HAV IgG/IgM Rapid Test

HAV IgG/IgM Rapid Test
In vitro Diagnostics

Cat No. S053-01

INTENDED USE

Sensit Hepatitis A Virus IgM Antibody (HAV IgM) test detects the presence of IgM antibodies specific to the hepatitis A virus (HAV) in the blood. A positive result indicates a recent or acute HAV infection, as IgM antibodies are produced early in the immune response and typically remain detectable for about two months after infection.

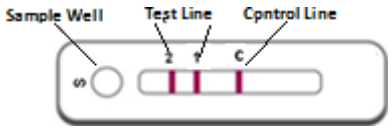
SUMMARY & TEST DESCRIPTION

Hepatitis A is a highly contagious liver infection caused by the hepatitis A virus (HAV). When the body is infected with HAV, it defends itself by producing two types of antibodies in sequence: first, IgM, which appears 2 to 4 weeks after infection and is present for 2 to 6 months, then IgG, which appears a few weeks after IgM and is present for the rest of the person's life. IgG provides long-term immunity (protection), whether due to a prior infection by the virus or due to vaccination. Testing for HAV antibodies Total (IgG plus IgM) is especially useful in confirming an individual's long-term immunity and the appropriateness of vaccination. The specific anti-HAV IgM test is used mainly to find the cause of an acute or very recent liver disease.

The HAV Total Antibody test measures both IgM and IgG antibodies against HAV. A positive result suggests past exposure to the virus or vaccination, indicating immunity. However, this test does not differentiate between current or past infections. For accurate diagnosis, especially in the early stages of infection, it's essential to use the HAV IgM test. If the HAV IgM test is negative but there's a strong suspicion of acute hepatitis A, retesting after a few weeks may be recommended, as IgM antibodies can take time to become detectable. In summary, while both tests detect antibodies to HAV, the HAV IgM test is specifically used to diagnose acute or recent infections, whereas the HAV Total Antibody test indicates past exposure or immunity.

TEST PRINCIPLE

Sensit HAV IgG/IgM test works on chromatographic immunoassay. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T2: Anti human IgM, T1: Anti human IgG and C: Goat Anti Mouse.



Test specimen, with adequate amount of buffer, migrates along the conjugate pad and further across the coated membrane by capillary action. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized Anti Human IgG/IgM

(on test lines) producing a visible lines on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zones and no test line is formed. If the respective antibody is not present in the sample, no reaction occurs and no test line is formed. The sample then migrates further along the strip until it reaches the control band, where excess Detection-CGC gets bound and produces a second visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended

REAGENTS & MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
   a. One test device
   b. Desiccant
2. Assay Diluent - In dropper bottle
3. Instruction Leaflet

PRECAUTIONS & WARNING

1. Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
2. Do not use with specimen containing precipitates
3. Use within 10 minutes after opening pouch.
4. Do not reuse test kit.
5. Use only the buffer supplied along with the kit.
6. Do not mix components from different kits.
7. Use only for in-vitro diagnostic purpose.

INTERPRETATION OF TEST RESULT

SAMPLE PREPARATION & STORAGE

- Blood: Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- Plasma: Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Centrifuge the blood to get plasma specimen as supernatant.
- Serum: Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5days, freezing is recommended. Store at -20ºC
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the foil pouch is brought to room temperature before opening.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. 2.Add 10 µl of Whole Blood/Serum to the Sample well "S"
3. 4.When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole
4. Wait for10- 15 minutes and interpret results. The result is considered invalid
5. after 15 minutes. All results where control band does not appear are considered invalid.

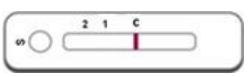
Aspirate sample till bubble point for 10 ul serum

HAV IgG & IgM Positive

HAV IgM Positive

HAV IgG Positive

HAV Negative



Invalid

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