Hantavirus IgG/IgM Rapid Test

(Whole Blood/Serum/Plasma)

A rapid test for the qualitative detection of Hantavirus IgG and IgM Antibody in human whole blood, serum or plasma specimens.
For professional in vitro diagnostic use only.
Please read the package insert carefully before using.

【SPECIFICATION】
25 Tests/Kit

【INTENDED USE】
The Hantavirus IgG/IgM Rapid Test is a serological, lateral flow chromatographic immunoassay for the simultaneous detection and differentiation Hantavirus IgG and IgM Antibody in human whole blood, serum or plasma specimens. It is intended to be used by healthcare professionals as a screening assay and as an aid in the diagnosis of infection with Hantavirus (HV). The test only provides preliminary analysis results but not critical diagnosis criteria. Any use or interpretation of the test must be analyzed and confirmed with alternative testing method(s) and clinical findings based on professional judgment of healthcare providers.

【SUMMARY】
Hantaviruses belong to the family Hantaviridae, within the order Bunyavirales. Each hantavirus is typically associated with a specific rodent reservoir species, in which the virus causes long-term infection without apparent illness. Hantaviruses are zoonotic viruses that naturally infect rodents and are occasionally transmitted to humans. Hantaviruses are a group of viruses carried by rodents that can cause severe disease in humans. People usually get infected through contact with infected rodents or their urine, droppings or saliva. Infection with hantaviruses can cause a range of illnesses, including severe disease and death.
Although many hantavirus species have been identified worldwide, only a limited number are known to cause human disease. Infection in people can result in severe illness and often death, although the diseases vary by type of virus and geographical location. In the Americas, infection has been known to lead to hantavirus cardiopulmonary syndrome (HCPS), a rapidly progressive condition affecting the lungs and heart, while in Europe and Asia hantaviruses have been known to cause haemorrhagic fever with renal syndrome (HFRS), which primarily affects the kidneys and blood vessels.
Since there is no specific treatment that cures hantavirus diseases, early detection of this virus is of great importance to aid in clinical diagnosis, prevention and control, as well as medical treatment for suspected individuals and infected patients.
The Hantavirus IgG/IgM Rapid Test utilizes Hantavirus recombinant antigens to simultaneously detect Hantavirus IgG and IgM Antibody simultaneously in human whole blood, serum or plasma specimens at 15-20 minutes.

【TEST PRINCIPLE】
The Hantavirus IgG/IgM Rapid Test is a qualitative membrane-based immunoassay using capture method for the detection of Hantavirus IgG and IgM Antibody in human whole blood, serum or plasma specimens. The test device consists of: 1) a burgundy-colored conjugate pad containing recombinant Hantavirus antigens conjugated with colloidal gold (Hantavirus conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (M and G lines) and a control line (C line). The M line is pre-coated with monoclonal anti-human IgM for the detection of Hantavirus IgM Antibody, the G line is pre-coated with monoclonal anti-human IgG for the detection of Hantavirus IgM Antibody, and the C line is pre-coated with a control antibody.

When an adequate volume of test specimen is added to the specimen well (S) of the cassette, the specimen migrates by capillary action across the cassette. If Hantavirus IgG and/or IgM Antibodies level in the specimen is at or above the detection limit of the test, it will bind to the Hantavirus conjugates and form an immunocomplex, the immunocomplex is then captured on the test line(s) of the membrane by the pre-coated anti-human IgG, and/or anti-human IgM antibody forming a burgundy-colored G line and/or M line, indicating Hantavirus IgG positive test result and/or IgM positive test result. Absence of any test lines (M and G) suggests a negative result.

An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control line, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.

【MATERIALS PROVIDED】
- 25 x Test device individually foil pouched with a desiccant
- 2 x Sample diluent
- 25 x Dropper (10uL)
- 1 x Package insert

【OPTIONAL MATERIALS】
- Blood lancet
- Alcohol pad

【MATERIALS REQUIRED BUT NOT PROVIDED】
Timer, Specimen collection containers

【WARNINGS AND PRECAUTIONS】
1. For *in vitro* diagnostic use only. Do not reuse the test.
2. Do not freeze the test kit or its components.
3. These instructions must be carefully read and strictly followed by a trained healthcare professional to achieve accurate results. All users have to read the instructions before performing test.
4. The test is only for the detection of Hantavirus IgG and IgM Antibody, not for any other viruses or pathogens.
5. Inadequate or inappropriate specimen collection, storage, and transportation are likely to result in false negative test results.
6. Do not use hemolyzed blood specimens for testing.
7. Do not eat, drink or smoke in the area where handling specimens or performing the test.
8. Do not use the test kit beyond its expiration date.
9. Do not mix components from different kit lots.
10. Leave test device sealed in its foil pouch until just before use. Do not use the test device if the pouch is damaged or the seal is broken.

11. To avoid contamination or inaccurate test result, do not touch the reaction area of test device when performing the test.
12. Wear appropriate personal protection equipment and gloves when performing the test, collecting and handling patient specimens.
13. Dispose of all used test devices and potentially contaminated materials in a biohazard container as if they were infectious waste and dispose according to applicable local laws and regulations.

【STORAGE AND STABILITY】

1. The test kit should be stored either at room temperature or refrigerated (2-30°C), away from direct sunlight. Do not freeze the kit or expose the kit to temperatures over 30°C.
2. The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
3. This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30°C) before use.
4. Perform the test immediately after taking out the test device from the foil pouch.

【SAMPLE COLLECTION AND PREPARATION】

Consider any materials of human origin as infectious and handle them using standard biosafety procedures. The test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma specimens. Follow standard laboratory procedures to collect specimens.

Plasma/Serum

1. Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.
2. To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.
3. To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C if not tested immediately. Specimens can be stored at 2-8°C for up to 3 days, and should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles (no more than 3 times). Prior to testing, equilibrate frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity so as to avoid interference on result interpretation.

Whole Blood

Collect whole blood by either fingertip puncture or by venipuncture into collection tube containing EDTA, citrate or heparin for plasma. Do not use any hemolyzed blood for testing.

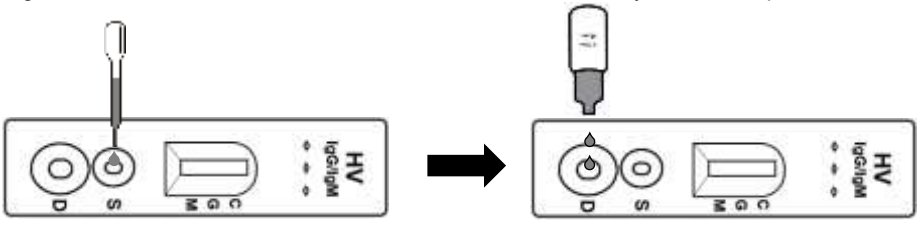
Do not freeze a whole blood specimen, otherwise the red blood cell will break, which may cause hemolysis. Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The specimens must be tested within 24 hours after collection.

【TEST PREPARATION】

Before testing, open the package and equilibrate the test device, sample diluent, specimens and/or controls to room temperature, and shake the sample diluent gently before use. The most suitable temperature condition to perform the test is room temperature (15-30°C). If the test kit is stored at room temperature, it can be opened and used immediately.

【TEST PROCEDURES】

1. Take out the test device from sealed foil pouch and place on a dry, clean and level surface.
2. Be sure to label the device with specimen's ID number.
3. Fill the pipette dropper with the specimen. Hold the dropper vertically and transfer one drop of specimen (approximately 10μL) into the specimen well (S) making sure that there are no air bubbles. Then add two drops of sample diluent to the diluent well (D) immediately. See illustration below.
4. Start the timer.
5. Wait for the colored line(s) to appear. Read test results at 15 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. Do not interpret the result after 20 minutes.



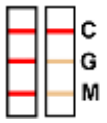
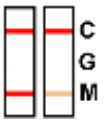
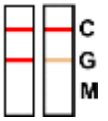
【INTERPRETATION OF TEST RESULTS】

(Please refer to the illustrations below)

POSITIVE: Two or three lines appear. One colored line should be in the control line region (C) and another apparent colored line(s) should be in the test line region ("G" and/or "M").

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, stop using the test kit immediately and contact your local distributor.

IgM & IgG Positive	IgM Positive	IgG Positive	Negative	Invalid
				

【QUALITY CONTROL】

1. **Internal Control:** An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control line, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.
2. **External Control:** Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The test is only used for the qualitative detection of Hantavirus IgG and IgM Antibody in human whole blood, serum or plasma specimens by healthcare professionals. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
2. The test does not indicate the level of Hantavirus IgG and IgM Antibody in the specimen, and should not be used as the sole criteria for the diagnosis of infection with Hantavirus.
3. A negative test result may occur if the level of Hantavirus IgG and IgM Antibody in a specimen is below the detection limits of the test, or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. A negative or non-reactive result indicates the Hantavirus IgG and IgM Antibody is not present in the specimen. However, a negative or non-reactive result at any time does not preclude the possibility of infection with Hantavirus.
5. The test cannot confirm and determine the Hantavirus genotypes present in a specimen.
6. Infection may develop rapidly. If symptoms are suspicious or persist while test result from the Hantavirus IgG/IgM Rapid Test is negative or non-reactive, additional testing using alternative clinical methods is recommended.
7. Test results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
8. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
9. There is a possibility that some whole blood specimens with very high viscosity or which have been stored for over 24 hours may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

【PERFORMANCE CHARACTERISTICS】

1. Clinical performance

The Hantavirus IgG/IgM Rapid Test has been evaluated with a reference commercial ELISA test using clinical specimens. Test results are presented in the tables below.

Clinical performance for IgG Test

Hantavirus IgG/IgM Rapid Test	IgG ELISA Test		
	IgG Positive	Negative	Total
IgG Positive	25	1	26
IgG Negative	1	219	220
Total	26	220	246

Sensitivity (Positive Percent Agreement): 96.15% = 25/26 (95% CI: 81.11%~99.32%)
Specificity (Negative Percent Agreement): 99.540% = 219/220 (95% CI: 97.47%~99.92%)
Accuracy (Overall Percent Agreement): 99.18% = (22+219)/226 (95% CI: 97.08~99.78%)

Clinical performance for IgM Test

Hantavirus IgG/IgM Rapid Test	IgM ELISA Test		
	Positive	Negative	Total
Positive	28	1	29
Negative	2	199	201
Total	30	200	230

Sensitivity (Positive Percent Agreement): 93.33% = 28/30 (95% CI: 78.68%~98.15%)
Specificity (Negative Percent Agreement): 99.50% = 199/200 (95% CI: 97.22%~99.91%)
Accuracy (Overall Percent Agreement): 98.69% = (28+199)/230 (95% CI: 96.24%~99.56%)

2. Cross-reactivity

No false positive anti-Hantavirus IgG and IgM test results were observed on specimens from the following disease states or specific conditions, respectively:
HAV, HBV, HCV, HEV, HIV, H. pylori, CMV, Dengue, Malaria, Chagas, Chikungunya, Rubella, and Syphilis.

3. Interference

The following potentially interfering substances were added to Hantavirus IgG negative and positive, and Hantavirus IgG negative and positive specimens, respectively. Test results demonstrate that performance of the Hantavirus IgG/IgM Rapid Test were not affected by the listed potentially interfering substances at the concentrations tested.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Ascorbic acid	20 mg/dL	Creatinine	442 µmol/L

Atropine	20 mg/dL	EDTA	3.4 µmol/L
Aspirin	20 mg/dL	Glucose	55 mmol/L
Albumin	60 g/dL	Heparin	3,000 U/L
Bilirubin	20 mg/dL	Hemoglobin	2 g/L
Salicylic acid	4.34 mmol/L	Sodium citrate	3.80%

【REFERENCES】

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【INDEX OF SYMBOLS】

	Consult instruction for use		For *in vitro* diagnostic use only		Catalog number		Temperature limit
	Lot number		Use by		Do not reuse		Contains sufficient for <X> tests
	Keep dry		Manufacturer		Date of manufacture		Keep away from sunlight
	Do not use if package is damaged						

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