HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF ISM-402	English

A rapid test for the qualitative detection of IgM antibody to HSV 1/2 in human whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The HSV 1/2 IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM anti-HSV 1/2 in human whole blood, serum or plasma. This kit is intended to be used as an aid in the diagnosis of infection with HSV 1/2.

【SUMMARY】

Herpes simplex virus 1 and 2 (HSV-1 and HSV-2), also known as human herpesvirus 1 and 2 (HHV-1 and HHV-2), are two members of the herpesvirus family, Herpesviridae, that infect humans.[1] Both HSV-1 (which produces most cold sores) and HSV-2 (which produces most genital herpes) are ubiquitous and contagious. They can be spread when an infected person is producing and shedding the virus.

In simple terms, herpes simplex 1 is most commonly known as a "cold sore," while herpes simplex 2 is the one known by the public as "herpes," or "genital herpes." According to the World Health Organization 67% of the world population under the age of 50 have HSV-1.[2]

Symptoms of herpes simplex virus infection include watery blisters in the skin or mucous membranes of the mouth, lips, nose or genitals.[1] Lesions heal with a scab characteristic of herpetic disease. Sometimes, the viruses cause very mild or atypical symptoms during outbreaks. However, they can also cause more troublesome forms of herpes simplex. As neurotropic and neuroinvasive viruses, HSV-1 and -2 persist in the body by becoming latent and hiding from the immune system in the cell bodies of neurons. After the initial or primary infection, some infected people experience sporadic episodes of viral reactivation or outbreaks. In an outbreak, the virus in a nerve cell becomes active and is transported via the neuron's axon to the skin, where virus replication and shedding occur and cause new sores.[3] It is one of the most common sexually transmitted infections.[4]

The detection of anti-HSV 1/2 IgM antibody enable effective diagnosis of acute or recent HSV 1/2 infection. The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgM antibody to HSV 1/2 in whole blood, serum or plasma specimens.

【PRINCIPLE】

The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgM antibody to HSV 1/2 in whole blood, serum or plasma specimens. In this test, HSV 1/2 Antigen coated in the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with goat anti-human IgM coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the HSV1/2 Antigen on the membrane in the test line region respectively. The presence of a colored line in the test line region indicates a positive result for HSV 1/2 infection, while its absence indicates a negative result for that infection.

To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains goat anti-human IgM and HSV 1/2 antigen. A Streptavidin-rabbit IgM is employed in the control line system.

【PRECAUTIONS】

1. For *in vitro diagnostic* use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely before performing the test.
5. Bring all reagents to room temperature (15°C -30°C) before use.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

【MATERIALS】

Materials provided

- Test Cassettes
- Droppers
- Package insert
- Buffer

Materials required but not provided

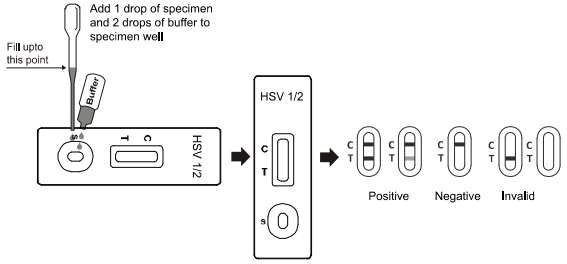
- Specimen collection containers
- Centrifuge
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically; draw the specimen about **1cm above** the upper end of the nozzle as shown in illustration below. Transfer **1 full drop (approx. 20μL) of specimen** to the sample well, then add **2 drops of buffer** (approximately 80μL) to the sample well and start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. **The result should be read at 15 minutes.** Do not interpret results after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another one apparent colored line(s) should be in the test line region.

***NOTE:** The intensity of the color in the test line region may vary depending on the concentration of HSV antibody present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line region.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

【LIMITATIONS】

1. The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of IgM antibody toHSV-1 and/or HSV-2 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM antibody to HSV-1 and/or HSV-2 can be determined by this qualitative test.
2. The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IgM antibody to HSV-1 and/or HSV-2 in the specimen and should not be used as the sole criteria for the diagnosis of HSV 1/2 infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of HSV 1/2 infection.
5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

【EXPECTED VALUES】

The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial HSV IgM ELISA test. The correlation between these two systems is 97.9%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with leading commercial ELISA HSV 1/2 tests; the results show that HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

Table: Clinical Study from ISM-402

Method		HSV 1/2 IgM ELISA		Total Results
HSV 1/2 IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	32	4	36
	Negative	3	301	304
Total Results		35	305	340

Relative Sensitivity: 91.4% (95%CI*: 76.9%-98.2%) *Confidence Interval

Relative Specificity: 98.7% (95%CI*: 96.7%-99.6%)

Accuracy: 97.9% (95%CI*: 95.8%-99.2%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive, and a high positive. The negative, low positive, and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive, and a high positive. Three different lots of the HSV 1/2 IgM Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV,HIV, Syphilis, *H. Pylori*, Toxo, CMV and Rubella positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the HSV 1/2 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

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

【BIBLIOGRAPHY】

1. Ryan KJ, Ray CG (editors) (2004). Sherris Medical Microbiology (4th ed.). McGraw Hill. pp. 555–62. ISBN 0-8385-8529-9.
2. World Health Organization. Herpes simplex virus.
3. "Herpes simplex". DermNet NZ — New Zealand Dermatological Society. 2006-09-16. Retrieved 2006-10-15.
4. Straface, Gianluca; Selmin, Alessia; Zanardo, Vincenzo; De Santis, Marco; Ercoli, Alfredo; Scambia, Giovanni (2012)."Herpes Simplex Virus Infection in Pregnancy". Infectious Diseases in Obstetrics and Gynecology. 2012: 1–6. doi:10.1155/2012/385697. ISSN 1064-7449.

Index of Symbols

	Consult Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co., Ltd.
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