

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

Package Insert

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

For professional in vitro diagnostic use only.

[INTENDED USE]

The HSV 1/2 IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to HSV 1/2 in whole blood, serum or plasma to aid in the diagnosis of HSV 1/2 infection.

[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. (<http://www.who.int/mediacentre/factsheets/fs400/en/>)

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.^[2] It is one of the most common sexually transmitted infections.^[3]

The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to HSV 1/2 in whole blood, serum or plasma specimens.

[PRINCIPLE]

The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgG and IgM antibodies to HSV 1/2 in whole blood, serum or plasma specimens. In this test, mouse anti-human IgG and goat anti-human IgM is coated in the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with HSV 1/2 antigen coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the mouse anti-human IgG or goat anti-human IgM 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 respective control line regions of all the two strips indicating that proper volume of specimen has been added and membrane wicking has occurred.

[REAGENTS]

The test contains goat anti-human IgM, mouse anti-human IgG and HSV 1/2 antigen. A streptavidin-IgG 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. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

[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 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood.
- 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 the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. 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
- Buffer
- Package Insert

Materials Required But Not Provided

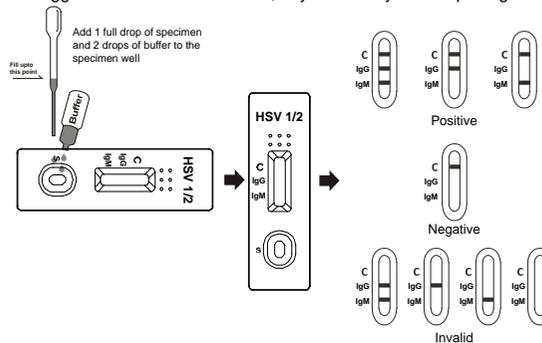
- Specimen Collection Containers
- Centrifuge (For plasma only)
- Timer

[DIRECTIONS FOR USE]

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

1. Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed as soon as possible.
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 each sample well, then add 2 drops of buffer (approximately 80µL) to each 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 30 days after opening the vial.



[INTERPRETATION OF RESULTS]

(Please refer to the illustration above)

POSITIVE: Two or three distinct colored lines appear. One color line should always appear in the control line region (C), and another one or two apparent colored line(s) should appear in the test line region(s) (IgG and/or IgM).

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of HSV 1/2 antibodies 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 regions.

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 individually for both two sections. Two colored lines appearing in control line regions (C) for both two sections is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, 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]

1. The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgM and IgG antibodies to

HSV 1/2 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM and IgG antibodies to HSV 1/2 can be determined by this qualitative test.

2. The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IgM or IgG antibodies to HSV 1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HSV 1/2 infections.
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 of the whole blood should be between 25% and 65%.

[EXPECTED VALUES]

The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with leading commercial EIA HSV 1/2 tests, demonstrating an overall accuracy of 97%.

[PERFORMANCE CHARACTERISTICS]

Sensitivity and Specificity

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

Method	HSV 1/2 EIA (IgM)		Total Results
HSV 1/2 IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative
	Positive	32	4
	Negative	3	301
Total Result	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%)

Method	HSV 1/2 EIA (IgG)		Total Results
HSV 1/2 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative
	Positive	3	5
	Negative	2	300
Total Result	35	305	340

Relative Sensitivity: 94.3% (95%CI*: 80.8%-99.3%) *Confidence Interval

Relative Specificity: 98.4% (95%CI*: 96.2%-99.5%)

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 IgG/IgM Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 10-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 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-HAV IgG, HBSAg, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-*H. Pylori* IgG, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG, anti-Toxo IgM, anti-Rubella IgG, anti-Rubella IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the HSV 1/2 IgG/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	Genitistic 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. Jump up^ "Herpes simplex". DermNet NZ — New Zealand Dermatological Society. 2006-09-16. Retrieved 2006-10-15.
3. Jump up^ 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.

Number: 145478302
Effective date: 2017-09-08