The **OnSite HAV IgM Rapid Test** is a lateral flow chromatographic immunoassay for the qualitative detection of IgM antibody to Hepatitis A virus (HAV) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HAV. Any reactive specimen with the OnSite HAV IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

**SUMMARY AND EXPLANATION OF THE TEST**

HAV is a positive RNA virus, a unique member of picomavirus1. 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 2-3. The presence of specific anti-HAV 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 7.

The OnSite HAV IgM Rapid Test is to be used to detect IgM anti-HAV in less than 15 min by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

**TEST PRINCIPLE**

The OnSite HAV IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-human IgM antibody conjugated with colloidal gold (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 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 IgM if present in the specimen will bind to the 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 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 IgM antibodies/ 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.

**ASSAY PROCEDURE**

**Step 1:** Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

**Step 2:** When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

**Step 3:** Be sure to label the device with specimen’s ID number.

**Step 4:** Fill the pipette dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles. Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.

**Step 5:** Set up timer

**Step 6:** Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute. Don’t read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock or Timer

**WARNINGS AND PRECAUTIONS**

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

2. Do not open the sealed pouch, unless ready to conduct the assay.

3. Do not use expired devices.

4. Bring all reagents to room temperature (15°C-30°C) before use.
QUALITY CONTROL

Using individual OnSite HAV IgM Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit fall outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

**Negative Control**
Only the C band shows color development. The T band shows no color development.

**Positive Control**
Both C and T bands show color development.

The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.

**INTERPRETATION OF ASSAY RESULT**

1. **NEGATIVE RESULT**: If only the C band is developed, the test indicates that no detectable IgM anti-HAV is present in the specimen. The result is negative.

2. **POSITIVE RESULT**: If both C and T bands are developed, the test indicates for the presence of IgM anti-HAV in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID**: If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

**PERFORMANCE CHARACTERISTICS**

**Clinical Performance**

A total of 200 samples from susceptible subjects were tested by the OnSite HAV IgM Rapid Test and by a commercial EIA test. Comparison for all subjects is showed in the following table:

<table>
<thead>
<tr>
<th></th>
<th>OnSite HAV IgM Rapid Test</th>
<th>EIA Positive</th>
<th>EIA Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>21</td>
<td>1</td>
<td>178</td>
<td>179</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td></td>
<td>178</td>
<td>178</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>179</td>
<td>178</td>
<td>200</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 95.5%, Relative Specificity: 100%, Overall Agreement: 99.5%

**LIMITATIONS OF TEST**

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-HAV IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.