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 whole human 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 immunassay 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.

[PRINCIPLE]

The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative lateral flow immunassay for the detection of IgG and IgM antibodies to HSV 1/2 in whole blood, serum, or plasma specimens. The test utilizes a lateral flow immunoassay format which incorporates goat anti-human IgG and HSV 1/2 antigen. A monoclonal antibody specific to human IgG is employed in the control line system and HSV 1/2 antigen 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 antibody-antigen complex migrates forward on the membrane by capillary action and reacts with the goat 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 IgG or HSV 1/2 IgM. As with all diagnostic tests, all results must be considered with other clinical information available.

[APPLICATIONS]

The HSV 1/2 IgG/IgM Rapid Test Cassette can be used for routine testing in the diagnosis of HSV 1/2 infection. The test should be performed using whole blood, serum, and plasma from patients suspected of having HSV 1/2 infection. Only specimens from patients for which a clinical need for testing has been determined should be tested. Specimens should not be collected or transported in the presence of anticoagulants or preservatives.

[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 30 minutes.

NOTE: It is suggested not to use the buffer, beyond 30 days after opening the vial of buffer.

[INTERPRETATION OF RESULTS]

• 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 and 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 should 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 ectrogic agents.

• EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

[EXPECTED VALUES]

The HSV 1/2 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with leading commercial ELISA 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 reference methods for the detection of HSV 1/2 IgG and/or IgM in whole blood, serum and plasma specimens. The test results showed no cross-reactivity with other diagnostic tests.

[STORAGE AND STABILITY]

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