

# MHS HAV – Test (test cassette)



Rapid test for the for the qualitative detection of IgM antibody to Hepatitis A virus (HAV) in human serum or plasma  
Single test cassettes, pouched separately  
Art. Nr. 622000

## INTENDED USE

The *MHS HAV IgM Rapid Test* is a lateral flow chromatographic immunoassay for the qualitative detection of IgM antibody to Hepatitis A virus (HAV) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HAV. Any reactive specimen with the *MHS HAV IgM Rapid Test* must be confirmed with alternative testing method(s) and clinical findings.

## SUMMARY AND EXPLANATION OF THE TEST

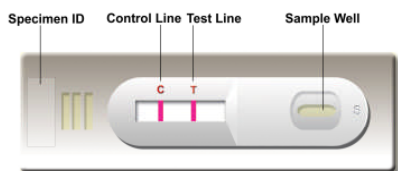
HAV is a positive RNA virus, a unique member of picornaviridae<sup>1</sup>. Its transmission depends primarily on serial transmission from person to person by the fecal-oral route. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate is high among male homosexuals, as result of oral-anal contact<sup>2,3</sup>.

The presence of specific anti-HAV IgM in blood samples suggests acute or recent HAV infection<sup>4-6</sup>. The IgM antibody 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 in most patients<sup>7</sup>.

The *MHS HAV IgM Rapid Test* is to be used to detect IgM anti-HAV in less than 15 min by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

## TEST PRINCIPLE

The *MHS HAV IgM Rapid Test* is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-human IgM antibody conjugated with colloidal gold (IgM conjugates) and, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with recombinant HAV antigen, and the C band is pre-coated with goat anti-mouse IgM antibodies.



When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-HAV IgM if present in the specimen will bind to the IgM conjugates. The immunocomplex is then captured on the membrane by the pre-coated HAV antigen, forming a burgundy colored T band, indicating a HAV IgM positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgM-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

## REAGENTS AND MATERIALS PROVIDED

- Each kit contains 30 test devices, each sealed in a foil pouch with three items inside:
  - One cassette device.
  - Plastic dropper
  - One desiccant.
- Sample Diluent (1 vial, 5 mL)
- One package insert (instruction for use).

## MATERIALS REQUIRED AND AVAILABLE FOR PURCHASE

- Positive Control (1 vial, red cap, 1 mL, Cat # R0090-P)
- Negative Control (1 vial, green cap, 1 mL, Cat # R0090-N)

## MATERIALS REQUIRED BUT NOT PROVIDED

Clock or Timer

## WARNINGS AND PRECAUTIONS

- For *in Vitro* Diagnostic Use
- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Do not use hemolyzed blood specimen for testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Handle the Negative and Positive Control in the same manner as patient specimens.
- The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading result after 15 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

## REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

### Plasma

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into new pre-labeled tube.

### Serum

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

## ASSAY PROCEDURE

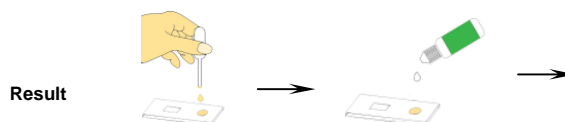
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: Fill the pipette dropper with the specimen.  
Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.

Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.



Result

1 drop of specimen      1 drop of sample diluent      15 minutes

Step 5: Set up timer

Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

**Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.**

## QUALITY CONTROL

Using individual *MHS HAV IgM Rapid Test* cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

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1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit fall outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

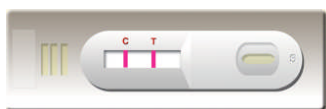
### Negative Control

Only the C band shows color development. The T band shows no color development.



### Positive Control

Both C and T bands show color development.



The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.

### INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C band is developed, the test indicates that no detectable IgM anti-HAV is present in the specimen. The result is negative.



2. **POSITIVE RESULT:** If both C and T bands are developed, the test indicates for the presence of IgM anti-HAV in the specimen. The result is positive.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.



### PERFORMANCE CHARACTERISTICS

#### Clinical Performance

A total of 200 samples from susceptible subjects were tested by the MHS HAV IgM Rapid Test and by a commercial EIA test. Comparison for all subjects is showed in the following table:

| EIA      | MHS HAV IgM Rapid Test |          | Total |
|----------|------------------------|----------|-------|
|          | Positive               | Negative |       |
| Positive | 21                     | 1        | 22    |
| Negative | 0                      | 178      | 178   |
| Total    | 21                     | 179      | 200   |

Relative Sensitivity: 95.5% , Relative Specificity: 100%, Overall Agreement: 99.5%

### LIMITATIONS OF TEST

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-HAV IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The MHS HAV IgM Rapid Test is limited to the qualitative detection of anti-HAV IgM in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-HAV IgM. However, a negative test result does not preclude the possibility of exposure to or infection with HAV.
4. A negative result can occur if the quantity of the anti-HAV IgM present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

### REFERENCES

1. Minor P. Picornaviridae. In: Francki RIB, Fauquet CM, Knudson DL, et al., eds. Classification and nomenclature of viruses (Arch Virol Supp 2). Wien: Springer-Verlag, 1991: 320-326.
2. Keefe EB. Clinical approach to viral hepatitis in homosexual men. *Med Clin North Am.* 1986;70(3):567-86.
3. Ballesteros J, Dal-Re R, Gonzalez A, del Romero J. Are homosexual males a risk group for hepatitis A infection in intermediate endemicity areas? *Epidemiol Infect.* 1996; 117(1):145-8.
4. Bradley DW, Maynard JE, Hindman SH, et al: Serodiagnosis of viral hepatitis A: Detection of acute-phase immunoglobulin M anti-hepatitis A virus by radioimmunoassay. *J Clin Microbiol* 1977; 5: 521-530.
5. Decker RH, Kosakowski SM, Vanderbilt AS, et al: Diagnosis of acute hepatitis A by HAVAB-M : A direct radioimmunoassay for IgM anti-HAV. *Am J Clin Pathol* 1981;76:140-147.
6. Locarnini SA, Ferris AA, Lehman NI, et al: The antibody response following hepatitis A infection. *Intervirology* 1974; 4:110-118.
7. Skinhoj P, Mikkelsen F, Hollinger FB. Hepatitis A in Greenland: Importance of specific antibody testing in epidemiologic surveillance. *Am J Epidemiol* 1977; 105: 104-147

### SYMBOLS

|              |                                  |  |                           |
|--------------|----------------------------------|--|---------------------------|
| <b>IVD</b>   | For in-vitro diagnostic use only |  | For single use only       |
| <b>Cont.</b> | Content                          |  | Expiry date               |
| <b>LOT</b>   | Lot number                       |  | Store at room temperature |

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