HSV-2 IgG/IgM
Rapid Test Device
(Whole Blood/Serum/Plasma)

HSV 2-W23M

INTENDED USE

The HSV-2 IgG/IgM Rapid Test Device (Whole blood/Serum/Plasma) is intended for the simultaneous detection and differentiation of IgG and IgM antibodies to herpes simplex virus 2 (HSV-2) in human whole blood/ serum/ plasma. The test is for professional use only.

INTRODUCTION

Herpes simplex virus 1 and 2 (HSV-1 and HSV-2) is two members of the herpesvirus family, *Herpesviridae*, that infect humans[1]. They can be spread when an infected person is producing and shedding the virus. Symptoms of HSV infection include watery blisters in the skin or mucous membranes of the mouth, lips or genitals[1]. HSV-1 and HSV-2 exhibit two unique biologic properties that influence pathogenesis and subsequent human disease. Both viruses have the capacity to invade and replicate in the central nervous system (CNS) and the capacity to establish a latent infection in dorsal root ganglia[2].

The most common sites of HSV infection include the skin and mucosal surfaces. HSV-1 and HSV-2 infections tend to be transmitted by different routes and infect different areas of the body but signs and symptoms of infection with either virus are similar[3]. In general, infections caused by HSV-1 occur above the waist and those caused by HSV-2 occur below the waist. However, over the last several decades considerable overlap in site of infection has evolved. The transmission of HSV infection is dependent upon intimate, personal contact of a susceptible seronegative individual with someone excreting HSV. The more severe the primary infection, as reflected by the size, number, and extent of lesions, the more likely it is that recurrences will ensue[3]. Replication sometimes leads to disease and, infrequently, results in life-threatening infection (e.g., encephalitis), the host-virus interaction leading to latency predominates[4].

Serological diagnosis can establish current and past infections with HSV. The antibody response to HSV is highly specific. Detection of IgG antibodies to HSV indicates that individuals have past infections, while detection of IgM antibodies to HSV signifies a current and acute infection. In cases of pregnant women, testing for HSV antibodies is usually done with a type-specific assay for HSV antibodies.

PRINCIPLE

The HSV-2 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) detects IgG and IgM antibodies to HSV-2 through visual interpretation of color development. Recombinant antigens of HSV-2, anti-human IgG and anti-human IgM antibodies are used to detect the specific antibodies in the human whole blood, serum or plasma samples. When a sample is added to the sample well, anti-HSV-2 IgG and/or anti-HSV-2 IgM antibodies, if present, will bind to the recombinant HSV-2 antigens conjugated to colored particles on the sample pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by anti-human IgG and/or anti-human IgM antibodies immobilized at the detection zone. Excess colored particle are captured at the internal control zone.

The presence of a red band(s) in the test region indicates a positive result for the particular IgG and/or IgM antibodies, while its absence indicates a negative result. A red band at the control region (C) serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- Individually packed test devices
- Droppers
- Sample diluent buffer
- Package insert

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Clock, timer or stopwatch

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The HSV-2 IgG/IgM Rapid Test Device (Whole blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Use clear, non-hemolyzed specimens only. Separate serum or plasma from blood as soon as possible to avoid hemolysis.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow the test, specimen 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 device from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test device on a clean and level surface.
   Hold the dropper vertically and transfer 2 dropsof whole blood (or 1 drop of serum or plasma) to the specimen well (S) of the test device, and add 1 drop of buffer, then start the timer.
3. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret results after 20 minutes.

RESULT INTERPRETATION

POSITIVE RESULT:

IgG+IgM Positive: One red band appears in the control region (C), and two other red bands appear in both IgG region and IgM region. The shade of color may vary from pink to purple, but it indicates a positive result even with a faint line.

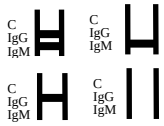
IgG Positive: One red band appears in the control region (C), and another red band in the IgG region. The shade of color may vary from pink to purple, but it indicates a positive result even with a faint line.

IgM Positive: One red band appears in the control region (C), and another red band in the IgM region. The shade of color may vary from pink to purple, but it indicates a positive result even with a faint line.

NEGATIVE RESULT:

Negative: Only one red band appears in the control region (C), and no band appears either in the IgG region or IgM region.

INVALID RESULT:



Invalid: No red band appears in the control region (C), whether a test band(s) is present or not. Repeat invalid tests with a new sample, new test device and reagent. Insufficient sample volume, inaccurate operating procedure or expired tests may yield an invalid result. Contact your local distributor if the problem continues.

NOTE:

1. The intensity of color in the test region may vary depending on the concentration of IgG/IgM antibodies present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of IgG/IgM antibodies in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen 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.

LIMITATIONS OF THE TEST

- The HSV-2 IgG/IgM Rapid Test Device (Whole blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of IgG and IgM antibodies to HSV-2. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
- Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
- Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret should be used in conjunction with other clinical information available to the physician.
- A high dose "hose effect" may occur where the color intensity of test band decreases as the concentration of antibodies increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the test band.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity

	HSV-2 IgG/IgM Rapid Test		
Reference ELISA	**Positive**	**Negative**	**Total**
Positive	54	9	63
Negative	9	86	95
Total	63	95	158

Relative Sensitivity: 85.7% (75.03%~92.30%)
Relative Specificity: 90.5% (82.30%~94.94%)
Overall Agreement: 88.6% (82.71%~92.67%)
*95% Confidence Interval

LITERATURE REFERENCES

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3. Whitley R. J., Roizman B. Herpes simplex viruses. Lancet. 2001;357:1513–1518.
4. Whitley R, Kimberlin DW, Prober CG. Pathogenesis and disease. In: Arvin A, Campadelli-Fiume G, Mocarski E, et al., editors. Human Herpesviruses: Biology, Therapy, and Immunoprophylaxis. Cambridge: Cambridge University Press; 2007. Chapter 32.

GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

μ
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