Accu-Screen HAV IgG/IgM Rapid Test Device Package Insert

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Hepatitis A virus in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HAV IgG/IgM Rapid Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Hepatitis A virus in human serum or plasma.

SUMMARY

HAV is a positive RNA virus,a unique member of picornaviridae.Its transmission depend 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 anti-HAV IgG is produced in the early stage of infection,its titer in serum or plasma has been quite high at the onset of serum and reach the peak after 2-3 months.The IgG antibody is a protective antibody and can be maintained for a long time.The emergence of anti-HAV IgG can't make a HAV diagnosis unless anti-HAV IgM exist at the same time.The presence of anti-HAV IgG,but no anti-HAV IgM is a marker of infected HAV and acquired immunity.The presence of specific anti-HAV IgM in blood samples suggests acute or recent HAV infection.The IgM antibody rapid 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.
The HAV IgG/IgM Rapid Test Device is to be used to detect IgG/IgM anti-HAV in less than 20 minutes by untrained or minimally skilled personnel,without cumbersome laboratory equipment.

PRINCIPLE

The HAV IgG/IgM Rapid Test Device is a qualitative membrane-based immunoassay for the detection of HAV antibodies in serum or plasma.This test consists of two components,an IgG component and an Igm component In the IgG component,anti-human IgG is coated in IgG test line region.During testing,the specimen reacts with anti-HAV antibody particles in the test Device.The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to HAV,a colored line will appear in IgG test line region.
In the IgM component,anti-human IgM is coated in IgM test line region.During testing.The specimen reacts with anti-human IgM HAV IgM antibodies,if present in the specimen, reacts with the anti-human IgM and the anti-HAV antibody particles in the test Device,and this complex is captured by the anti-human IgM,forming a colored line in IgM test line region therefore if the specimen contains HAV IgG antibodies,a colored line will appear in log test line region.If the specimen contains HAV IgM antibodies,a colored line will appear in IgM test line region. If the specimen does not contain HAV antibodies,no colored line will appear in either of the test line regions, indicating a negative result.To sever as a procedural control,a colored line will always appear in the control line region indicating that membrane wicking has occurred.

REAGENTS

The test Device contains anti-HAV antibody particles and anti-human IgG,anti-human IgM coated on the membrane.

PRECAUTIONS

1. Please read all the information in this package insert before performing the test.
2. For professional in vitro diagnostic use only. Do not use after the expiration date.
3. The test should remain in the sealed pouch until ready to use.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
5. The used test,including test Device,dropper,buffer and so on,should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30℃).The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HAV IgG/IgM Rapid Test Device can be performed using serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis.Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection.Do not leave the specimens at room temperature for prolonged specimens may be stored at 2-8℃ for up to 3 days.For long term storage,should be kept below -20℃.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided Droppers

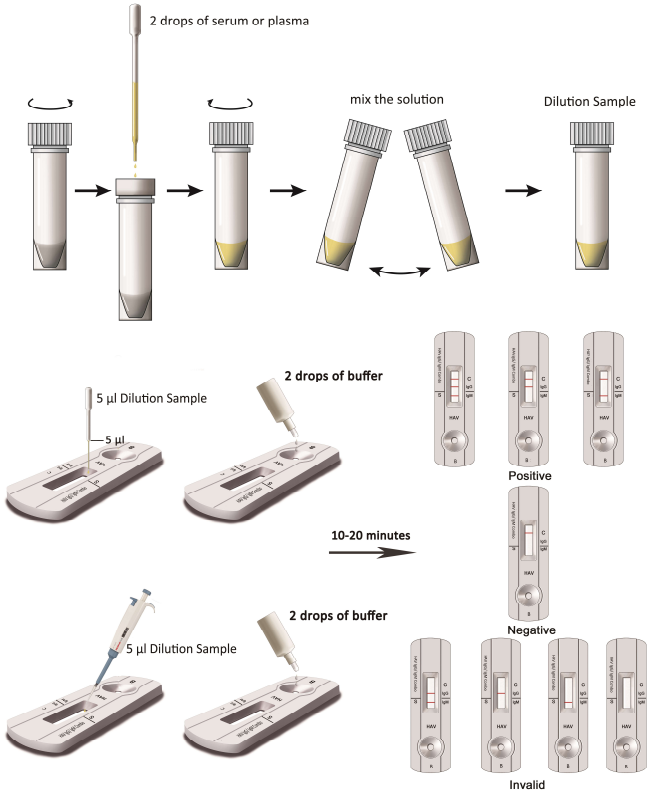
- Test devices
- 5μl Droppers
- HAV buffer
- Sample dilution tube
- 25μl Droppers
- Package Insert

Materials Required But Not Provided

- Timer
- Specimen collection containers
- Centrifuge(for plasma only)

DIRECTIONS FOR USE

1. Sample dilution:**Add 2 drops of serum or plasma (approx.50μl)** into the sample dilution tube first,then mix the solution plenty.
2. Remove the test device from sealed pouch and used it within one hour.Best results will be obtained if the assay is performed immediately after opening foil pouch.
3. Hold the dropper vertically,**draw the sample dilution up to the Fill Line as shown in illustration below (approximately 5μl).**Then **transfer the sample dilution to the sample port(S)** which part have been marked.Or using micropipette add 5ul dilution sample into the sample port (S) which part have been marked.
4. **Add 2 drops of buffer (approx.80μl)** into the **dilution well (B)** of the test device,start the time.
5. **Read the result at 10 minutes;Do not interpret after 20 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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 virus specific-IgG and is indicative of primary 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 virus 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,a 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 t procedure and repeat the procedure with a new test Device.If the problem persists discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region is an internal valid procedural control,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.

LIMITATIONS

1. The HAV IgG/IgM Rapid Test Device is for in vitro diagnostic use only.The test should be used for the detection of HAV IgG/IgM antibodies in serum plasma specimens only.Neither the quantitative value nor the rate of increase in HAV antibody concentration can be determined by this qualitative test.
2. The HAV IgG/IgM Rapid Test Device will only indicate the presence of HAV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HAV.
3. The HAV IgG/IgM Rapid Test Device 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.
4. A negative result for an individual subject indicates absence of detectable anti-HAV IgG and anti-HAV IgM.However,a negative test result does not preclude the possibility of exposure to or infection with HAV.
5. A negative result can occur if the quantity of the anti-HAV IgG and 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 collected
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

The HAV IgG/IgM Rapid Test Device has been compared with a leading commercial HAV EIA test. The correlation between these two systems is over 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HAV IgG/IgM Rapid Test Device was compared with a leading commercial HAV ELISA test. The results show that the overall relative sensitivity for the primary and secondary infection of the HAV IgG/IgM Rapid Test Device is 95.6%,and the relative specificity is >99.9%,and the relative accuracy is 99.1%.

HAV Primary Infection for IgG/IgM test results

Method			ELISA		
HAV IgG/IgM Rapid Test Device	Results		Positive		Negative
			IgG	IgM	
	Positive	IgM	25	0	0
		IgG	3	0	0
	Negative		0	0	0
Relative Sensitivity			89 3 %	/	/

HAV Secondary Infection for IgG/IgM test results

Method			ELISA		
HAV IgG/IgM Rapid Test Device	Results		Positive		Negative
			IgG	IgM	
	Positive	IgM	36	0	0
		IgG	4	40	0
	Negative		0	0	0
Relative Sensitivity			90.0 %	＞99.9%	/

Non-HAV Infection for IgG/IgM test results

Method			ELISA		
HAV IgG/IgM Rapid Test Device	Results		Positive		Negative
			IgG	IgM	
	Positive	IgM	0	0	0
		IgG	0	0	0
	Negative		0	0	0
Relative Sensitivity			/	/	› 99.9%

Relative Sensitivity:(25+ 40)/(28+40)=95.6%(95%CI:87.6%-99.1%);
Relative Specificity:248/248＞99.9%(95%CI:98.8%-100.0%);
Accuracy: (25+40+248) /(28+40+248)=99.1%(95%CI:97.2%-99.8%);
95%Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens:negative,an IgG positive,an IgM positive and an IgG/IgM dual positive.The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens:a negative,an IgG positive,an IgM positive and an IgG/IgM dual positive.Three different lots of the HAV IgG/IgM Rapid Test Device have been tested using these specimens.The specimens were correctly identified >99 % of the time.

Cross-reactivity

The HAV IgG/IgM Rapid Test Device has been tested by HAMA,RF HBsAg, HBsAb,HBeAg,HBeAb,HBcAb,Syphilis,HIV,HCV,H.Pylori,MONO,CMV Rubella and TOXO positive specimens.The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HAV negative and positive specimens.

Acetaminophen: 20 mg/Dl	Ascorbic Acid: 2g/dL	Creatin:200 mg/dL
Gentisic Acid: 20 mg/dL	Hemoglobin:1000mg/dL	Acid: 20 mg/dL
Caffeine: 20 mg/dL	Albumin:2 g/dL	Oxalic Acid: 60mg/dl
Bilirubin:1g/dL		

None of the substances at the concentration tested interfered in the assay

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number		Contains sufficient for <n> tests

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