HAV IgM CARD

For i*n Vitro* diagnostic use only

Immunochromatographic test for the qualitative detection of IgM antibody to Hepatitis A virus (HAV) in human serum or plasma

I. INTENDED USE

HAV IgM Card 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 HAV IgM Card must be confirmed with alternative testing method(s) and clinical findings.

II. SUMMARY AND EXPLANATION OF THE TEST

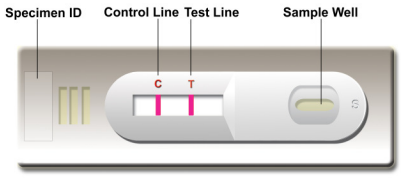
HAV is a positive RNA virus, a unique member of picornaviridae[1]. Its transmission depends primarily on serial transmission from person to person by the fecal-oral route. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate is high among male homosexuals, as result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

The presence of specific anti-HAV IgM in blood samples suggests acute or recent HAV infection [4-6]. 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 [7].

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

III.PRINCIPLE

HAV IgM Card 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 colloid 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 antibodies/ 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.

IV. COMPOSITION OF KIT

1. Each kit contains 30 test devices, each sealed in a foil pouch with three items inside:
   a. One card (cassette) device.
   b. Plastic dropper
   c. One desiccant.
2. Sample Diluent (1 vial, 5 mL)
3. Instruction for use.

V. STORAGE AND STABILITY

1. Kit components should be stored at room temperature (between +2℃ and +30℃).
2. Do not freeze the test kit.
3. HAV IgM Card is stable until the expiry date stated on the package label.

VI. PRECAUTIONS

1. For in vitro diagnostic use and professional use only.
2. Handle all specimens as if they contained infectious agents.
3. Wear protective clothing such as laboratory coats and disposable gloves while assaying samples. Avoid any contact between hands and eyes or nose during specimens collection and testing.
4. Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
5. Do not use hemolized blood specimen for testing.
6. Do not use beyond the expiration date which appears on the package label.
7. Do not use a test from a damaged protective wrapper.

VII. REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2℃-30℃. The positive and negative controls should be kept at 2℃-8℃**.** If stored at 2℃-8℃, 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℃.

VIII. SPECIMEN COLLECTION AND HANDLING

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

Plasma

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

Serum

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

Test specimens as soon as possible after collecting. Store specimens at 2℃-8℃ if not tested immediately, up to 5 days. The specimens should be frozen at -20℃ 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.

IX. 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.

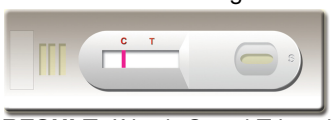
1 drop of specimen **1 drop of sample diluent** **15 minutes**

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.
Recommendation: Take a digital photograph for record keeping.

X. READING TEST RESULTS

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.

XI. PERFORMANCES CHARACTERISTICS

Clinical Performance

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

	HAV IgM Card		
EIA	**Positive**	**Negative**	**Total**
Positive	21	1	22
Negative	0	178	178
Total	21	179	200

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

XII. LIMITATIONS

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 HAV IgM Card 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.

XIII. REFERENCES (see Italian version)

IVD	Dispositivo medico-diagnostico in vitro In Vitro Diagnostic Medical Device	LOT	Codice del lotto (EXXX) Batch code (EXXX)
	Consultare le istruzioni per l'uso Consult Instructions for Use	REF	Numero di catalogo Catalogue number
	Mantenere asciutto Keep dry	NON STERILE	Non sterile Non-sterile
	Limiti di temperatura Temperature limitation		Fabbricante Manufacturer
	Utilizzare entro (anno/mese) Use By (year/month)		Non riutilizzare Do not reuse
	Fragile, maneggiare con cura Fragile, handle with care		Tenere lontano dal calore Keep away from heat

CONTENTS **Cod. VR82005 (30 test)**

Card (cassette) device	30 items
N.1 Vial with Sample Diluent	5 mL
Instruction for use	1 item

CE IVD