HAV IgG/IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO HAV IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO HAV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of antibodies (IgG and IgM) to hepatitis A virus (HAV) in human serum, plasma or whole blood. It is intended to be used by healthcare professionals to aid in the diagnosis of active and/or past HAV infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

HAV, a positive-sense RNA virus, is a unique member of the Picornaviridae family. HAV is highly contagious and is primarily transmitted by the fecal-oral route, either through person to person contact or consumption of contaminated food or water. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate can increase following oral-anal contact.

The presence of anti-HAV IgM in blood samples suggests an acute or recent HAV infection. In most infected individuals, anti-HAV IgM rapidly increases in titer over a period of 4-6 weeks post-infection, and then declines to non-detectable levels within 3 to 6 months. Anti-HAV IgG can be detected at the onset of symptoms, and levels remain elevated throughout the life of an individual. Protective immunity from an infection with HAV is indicated by an anti-HAV IgG level ≥ 20-33 mIU/mL, however these levels do not necessarily ensure protection from a future HAV infection. A patient without protective levels of anti-HAV IgG (< 20-33 mIU/mL) is considered at risk of acquiring an HAV infection.

FRENOVO HAV IgG/IgM Rapid Test a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: 1) a colored conjugate pad containing HAV antigens conjugated with colloidal gold (HAV conjugates) and a control antibody conjugated with colloidal gold; 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with mouse anti-human IgG for detection of anti-HAV IgG. The M line is pre-coated with mouse anti-human IgM for detection of anti-HAV IgM. The C line is pre-coated with a control antibody. When an adequate volume of test specimen and sample diluent are dispensed into the sample and buffer wells, respectively, the specimen migrates by capillary action across the test strip. If anti-HAV IgG is present in the specimen, it will bind to the HAV conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a colored G line, indicating an HAV IgG positive test result. If anti-HAV IgM is present in the specimen it will bind to the HAV conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgM forming a colored M line, indicating an HAV IgM positive test result. Absence of any test lines (G or M) suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies, regardless of color development on the test lines (G and M). If no control line (C line) develops, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micro-pipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO HAV IgG/IgM Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test cassettes from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected as soon as possible. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage,serum/ plasma specimens should be kept below -20 ℃. Whole blood collected by venipuncture should be stored at 2~8 ℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

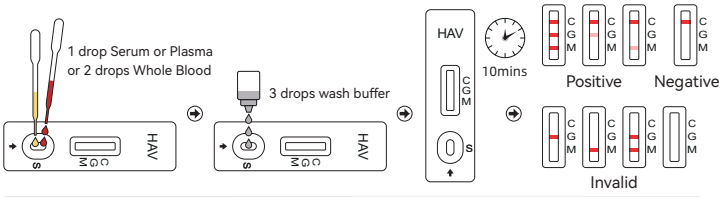
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

TEST PROCEDURE

Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. **For Serum or Plasma Specimens**
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
   To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.
   For Whole Blood Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 20ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
   To use a micro-pipette: Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region(C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. the result is positive for IgG & IgM antibodies and is indicative of secondary HAV infection.

IgG POSITIVE: Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region. The result is positive for HAV specific-IgG and is probably indicative of secondary HAV infection.

IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for HAV specific-IgM antibodies and is indicative of primary HAV infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of HAV antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s)

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

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of HAV IgG/IgM antibodies in serum, plasma or whole blood specimens only.
2. A negative test result cannot exclude a recent infection. A positive result may not indicate previous HAV infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
3. Infection may progress rapidly. If the symptom persists, while the result from FRENOVO HAV IgG/IgM Rapid Testis negative or non-reactive result, it is recommended to test with an alternative test method, such as bacterial culture method.
4. Results from this test should not be used to diagnose or to exclude acute HAV infection or to inform infection status.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

HAV IgM Study		PCR		
HAV IgG/IgM Rapid test	Results	IgM Positive	IgM Negative	Total Results
	IgM Positive	91	5	96
	IgM Negative	7	203	210
Total Results		98	208	306

HAV IgM Study Summary Results:
Clinical sensitivity =92.86% (95%CI*85.84%～97.08%)
Clinical specificity =97.60% (95%CI*94.48%～99.22%)
Accuracy=96.08% (95%CI*93.25%～97.68%)

HAV IgG Study		PCR		
HAV IgG/IgM Rapid test	Results	IgG Positive	IgG Negative	Total Results
	IgG Positive	125	0	125
	IgG Negative	4	71	75
Total Results		129	71	200

HAV IgG Study Summary Results:
Clinical sensitivity =96.90% (95%CI*92.25%～99.15%)
Clinical specificity >99.00% (95%CI*95.88%～100.0%)
Accuracy=98.00% (95%CI*94.96%～99.45%)

Interference Substances

The following potential interfering substances have been tested using The kit and no interference was observed:

Substance	Tested Concentration
HAMA	positive sample
Rheumatoid factor	100 IU/mL
Antinuclear antibody (ANA)	103.748 IU/mL
Anti-mitochondrial antibody(AMA)	80 U/mL
Bilirubin	0.3 mg/mL
Hemoglobin	8 mg/mL
Triglycerides	5 mg/mL
α-interferon	2 ng/mL
Zanamivir	142 ng/mL
Ritonavir	53 μg/mL
Tramadol	12 μg/mL
Azithromycin	4 μg/mL
Azithromycin	156 μg/mL
Meropenem	10 mg/mL
Levofloxacin	2 mg/mL

Cross Reaction

Cross-reactivity of The kit was evaluated using serum samples containing antibodies to other pathogens., which has no effect on the negative and positive test results, and there is no cross-reaction.

IgM potential cross-reactant	IgG potential cross-reactant
Influenza A virus (H1N1, H3N2)	Influenza A virus (H1N1, H3N2)
Influenza B virus (Yamagata IgM,Victoria IgM)	Influenza B virus (Yamagata IgG, Victoria IgG)
Endemic human coronavirus (OC43, 229E)	Endemic human coronavirus (OC43, 229E)
CMV IgM	CMV IgG
Rubella IgM	Rubella IgG
Toxo IgM	Toxo IgG
HSV IgM	HSV IgG
Coxsackie virus group B IgM	Coxsackie virus group B IgG
Epstein-Barr virus IgM	Epstein-Barr virus IgG
Enterovirus 71 IgM	Enterovirus 71 IgG
Coxsackie virus type A16 IgM	Coxsackie virus type A16 IgG
Varicella zoster virus IgM	Varicella zoster virus IgG
Mumps Virus IgM	Mumps Virus IgG
Respiratory syncytial virus IgM	Respiratory syncytial virus IgG
Adenovirus IgM	Adenovirus IgG
Chlamydia pneumoniae IgM	Chlamydia pneumoniae IgG
Mycoplasma pneumoniae IgM	Mycoplasma pneumoniae IgG
Measles virus IgM	Measles virus IgG

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks	CE	CE mark

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INSTRUCTION APPROVAL AND REVISION DATE

Revision Date: 2023.01.23
Approval Date: 2023.01.23
Date of Issue: 2023.01.23