HSV 1/2 IgM/IgG Device (2 – 30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHS13	20 Tests

Intended Use:
Used for the qualitative detection of HSV 1/2 IgM/IgG antibodies in human serum or plasma.

Test Principle:
The HSV 1/2 IgM/IgG device is an immunochromatographic device. Sample is added to the sample well and interacts with HSV 1/2 antigen coated particles precoated there. The mixture migrates towards the Test line regions of the device which are coated with anti-human IgM and anti-human IgG respectively. If the sample contains HSV-1 or HSV-2 IgM and/or IgG these antibodies, now complexed with the conjugated particles, are captured by the Test line coated antibody which results in positive line(s). Formation of lines in the Control regions signifies that the correct volume of sample has been added and that membrane wicking has properly occurred.

Main Components:
PVC test device, nitrocellulose membrane, anti-human IgM, anti-human IgG and HSV 1/2 antigen.

Materials Provided
Individually pouched test devices
Droppers
Buffer
Instructions for Use sheet

Precautions:
- Do not use the device after the expiry date.
- The serum or plasma must be fresh for test, avoiding freezing repeatedly.
- A Negative result does not completely rule out HSV infection, since the concentration of specific antibody up to 5 days after infection is below detection limit for patients who are infected for the first time.
- The HSV-1 IgM/IgG Rapid Test will only indicate the presence of IgM and/or IgG antibodies to HSV-1 in the sample and the result should not be used as the sole criteria for the diagnosis of HSV-1 infection but used in conjunction with other clinical data.

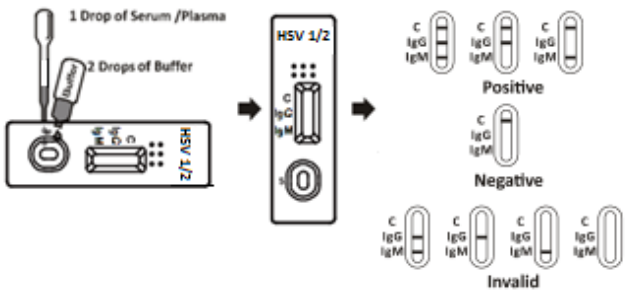
Reagent Storage and Expiry:
- The kit should be stored at 2 - 30°C until the expiry date printed on the sealed pouch.
- Keep away from direct sunlight, in a dry dark place.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**

Specimen Collection:

1. Serum**:** Collect serum using approved methods and centrifuge as soon as complete clotting has occurred.
2. Plasma: EDTA, Sodium citrate, oxalate and heparin can be used as anticoagulants.
3. Serum and plasma specimens may be stored at 2 - 8°C for 3 days prior to assay, and at -20°C for 6 months. Avoid repeated freeze/thaw cycles.
4. Do not use haemolytic samples.

Assay Procedure:

1. Do not open the sealed pouch until ready for use, then use as soon as possible or within one hour.
2. Ensure samples and buffer are at room temperature before testing.
3. Remove the test from its sealed pouch, and place it on a clean, level surface.
4. Draw up sample about 1 cm into the dropper. Transfer 1 drop (approximately 20µl) of sample to the sample well of the device. Add 2 drops of buffer (approximately 80 µl) and start the timer.
5. Observe the test results at 15 minutes, do not interpret results after 20 minutes.



Interpretation of Results:

POSITIVE: Two or three coloured bands appear. One band appears in the control region (C) and another band appears in either the IgM and/or IgG Test regions (IgM / IgG).

NEGATIVE: Only one coloured band appears, in the control region (C). No band appears 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.

Limitations of the Test:
1. The HSV 1/2 Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the qualitative detection of antibodies to HSV 1/2. The concentration of antibody cannot be calculated.
2. The HSV 1/2 Rapid Test Device provides only a preliminary analytical result and clinical diagnosis should not be made on this result alone. A secondary analytical method must be used to obtain a confirmed result.
3. A negative result with the test does not preclude the possibility of infection with HSV-1 and/or HSV-2.
4. There is a possibility that technical or procedural errors as well as other substances and factors not listed may interfere with the test and cause false results.

Quality Controls:
- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient sample volume 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.

Cross-Reactivity
The HSV 1/2 Rapid Test Device has been tested using HAV, HBV, HCV, HIV, RF, Syphilis and *H. pylori,* CMV, Toxo and Rubella antibody positive samples and the results showed no cross-reactivity.

Interfering Substances
The following compounds have been tested in the HSV 1/2 Rapid Test Device and no interference was observed.

Acetaminophen: 20 mg/dl	Caffeine: 20 mg/dl	EDTA: 20 mg/dl
Acetylsalicylic Acid: 20 mg/dl	Gentisic Acid: 20 mg/dl	Ethanol: 10 %
Ascorbic Acid: 2 g/dl	Phenylpropanolamine: 20 mg/dl	Glucose 20 mg/dl
Bilirubin 1000 mg/dl	Salicylic Acid: 20 mg/dl	Phenothiazine: 20 mg/dl

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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