Camp Medica D. - No. 29 Stanei Street, S4, Bucharest, Romania
phone: +4021-450 58 90
e-mail: export@campmedica.ro
http : //www.campmedica.ro

"See Now" Anti-HAV IgG/IgM Cassette Test

Whole blood/Serum/Plasma

For in vitro Diagnosis Use

Product Code: SN 5.9

INTENDED USE

The*"See Now"* HAV IgG/IgM Test is used for the qualitative determination of IgG-class and IgM class antibodies to hepatitis A virus (HAV) in human serum, plasma or whole blood. This test is intended for the diagnosis of acute hepatitis A and management of patients related to infection with hepatitis A virus.

PRINCIPLE

The*"See Now"* HAV test utilizes the principle of Immuno- chromatography.

Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. As the test sample flows through the membrane within the test device, the colored–HAV specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of HAV, if is present in the sample.

MATERIALS SUPPLIED

- Test Device, Test Instruction, Sample bottle with 2 mL of sample buffer, Capillary pipette 2uL

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

STORAGE AND STABILITY

- The*"See Now"* HAV IgG/IgM Test should be stored at room temperature (4-30ºC) in the sealed pouch or desiccated container.
- Do not use it after the expiration date.

PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- The test device should remain in the sealed pouch until use.
- There should be no smoking or eating where antigen containing materials are being handled. Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.
- Decontaminate and dispose of specimens and all potentially contaminated materials if they contain infectious agent.
- As with all diagnostic tests, a definitive clinical diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test， but should only be made by the physician after all clinical and laboratory have been evaluated.

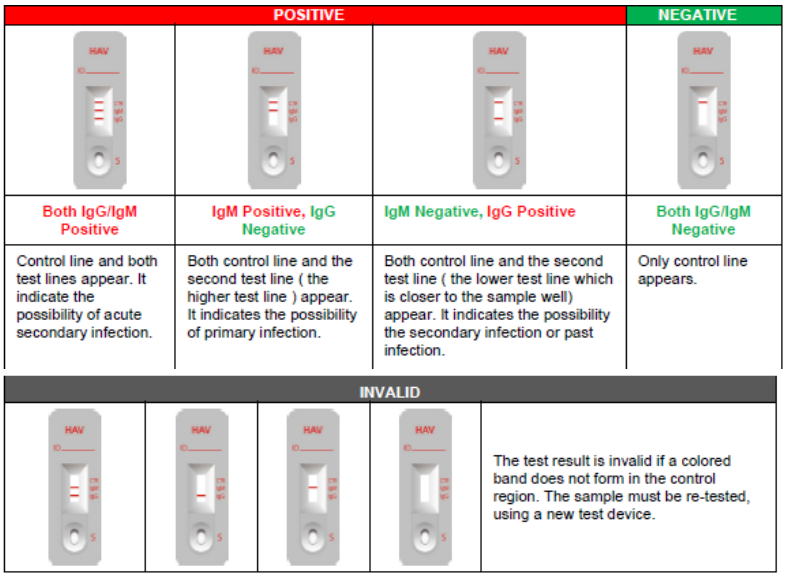
SPECIMEN COLLECTIONAND STORAGE

- For serum samples collect blood in a tube without anticoagulant and allow it to clot.
- For whole blood or plasma samples collect blood in a tube containing anticoagulant (EDTA, citrate or heparin, respectively).
- 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 the specimens have been collected. Do not leave the specimens at room temperature.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface.
- Unscrew the white cap/white tip assembly from the sample bottle.
- Holding the capillary pipette vertically, add 2μL of specimen without air bubbles into the buffer bottle.
- Return the white cap/white tip assembly to the bottle neck and mix the sample with the buffer completely by gently shaking the bottle a few times.
- Remove the white cap and, holding the bottle in a vertical position over the sample well of the test card, add 2 drops(80-100 uL) of test sample intro the sample well "S".
- Read the results in 20 minutes. Ensure that the background of the test area is white before interpreting the result. **Do not interpret result after 30 minutes.**

INTERPRETATION OF RESULTS



LIMITATION OF PROCEDURE

- Anti-HAV IgG/IgM test device is used for the detection of antibodies IgG/IgM of HAV in human serum, plasma, whole blood. Based on a single reactive test result, a sample should not be considered HAV positive. Further testing, including confirmatory testing, should be performed before a specimen is considered positive for HAV Ab. A non-reactive test result does not exclude the possibility of exposure to hepatitis A virus. Specimens containing precipitate may give inconsistent test results.

QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance and reactive reagents.

Good laboratory practices the use of external control specimens to ensure proper kit performance. Each day of testing， two level of commercial controls should be tested on the *"See Now"* Anti-HAV IgG/IgM Test cassette.

PERFORMANCE CHARACTERISTICS

Sensitivity:

HAV IgG - 96,2% HAV IgM - 96,4%

Specificity:

HAV IgG - 98,6% HAV IgM - 99,3%