SPECTRUM

The Creative Approach To Bioscience

HAV IgM Rapid Test-Cassette

(Serum / Plasma)

REF: 1192 001 30 test

SYMBOLS IN PRODUCT LABELLING			
EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

INTENDED USE

The Spectrum HAV IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgM antibodies 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 Spectrum HAV IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

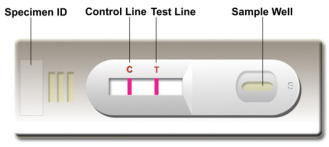
HAV is a positive-sense RNA virus, a unique member of picornaviridae1. Its transmission depends primarily on serial transmission from person to person by the fecal-oral route. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate is high among male homosexuals as result of oral-anal contact.

The presence of specific anti-HAV IgM in blood samples suggests acute or recent HAV infection4-6. 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 Spectrum HAV IgM Rapid Test is to be used to detect IgM anti-HAV in less than 15 minutes by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

TEST PRINCIPLE

The Spectrum 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 line, indicating a HAV IgM positive test result. Absence of the T line suggests a negative result.

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

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing::
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample Diluent (1 vial, 5 mL)
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. 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 the results after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. 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. Do not expose the kit over 30°C. Do not freeze the kit. The negative and positive controls should be store at 2-8°C or the temperature indicated. 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.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
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 veinpuncture.
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°C-8°C if not tested immediately.

Store specimens at 2°C-8°C for 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.

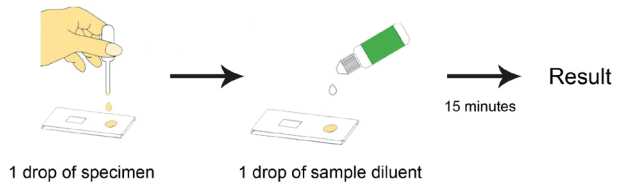
ASSAY PROCEDURE

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 the specimen's ID number.

Step 4: Fill the plastic 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.



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

1. ***Internal Control:*** This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. ***External Control:*** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kits fall outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. ***NEGATIVE RESULT:*** If only the C line 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 the C and the T lines are developed, the test indicates 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 line is developed, the assay is invalid regardless of color development on the T line 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 Spectrum HAV IgM Rapid Test and by a commercial EIA test. Comparison of the results for all subjects is shown in the following table:

	Spectrum HAV IgM Rapid Test		
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%

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of anti-HAV IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Spectrum HAV IgM Rapid Test is limited to the qualitative detection of anti-HAV IgM in human serum or plasma. The intensity of the test line 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 titers 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

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