoagulant tubes or blood collection tubes pre-added with anticoagulant (heparin, EDTA, sodium citrate and other anticoagulants are recommended), and then shaken for later use. The sample should be used as soon as possible after collection: If it cannot be tested immediately, the sample can be refrigerated at 2-8℃, and the whole blood sample should be tested within 3 days.
2.Serum/plasma sample collection: Venous blood is collected, after blood coagulation, the supernatant is drawn directly or after centrifugation, which is the serum. Blood is collected with a collection tube or anticoagulant tube added with anticoagulant (it is recommended to use heparin, EDTA, sodium citrate, etc.), and the upper layer of light yellow clear liquid is taken after centrifugation or resting, which is the plasma sample. If the serum/plasma samples cannot be tested in time, they should be refrigerated at 2-8 ° C for two weeks. If long-term storage is required, they should be refrigerated at -20 ° C and returned to room temperature before testing.
3.Note: A high concentration of jaundice samples (the visual appearance of the sample solution is yellow), a high hemolysis sample (free hemoglobin concentration >9g/L), or a visually visible chylous sample will interfere with the interpretation of the test results, so attention should be paid to the appearance of the sample before using the sample.

Test Procedure

Before conducting the test, please read the user manual completely. Before use, restore the test card and samples to room temperature and number them.
1. Take the test card out of the packaging bag and use it within one hour.
2. Place the test card on a clean, level table, and mark it.
3. Test the collected whole blood, serum and plasma: Use a dropper to draw the sample and add 1 drop （10μL） into the sample well (S) of the test card. Then, drop 2 drops sample diluent buffer into the diluent well (D). Start timing.
Note: If the liquid doesn't move to the position of the control area (C) in 2 minutes, add one more drop of the sample diluent buffer into the diluent well.
4.Test for fingertip blood: First, wipe the fingertip with the alcohol pad. Then, place a sterile lancets against the fingertip and press it down slightly with force. Squeeze out a drop of fingertip blood and draw it with a dropper. Add 1 drop （10μL） into the sample well (S) of the test card. Next, drop 2 drops sample diluent buffer into the diluent well (D). Start timing.
5.The final result should be read in 10 minutes. The result read after 20 minutes has no clinical significance.

Interpretation of Results

Positive: Two red lines, that is, one red reaction line in the detection area (IgG or IgM) and one in the quality control area (C).
Negative: One red line, that is, a red response line appears only in the quality control area (C).
Invalid: No red reaction line appears in the quality control area (C). The test is invalid, it is recommended to re-test with a new test card at this time, especially pay attention to whether the added sample is enough.



Limitations

1.This kit is only for the qualitative detection of Hantavirus IgG antibody and IgM antibody in samples.
2.A negative result will occur when the Hantavirus IgG antibody and IgM antibody in the test sample is below the minimum detection limit or is absent at some stage of infection. A negative result does not rule out the possibility of recent infection.
3.The test results of this product are for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with their symptoms/signs, medical history, other laboratory tests, treatment response and epidemiological information.

Performance Index

1.Clinical Performance:

Table 1: Analysis of Sensitivity and Specificity of Hantavirus IgM

Hantavirus IgM/IgG Antibody Rapid Test Kit	Comparative Reagent		
	Positive	Negative	Total
Positive	372	5	377
Negative	2	671	673
Total	374	676	1050

Sensitivity=372/374=99.47%(95% CI: 98.08%-99.93%)
Specificity=671/676=99.26%(95% CI: 98.28%-99.76%)
Agreement=(372+671)/1050=99.33%(95% CI: 98.63%-99.73%)

Table 2: Analysis of Sensitivity and Specificity of Hantavirus IgG

Hantavirus IgM/IgG Antibody Rapid Test Kit	Comparative Reagent		
	Positive	Negative	Total
Positive	373	5	378
Negative	2	670	672
Total	375	675	1050

Sensitivity=373/375=99.47%(95% CI: 98.09%-99.94%)
Specificity=670/675=99.26%(95% CI: 98.28%-99.76%)
Agreement=(373+670)/1050=99.33%(95% CI: 98.63%-99.73%)

2.Sensitivity: The minimum detection limit of the kit is not higher than the standard.
3. Cross reaction: No cross reactions were observed with IgM/IgG to Influenza A virus, Leptospira, Mycoplasma pneumoniae, HIV-IgG, anti-HBsAg antibodies, Rheumatoid factor (RF), IgM/IgG to Dengue, and IgM/IgG to xinjiang hemorrhagic fever virus.
4.Samples with hemoglobin concentration ≤500mg/L, the triglyceride concentration ≤180mmol/L, and the bilirubin concentration ≤1.8mmol/L will not interfere with the detection of Hantavirus IgG antibody and IgM antibody by this kit.

INDEX OF SYMBOLS

REF	Catalogue number	IVD	In vitro diagnostic medical device
Σ	Contains sufficient for <n> tests	LOT	Batch code
	Manufacturer		Date of manufacture
EU REP	Authorized representative in the european community		Use-by date
	Consult instructions for use		Storage temperature limit
	Keep away from sunlight		Do not re-use
	Keep dry		Do not use if package is damaged
CE	CE mark		

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Precision and Quality Beyond Value

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