HSV 2 IgM Device (2 – 30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHS21	20 Tests

Intended Use:
The HSV 2 IgM Rapid Test Device is used for the detection of IgM antibody to herpes simplex virus 2 (HSV 2) in human whole blood, serum or plasma for the presumptive diagnosis of HSV 2 infection.

Test Principle:
The HSV 2 IgM Device is an immunochromatographic test. In the test anti-human IgM antibody is conjugated to particles and coated on the membrane in the sample area. Whole blood, serum or plasma is added to the sample well where it reacts with the particles which capture IgM antibodies in the sample. The mixture migrates upwards by capillary action to the test region. If the sample contains HSV 2 IgM, these complexes are specifically immobilised by recombinant HSV 2 antigen coated at the test region resulting in a coloured band and indicating a positive result. The absence of colour development at the test line indicates a negative result. A coloured band at the control region serves as a procedural control, indicating that correct volume of sample has been added and proper membrane wicking has occurred.

Materials Provided:
Individually pouched test devices
Disposable pipettes
Buffer
Instructions for Use Sheet

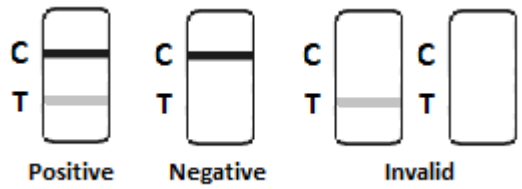
Precautions:
- Do not use the device after the expiry date.
- The test device should remain in the sealed pouches until use. Do not use the test if the pouch is damaged.
- Handle the products as potentially infectious and observe usual safety precautions: wear a laboratory coat, disposable gloves and safety glasses, do not eat, drink or smoke in the area where the samples and kits are handled.
- Humidity and temperature can adversely affect results.

Reagent Storage and Expiry:
- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- Keep away from direct sunlight, in a dry dark place.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**

Specimen Collection:
Whole blood, serum and plasma: Collect venous blood samples using approved phlebotomy techniques.
Serum and plasma samples may be stored at 2-8°C for 3 days prior to assay, and at -20°C for 2 years. Repeat freeze and thaw for no more than 3 times. Do not use haemolytic samples.
Whole blood samples should be stored at 2--8°C and the test performed within 2 days. Do not freeze whole blood samples. Fingerstick whole blood should be tested immediately.

Assay Procedure:
1. Bring devices, samples and controls to room temperature (15-30°C) before use.
2. Remove the device from its sealed pouch, and place it on a clean, level surface. Use the device as soon as possible.
3. For serum and plasma samples:
   Hold the dropper vertically and transfer 1 drop of serum or plasma to the sample well of the device, add 1 drop of buffer and start the timer.
   For whole blood samples:
   Hold the dropper vertically and transfer 2 drops of whole blood to the sample well, add 1 drop of buffer and start the timer.
4. Wait for coloured line(s) to appear. Read results at 15 minutes. Do not interpret results after 20 minutes.

Interpretation of Results:



POSITIVE: Two coloured bands appear. One band appears in the control region (C) and one band appears in the Test region (T).

NEGATIVE: One coloured band appears, in the control region (C). There is no colour development in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE: The intensity of the colour in the test line region (T) will vary depending on the levels of IgM present in the sample. Therefore, any shade of colour in the test region (T) should be considered positive.

Quality Controls:
Internal procedural controls are included in the test. A coloured band appearing in the control region (C) acts as an internal positive procedural control, confirming sufficient sample volume was added and correct procedural technique.
External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The HSV 2 IgM Rapid Test Device is for professional in vitro diagnostic use only. The test should be used for the detection of IgM antibody to HSV 2 in whole blood, serum or plasma. Neither the quantitative or semi quantitative concentration can be determined by this test.
2. The HSV 2 IgM Rapid Test Device will only indicate the presence of antibodies in the sample and should not be used as the sole criteria for the diagnosis of infection. As with all diagnostic tests, the results must be considered with other clinical information available to the physician.
3. If the test result is negative yet clinical symptoms persist, additional follow-up testing using other clinical methods is suggested.
4. Prozone may occur in the case of very high levels of antibody in a sample resulting in a decrease in band intensity. If Prozone is suspected, dilute the sample to see if band intensity is higher in diluted sample.

Performance Characteristics:
Sensitivity and Specificity:
The HSV 2 IgM Rapid Test Device was tested against a leading EIA assay for HSV 2 IgM using clinical samples from symptomatic and asymptomatic subjects. The overall agreement between the methods was 90.0%.

Precision:
Intra Assay Precision was determined by testing 10 replicates of negative and positive samples. The samples were correctly identified >99% of the time.
Inter Assay Precision was determined in 10 separate assays using negative and positive samples and three different batches of HSV 2 IgM Rapid Test Device. The samples were correctly identified >99% of the time.

References:
1. Blumberg Ryan KJ and Ray CG (Eds) Sherris Medical Microbiology (4th ed) (2004) McGraw Hill, 555-562. ISBN 0-8385-8529-9.
2. Knipe DM, Roizman B and Pellett PE Herpesviridae. In Fields' Virology (4th ed) (2001) Lippincott Williams & Wilkins, 2381-2397.
3. Whitley R, Roizman B. Herpes simplex viruses. 2001, Lancet 357: 1513-1518.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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