ACCU-TELL®
HAV IgG/IgM Cassette (Serum/Plasma)

For professional in vitro diagnostic Use only

For Serum/Plasma Samples

This package insert is applied to the below products:

Catalog No.	**Product Name**
ABT-IDT-B226	HAV IgG/IgM Cassette (Serum/Plasma)

Intended Use

ACCU-TELL®HAV IgG/IgM Cassette (Serum/Plasma) is used for the qualitative determination of antibodies (IgG and IgM) to Hepatitis A virus in human serum/plasma as an aid in the diagnosis of Hepatitis A viral infection.

Principle

IgG to HAV:

This kit takes use of colloidal gold immune chromatography principle, coated IgG monoclonal antibody and IgG monoclonal antibody on the nitrocellulose membrane for test line, the control line is coated with anti-rabbit HAV antibody, fix HAV antigen on colloidal gold pad. If the sample contains HAV-IgG antibody, can combine with colloidal gold marked HAV antigen, anti-human IgG monoclonal antibody to form sandwich complex, form two red reaction lines that naked-eye can see in the test area, otherwise, only one red reaction line appears in control line(C).

IgM to HAV:

This kit takes use of colloidal gold immune chromatography principle, coated IgM monoclonal antibody and IgM monoclonal antibody on the nitrocellulose membrane for test line, the control line is coated with anti-rabbit HAV antibody, fix HAV antigen on colloidal gold pad. If the sample contains HAV-IgM antibody, can combine with colloidal gold marked HAV antigen, anti-human IgM monoclonal antibody to form sandwich complex, form two red reaction lines that naked-eye can see in the test area, otherwise, only one red reaction line appears in control line(C).

Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board

Materials

Test Cassettes
Sample Loops
Buffer
Package insert

Storage and Expiry

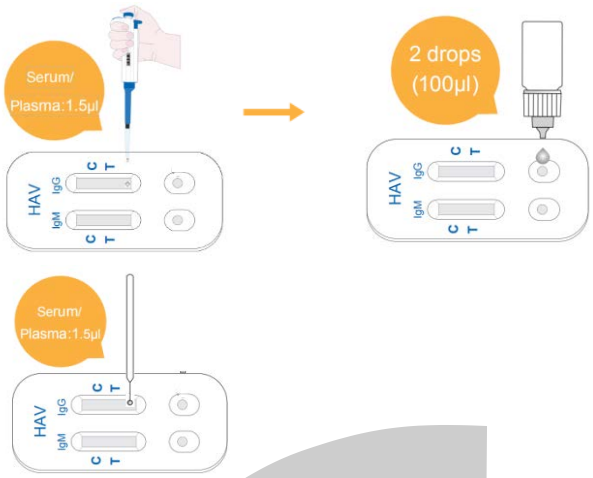
Store as packaged in the sealed pouch at room temperature (2-30°C), avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. Collect venous blood into container according to the standard method. Separate the serum or plasma for testing.
2. If the sample cannot be tested on the day of collection, store it in a refrigerator or freezer.
3. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Do not freeze and thaw the sample repeatedly.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃ -30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened.



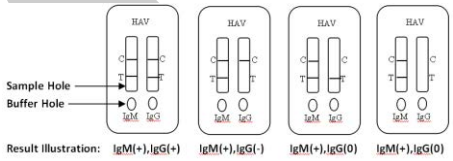
1. Take off the foil bag, put the cassette onto the desk with the sample window of the cassette up.
2. Drop **1.5μl** serum/plasma vertically onto the membrane in the Sample well. The tip of micro pipette or sample loop is required to touch the membrane gently for an accurate operation when the sample is added.
3. Add about 2 drops of (80μl-100μl) sample buffer into the Buffer well of cassette. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Limitation

1. This reagent is designed for the qualitative screening test. Concentration of HAV-IgM and HAV-IgG cannot be determined by this qualitative test.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Sensitivity can be lowered by the competition between high titers of HAV-IgG and HAV-IgM antibody to the antigen binding site. Results of this kind of samples should be analyzed cautiously.
4. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of HAV does not exist or the concentration is below detection limit. If HAV infection is still suspected, the sample should be collected 1-2 weeks later and carry the parallel detection with the first sample.
5. Results of patients who used to receive immunosuppressive therapy or with immune function damage may have a low

serology reference value.

6. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
7. Abnormal results may occur according to operator error or drug use. If HAV infection is still suspected, the sample should be collected later and carry the parallel detection with the first sample.

Performance Characteristics

1. Negative specificity:

The results should all be negative when detecting 10 kits of HAV-IgM/IgG negative quality control samples

Positive specificity:

The results should all be positive when detecting 10 kits of HAV-IgM/IgG positive quality control samples.(Including strong, medium and weak positive samples)

Limit of detection:

The results should all be positive when detecting the internal quality control samples or the diluted national HAV-IgM/IgG positive quality control samples with the diluents rate at 1:8.

Repeatability:

The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

A clinical evaluation was conducted on 1040 samples comparing the results obtained using ACCU-TELL®HAV IgG/IgM Cassette (Serum/Plasma) and other commercially available HAV tests. The results demonstrated a 98.48% positive agreement, 99.23% negative agreement, and a 99.04% overall agreement of ACCU-TELL®HAV IgG/IgM Cassette (Serum/Plasma) for **IgM** when compared to the other HAV- IgM test.

For IgM	Reference Product		Total
	Positive	Negative	
Positive	259	6	265
Negative	4	771	775
Total	263	777	1040

The results demonstrated a 98.10% positive agreement, 99.10% negative agreement, and a 98.85% overall agreement of ACCU-TELL®HAV IgG/IgM Cassette (Serum/Plasma) for **IgG** when compared to the other HAV- IgG test.

For IgG	Reference Product		Total
	Positive	Negative	
Positive	258	7	265
Negative	5	770	775
Total	263	777	1040

3. Analytical sensitivity:

1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result. The reagent is not affected by the rheumatoid factor, antinuclear antibodies.

The addition of HEV、HBV、HCV、TP and HIV showed no cross-reactivity.

Precaution

1. The serum must be fresh for test, avoiding freezing repeatedly.
2. The test result is invalid over 20 minutes.
3. Do not use after the expiration.
4. If the patient, for the first time, is infected in less than 5 days, with no detected specific antibody, the result will be negative when testing.
5. The parent antibody can be detected from the samples of a yearling baby, therefore, it is not appropriate to take this test to evaluate the baby's history of infection and immunization.
6. Do not use other kinds of quality control sample to test the reag ent. Components of different batches cannot be exchanged for use to avoid erroneous results.

BIBLIOGRAPHY

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2. Koff RS. Hepatitis A. Lancet 1998;341:1643–49.

3. Martin A ,Lemon S M. Hepatitis A virus: from discovery to vaccines[J]. Hepat. 2006,43(2 Suppl 1): S164-172.doi: 10.1002/hep.21052.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

EC REP

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