ACCUCARE®

ONE STEP HEPATITIS A VIRUS (HAV) IgM AB RAPID TEST
(Whole Blood/Serum/Plasma)

One step rapid Card Test for qualitative detection of IgM antibodies to Hepatitis A Virus (HAV) in human Whole Blood/Serum/Plasma

Store at 2-30°C. DO NOT FREEZE.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	HAVC 10
25 Tests	HAVC 25

CLINICAL SIGNIFICANCE

HAV is a positive RNA virus, a unique member of picornavirdae1. 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 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.

PRINCIPLE

The ACCUCARE® ONE STEP HEPATITIS A VIRUS (HAV) 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 colloid gold (IgM conjugates) and, 2) a nitrocellulose membrane strip containing a test band and a control band. The Test band is pre-coated with recombinant HAV antigen, and the C band is pre-coated with goat anti-mouse IgG 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 Test band, indicating a HAV IgM positive test result. Absence of the Test 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.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable Sampling device (25 µl)
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

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 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.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP HEPATITIS A VIRUS (HAV) RAPID TEST can be performed using either Whole Blood or serum or plasma.
2. If you want to use Serum or Plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. 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.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

ISO 13485:2016

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PROCEDURE

1. Allow test device, Assay buffer and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Add 8 drops of buffer into the specimen tube.
3. Add 2 µl Whole Blood/Serum/Plasma into the specimen tube and mix it properly.
4. Remove the test device from the aluminum foil pouch and use it as soon as possible.
5. Place the test device on a clean and flat surface. Reverse the specimen tube and carefully dispense 3 drops (appx. 100 µl) specimen in the sample well "S" by squeezing the specimen tube.
6. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS

1. POSITIVE

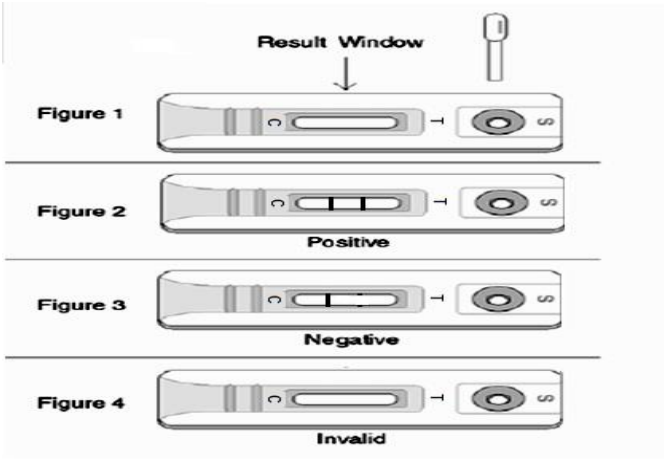
In addition to the coloured line in the control region a clearly distinguishable pink purple coloured line also appears in the test region 'T' (Test line) indicating a positive result.

2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for HAV infection.

3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP HEPATITIS A VIRUS (HAV) RAPID TEST has been evaluated with positive and negative samples and data are as below:

EIA	POSITIVE	NEGATIVE	TOTAL
POSITIVE	87	9	96
NEGATIVE	5	205	210
TOTAL	92	214	306

Relative Sensitivity: 90.6%, Relative Specificity: 97.6%, Overall Agreement: 95.4%.

BIBLIOGRAPHY

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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.
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GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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