HSV-2 IgG/IgM Rapid Test

For detection of Herpes simplex virus-2 antibodies in Human Serum, Plasma or Whole Blood.

**Materials Included and Active Ingredients**

1) HSV-2 IgG/IgM test kit contains the following items to perform the assay:
   - HSV-2 IgG/IgM test device foil packed with a desiccant
   - Disposable dropper capable of delivering 15 µL sample volume (may not provided)
   - Assay diluents
   - Instruction for use

2) Active ingredients of main components of one HSV-2 IgG/IgM test strips
   - Gold Conjugates (as main component): Mouse monoclonal anti-herpes simplex virus – gold colloid (1.2 ± 0.2 µg).
   - Test Line “M” (as main component): Mouse monoclonal anti-human IgM (4 ± 0.8 µg).
   - Test Line “G” (as main component): Mouse monoclonal anti-human IgG (4 ± 0.8 µg).
   - Control Line (as main component): Goat anti-mouse IgG(8 ± 0.4 µg).

**Kit Precautions and Storage Instructions**

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
9) Store kit at room temperature (2 - 30°C). Do not expose the kit to temperature over 30°C.

**Specimen Collection, Storage and Precautions**

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30°C) prior to use.
5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

**Warnings**

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

**Test Procedure (Refer to Figure)**

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/plasma or whole blood specimen into the sample well marked “S”.
4) Allow about 30 seconds for the specimen to be absorbed totally.
5) Add 3 drop of diluents buffer to the sample well.
6) As the test begins to work, you will see red color move across the result window in the center of the test device.
7) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.
Interpretation of Test Results (Refer to Figure)

1) **Negative**
The control line is the only visible line on the test device. No IgG or IgM antibodies were detected. Retest in 3–5 days if HSV-2 infection is suspected.

2) **IgM Positive**
The control line (C) and the IgM line (M) are visible on the test device. This is positive for IgM antibodies to HSV-2 virus. This is indicative of secondary or previous HSV-2 infection.

3) **IgG Positive**
The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to HSV-2 virus. This is indicative of late primary or early secondary HSV-2 infection.

4) **IgG and IgM Positive**
The control line (C), IgG (G) and IgM (M) lines are all visible on the test device. This is positive for both IgG and IgM antibodies. This is indicative of late primary or early secondary HSV-2 infection.

5) **Invalid**
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

HSV-2 IgG/IgM Test Procedure

Using micropipette, add 10 µl of serum, plasma or whole blood specimen in the sample well “S”

Put 2 or 3 drops (“80 µl) of assay diluents into the sample well marked as “S”

Interpret test results in 15–20 minutes.

Do not read the results after 20 minutes. Reading too late can give false results.

Limitations of the Test

1) The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to HSV-2 in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.

2) The HSV-2 IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to HSV-2 in human serum or plasma. The intensity of the test band does not correlate with antibody titer of the specimen.

3) A negative result for an individual subject indicates absence of detectable HSV-2 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with CMV.

Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Suggested Reading List


**REF** RT-SV1105-C-1

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