Dia Sure

HAV IgM -W23

HAV IgM Rapid Test Device

(Whole Blood/Serum/Plasma)

INTENDED USE

The HAV IgM Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic kit for the qualitative, presumptive detection of specific anti-HAV IgM in human whole blood, serum or plasma specimens. This kit is intended to be used as an aid in the diagnosis of HAV infection. The results obtained should be confirmed with alternative testing method(s).

INTRODUCTION

Hepatitis A is an acute infectious disease of the liver caused by hepatitis A virus[1] (HAV). About 40% of all acute hepatitis is caused by HAV. Hepatitis A occurs endemically in all parts of the world. Globally, around 1.5 million symptomatic cases occur each year with likely tens of millions of infections in all[2]. Unlike hepatitis B and C, hepatitis A infection does not cause chronic liver disease and is rarely fatal, but it can cause debilitating symptoms and fulminant hepatitis (acute liver failure), which is associated with high mortality. HAV is one of the most frequent causes of foodborne infection[3]. HAV can be transmitted by oral-fecal route and rarely by blood (parenteral route). Insufficiently cooked shellfish are relatively common sources[4].

Cases of hepatitis A are not clinically distinguishable from other types of acute viral hepatitis. Diagnostic methods include detection of the virus or antigen, RT-PCR to detect the HAV RNA, detection of alanine transferase (ALT) during acute stage of infection[5]. Additionally, serological diagnosis of hepatitis A is made by the detection of specific IgG and IgM in the blood[6]. Serum IgG is used in determining the immune status of the individual before the prescription of immunoglobulin for foreign travel. The detection of specific IgM is diagnostic of recent infection. Anti-HAV IgM is detectable from 1~2 weeks after the initial infection and persists for up to 14 weeks. Anti-HAV IgM is only present in the blood following an acute hepatitis A infection.

The HAV IgM Rapid Test Device is a simple lateral flow immunoassay for the direct detection and IgM antibodies to HAV. It will provide a presumptive diagnosis of acute infection of hepatitis A.

PRINCIPLE

The HAV IgM Rapid Test Device (Whole Blood/Serum/Plasma) detects IgM antibodies to HAV through visual interpretation of color development. HAV antigen, anti-human IgM antibodies are used to detect the specific IgM in human, serum or plasma samples. When a sample is added to the sample well on the test panel, anti-HAV IgM, if present, will bind to the anti-human IgM antibodies conjugated to colored particles on the sample pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by HAV antigen immobilized at the detection zone. Excess colored particle are captured at the internal control zone.

The presence of a red band in the test region (T) indicates a positive result for the particular IgM antibody, while its absence indicates a negative result. A red band at the control region (C) serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- Individually packed test devices
- Package insert
- Disposable droppers
- HAV Assay Buffer

Materials Required but Not provided

- Specimen collection containers
- Centrifuge
- Timer

PRECAUTIONS

- Do not use the kit after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **DO NOT FREEZE.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION

- The HAV IgM Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. For serum/plasma specimens:

   Using the provided disposable dropper, draw the specimen up to the Fill Line, and transfer 1 drop of serum/plasma (approximately 5 uL), to the sample well (S), and then add 3 drops of buffer.

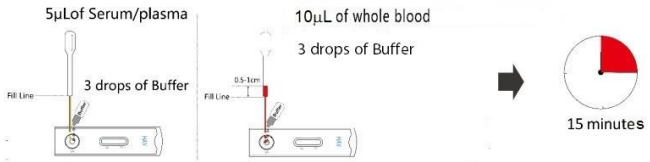
   For whole blood specimens:

   Using the provided disposable dropper, draw the specimen 0.5-1cm above the Fill Line, and transfer the whole blood (approximately 10 µL) to the sample well (S) of the test device, then add 3 drops of buffer

   Note: Specimen application can also be performed with pipette.

   Note:*Avoid trapping air bubbles in the sample well (S), and do not add any solution to the result area.*

3. As the test begins to work, sample will migrate across the membrane.
4. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 OF THE TEST

1. The HAV IgM Rapid Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of specific anti-HAV IgM.
2. The HAV IgM Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of anti-HAV IgM in the specimen, and should not be used as the sole criteria for the diagnosis of hepatitis A viral infection.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of anti-HAV IgM in blood, as anti-HAV IgM may be present below the minimum detection level of the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Table: HAV IgM Rapid Test vs. EIA

Relative Sensitivity:
99.5% (97.5%-99.9%)*
Relative Specificity:
99.3% (95.9%-99.9%)*
Overall Agreement:
99.4% (98.0%-99.8%)*

***95% Confidence Interval**

		EIA +	EIA -	Total
HAV IgM Rapid Test	+	220	1	221
	-	1	134	135
		221	135	356

LITERATURE REFERENCES

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2. Matheny, SC; Kingery, JE (1 December 2012). "Hepatitis A.". Am Fam Physician. 86 (11): 1027–34; quiz 1010–2. PMID 23198670.
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4. Bellou, M.; Kokkinos, P.; Vantarakis, A. (March 2013). "Shellfish-borne viral outbreaks: a systematic review". Food Environ Virol. 5 (1): 13–23. doi:10.1007/s12560-012-9097-6. PMID 23412719.
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GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
µ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

Dia Sure

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