ACCUCARE™

HEPATITIS A VIRUS TEST DEVICE

(Serum, Plasma or whole blood)

A rapid and sensitive one-step test for the qualitative detection of IgG/IgM antibodies to Hepatitis A in human serum, plasma, or whole blood.

Only for *In vitro diagnostic* use

ORDER INFORMATION

REF	Cont.
HAVC 10	10 Test
HAVC 25	25 Test

CLINICAL SIGNIFICANCE

HAV is a positive RNA virus, a unique member of picornavirdae1. Its transmission depends primarily on serial transmission from person to person by the fecal-oral route. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate is high among male homosexuals, as result of oral-anal contact.
The presence of specific anti-HAV IgG/IgM in blood samples suggests acute or recent HAV infection 4-6. The IgM antibody rapidly increases in titer over a period of 4-6 weeks post infection, and then declines to non-detectable levels within 3 to 6 months in most patients.

PRINCIPLE

The HAV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-human IgG/IgM antibody conjugated with colloid gold (IgG/IgM conjugates) and, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with recombinant HAV antigen, and the C band is pre-coated with goat anti-mouse IgG/IgM antibodies.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-HAV IgG/IgM if present in the specimen will bind to the IgG/IgM conjugates. The immunocomplex is then captured on the membrane by the pre-coated HAV antigen, forming a burgundy colored T band, indicating a HAV IgG/IgM positive test result. Absence of the T band suggests a negative result.
The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/IgM antibodies**/** IgG/IgM-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and product insert.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2 - 30°C and not in direct sunlight. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION & PREPARATION

- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

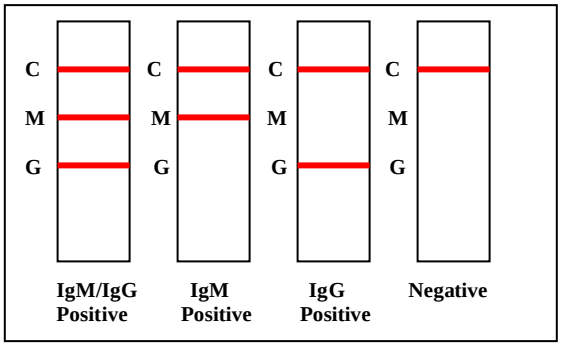
PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as infectious agents.
- The test should be discarded in a proper biohazard container after testing.
- Optimal assay performance requires strict adherence to the assay procedure described in this Instruction sheet and any deviations from the procedure may lead to aberrant results.

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature 15-30 ℃
1.Bring the pouch to room temperature before opening it
2. Add 8 drops of buffer to a specimen tube.
3. Add 2μL of serum/plasma/wholeblood into the specimen tube and mix completely.
4. Remove the test device from the sealed pouch and use it as soon as possible.
5.Place the test device on a clean and level surface
6.Reverse the specimen tube, and add 3 drops (about 100μL) of **test specimen** into the specimen well(S) by squeezing the specimen tube.
Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF THE RESULTS



Both IgG/IgM Positive: Control line and both test line appear on the membrane. It indicates the
possibility of acute secondary infection.
IgM Positive, IgG Negative: Both control line and the test line appear. It indicates the possibility
of primary infection.
IgG Positive, IgM Negative: Both control line and the test line appear. It indicates the possibility
the secondary infection or past infection.
Both IgG/IgM Negative: One colored line appears in the control region(C).No apparent colored
line appear in the test line region.

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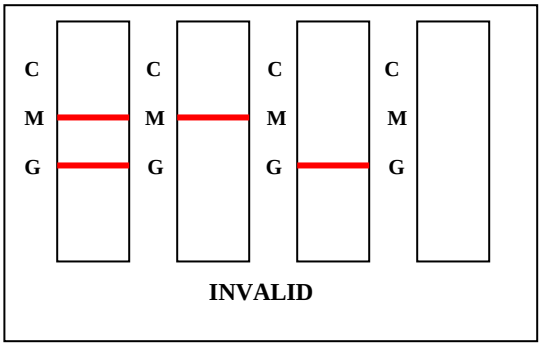

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural

LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-HAV IgG/IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HAV IgG/IgM Rapid Test is limited to the qualitative detection of anti-HAV IgG/IgM in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-HAV IgG/IgM. However, a negative test result does not preclude the possibility of exposure to or infection with HAV.
4. A negative result can occur if the quantity of the anti-HAV IgG/IgM present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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