CE
IVD

# HEV IgM Rapid Test Kit (Colloidal Gold)

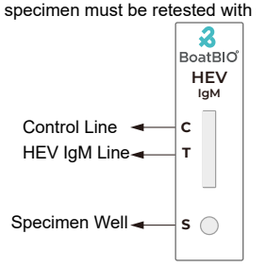
## PRODUCT NAME
HEV IgM Rapid Test Kit (Colloidal Gold)

## SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

## INTENDED USE
The HEV IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis E virus (HEV) IgM in human serum or plasma. It is intended to be used as a screening test by professionals and provides a preliminary test result to aid in the diagnosis of infection with HEV.
Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of the health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

## INTRODUCTION AND CLINICAL SIGNIFICANCE
Hepatitis E, a major form of enterically transmitted hepatitis, is widespread in many developing countries but is currently considered an emerging threat to other parts of the world. HEV is a non-enveloped, positive-sense, single-stranded RNA virus is currently classified within the family Caliciviridae. It is mainly transmitted through fecal-oral route. At least four major genotypes of HEV have been recognized: genotypes 1 and 2 are restricted to humans while genotypes 3 and 4 can infect both humans and animals. Antibody responses peak at about one month after initial infection. Antiviral IgM is detected in >90% of patients and persists for 3 months. Anti-HEV IgM is also a well-established marker of recent infection• and is the most convenient one for diagnosis.
Reliable techniques for anti-HEV IgM detection such as immunofluorescence and immune electron microscopy (IEM) have been developed. However, these techniques require labor-intensive procedures that are not available to many laboratories. The HEV IgM Rapid Test is designed to detect anti-HEV IgM in human serum or plasma. It can be performed within 15 minutes by minimally skilled personnel without laboratory equipment.

## TEST PRINCIPLE
The HEV IgM Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: 1) a colored conjugate pad containing HEV antigens conjugated with colloidal gold (HEV conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with monoclonal anti-human IgM antibody, and the C line is pre-coated with a control line antibody.
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-HEV IgM if present in the specimen will bind to the HEV conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM forming a colored T line, indicating a HEV IgM positive test result and suggesting an acute infection.
Absence of the test line suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control line antibodies regardless of color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.




## REAGENTS AND MATERIALS SUPPLIED
1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. 10 µL Capillary tubes
3. Sample diluent (5 ml/bottle)
4. Instructions for Use

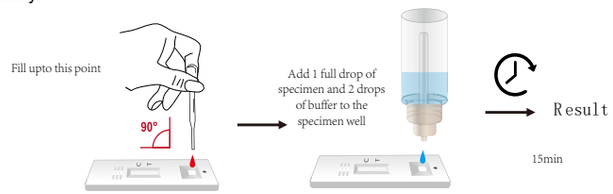
## ADDITIONAL MATERIALS REQUIRED
• Clock or timer
• Lancing device (for whole blood testing)

## STORAGE AND STABILITY
All reagents are ready to use as supplied. Store unused test cassettesunopened at 2-30°C. If tests are stored at 2-8°C, ensure that they arebrought to room temperature before opening. The test cassette is stableuntil the expiration date printed on the sealed foil pouch. Do not freeze testkits or expose them to temperatures over 30°C.

## WARNINGS AND PRECAUTIONS
•For professional in-vitro diagnostic use only.
•Carefully read through the test procedure prior to testing.
•Do not use the test after the expiration date indicated on the package.
•Do not use the test if the foil pouch is damaged.
•Do not reuse tests.
•Do not add samples to the reaction area (result area).
•In order to avoid contamination, do not touch the reaction area (resultarea).
•Do not substitute or mix components from different test kits.
•Do not use hemolysed specimens for testing.
•Do not eat, drink or smoke in the area where specimens and test kits arehandled.
•Wear protective clothing such as laboratory coats, disposable gloves andeye protection when specimens are being assayed. Wash handsthoroughly after performing the test.
•Handle all specimens as if they contain infectious agents. Observeestablished precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
•The test results should be read at 15 minutes after the specimen isapplied to the sample well of the test cassette. Reading the results aftermore than 20 minutes may give erroneous results.
•Do not perform the test in a room with strong air flow, i.e. an electric fanor strong air-conditioning.

## SPECIMEN COLLECTION
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
**Plasma/Serum**
Step 1: Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.
Step 2: To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.
Step 3: To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.
Test specimens as soon as possible after collecting. Store specimens at 20° C, if not tested immediately. The specimens can be stored at 20° C for up to 5 days. The specimens should be frozen at -20° C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

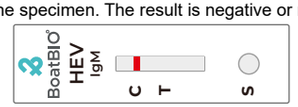
## ASSAY PROCEDURE
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.
Step 4: Fill the capillary tube with the specimen not to exceed the specimen line as indicated in the illustration below.
Holding the capillary tube vertically, dispense 10 µL of specimen into the sample well making sure that there are no air bubbles.
Then, immediately add 2 drops (about 70-100 µL) of sample diluent holding the bottle vertically.




Step 5: Set up the timer.
Step 6: Results can be read at 15 minutes. Positive results can be visible in as short as 1 minute. However, negative results must be confirmed at the end of 15 minutes only. **Any results interpreted outside of the 15-minute window should be considered Invalld and must be repeated. Discard used devices after Interpreting the result fol/owing local laws governing the disposal of devices.**

## QUALITY CONTROL
**Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen and sample diluent. If the C line does not develop, review the whole procedure and repeat test with a new device.
**External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
• A new operator uses the kit, prior to performing testing of specimens.
• A new lot of test kits is used.
• A new shipment of kits is used.
• The temperature during storage of the kit falls outside of 2-30° C.
• The temperature of the test area falls outside of 15-30° C.
• To verify a higher than expected frequency of positive or negative results.
• To investigate the cause of repeated invalid results.

## INTERPRETATION OF ASSAY RESULT
**Negative Control:** Only the Cline develops. the test indicates that no detectable IgM anti-HEV is present in the specimen. The result is negative or non-reactive.




**Positive Control:** both C and T lines develop, the test indicates the presence of anti-HEV IgM in the specimen. The result is positive or reactive.


*Samples with positive or reactive results should be confirmed with alternative testing method/s) and clinical findings before a diagnosis is made.*
**INVALID:** C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

## PERFORMANCE CHARACTERISTICS

**1. Clinical Performance For IgM Test**

A total of 1060 samples were collected from susceptible subjects and tested by the OnSite HEV IgM Rapid Test and by a commercial ELISA test. Comparison for all subjects is shown in the following table:

| | HEV IgM Rapid Test | | |
|---|---|---|---|
| HEM IgM ELISA | Positive | Negative | Total |
| Positive | 314 | 6 | 320 |
| Negative | 6 | 734 | 740 |
| Total | 320 | 740 | 1060 |

Relative Sensitivity: 98.1% (95% CI: 96.0-99.3%),
Relative Specificity: 99.2% (95% CI: 98.2-99.7%),
Overall Agreement: 98.9% (95% CI: 98.0-99.4%).

## LMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of anti-HEV IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HEV IgM Rapid Test is limited to the qualitative detection of anti-HEV IgM in human serum or plasma. The intensity of the test line does not have a linear correlation with the antibody tiler in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable anti-HEV IgM. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with HEV.
4. A negative or non-reactive result can occur if the quantity of the anti-HEV 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 tilers of heterophile antibodies or rheumatoid factor may affect expected results.
6. Infection may progress rapidly. If the symptoms persist and the result from HEV IgM Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method such as ELISA or PCR.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## INDEX OF SYMBOLS

| Symbol | Used For | Symbol | Used For |
|---|---|---|---|
| | Use-by date | | Consult instructions for use |
| LOT | Batch code | IVD | In vitro diagnostic medical device |
| | Temperature limit | | Manufacturer |
| | Please don't reuse it | | Keep away from sunlight |
| | Don’t use the product when the package is damaged | | Keep dry |
| | Date of manufacture | Σ | Tests per kit |
| CE | CE Mark | | Biological Risks |
| EC REP | Authorized representative in the European Community | | |

## BASIC INFORMATION

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