IVD

Asan Easy Test® HAV IgG/IgM

ASAN

Diagnostic Kit for the differential detection of IgG and IgM against HAV in human serum and plasma

Immunochromatography

EXPLANATION OF THE TEST

Hepatitis A is an acute infectious disease of the liver caused by hepatitis A virus (HAV). It usually spread the fecal-oral route; transmitted person-to-person by ingestion of contaminated food or water or through direct contact with an infectious person. The time between infection and the appearance of the symptoms (the incubation period) is between two and six weeks and the average incubation period is 28 days. Asan Easy Test® HAV IgG/IgM is immuno-chromatographic kit for the rapid, qualitative and differential determination of specific antibodies (IgG & IgM) against HAV in human serum and plasma.

MATERIALS PROVIDED

Asan Easy Test® HAV IgG/IgM contains following items to perform the assay.

1. Test device in aluminium pouch with a dessicant.
2. Assay solution
3. Capillary pipette
4. Instructions manual for use

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1. Specimen Collection and Storage

[Serum] Collect the whole blood into the collection tube(NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

[Plasma] Collect the whole blood into the collection tube(containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8℃ or -20℃ for longer period.

2. Precaution

1) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

2) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.

3) Use separately disposable capillay pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

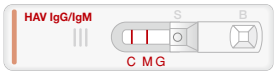
TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. [Capillary pipette use] Add 5㎕ of serum or plasma specimen drawn to black line into the sample well(S) of the test device.
   [Micropipette use] Add 5㎕ of serum or plasma specimen into the sample well(S) of the test device.
3. Dispense 4 drop (about 90~120㎕) of assay solution into the buffer dropping well(B) of the test device.
4. Interpret the test results within 15~20 minutes. Do not read the result after 20 minutes.

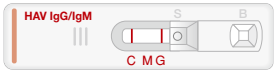
INTERPRETATION OF THE TEST

A. NEGATIVE RESULTS:
The presence of only one purple color band ("C" band) within the result window indicates a negative result.

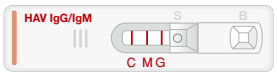
B. POSITIVE RESULTS:
- Positive for IgM: two bands are appeared in the test IgM line (IgM) and control line (C).



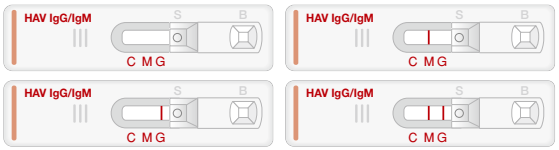
- Positive for IgG: two bands are appeared in the test IgG line (IgG) and control line (C).



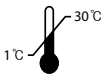
- Positive for IgM and IgG: Three bands are appeared in the IgG line and IgM line, control line, it shall be suggested to do sample dilution and re-testing process. The re-test result is true. If the re-test result still showed three bands, the result is positive for IgG and IgM.



C. INVALID RESULTS:
If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



STORAGE & EXPIRATION



1. Asan Easy Test® HAV IgG/IgM should be stored at 1 to 30℃ (33.8~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

The Asan Easy Test® HAV IgG/IgM have compared with other commercial kit. The results are summarized in the following tables.

n= 536		Commercial Kit		Total
		Positive	Negative	
Asan Easy Test® HAV IgG	Positive	211	20	231
	Negative	37	268	305
Total		248	288	536

*HAV IgG sensitivity: 85.1% (211/248)
*HAV IgG specificity: 93.1% (268/288)

n= 530		Commercial Kit		Total
		Positive	Negative	
Asan Easy Test® HAV IgM	Positive	184	6	190
	Negative	0	340	340
Total		184	346	530

*HAV IgM sensitivity: 100% (184/184)
*HAV IgM specificity: 98.3% (340/346)

LIMITATIONS OF THE TEST

Asan Easy Test® HAV IgG/IgM is designed for primary screening test of antibodies against HAV. Although this can provide fast and easy way to get a result, the testing do not completely exclude the possibility of false and positive or negative result caused by various factors. So, refer to the result of the kit, please make a final decision with clinical manifestation, other test results and doctor's view, collectively.

ASAN
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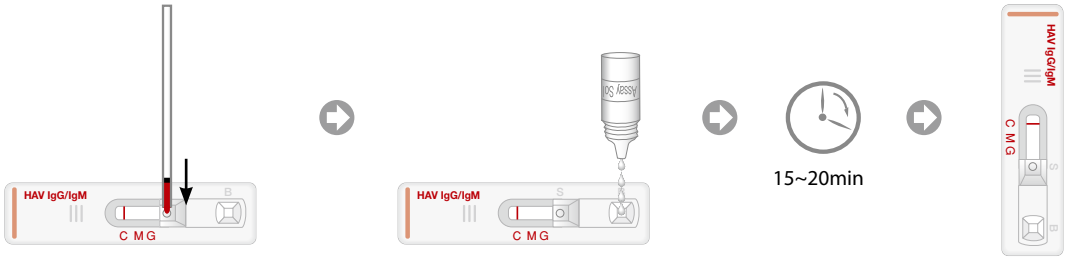

Add 5㎕ of serum/plasma

4drops of assay solution

Reading