Herpes-2 Rapid Screen Test instructions

WHAT IS HERPES
Herpes is an inflammatory viral disease that affects the skin and nervous system. There are nine types of herpes known to affect humans. The Herpes 2 Rapid Screen Test helps in the diagnosis for Herpes Simplex 2 (HSV-2) which is also called genital herpes. Herpes simplex is characterized by the formation of small watery blisters. Herpes simplex virus 1 (HSV-1), also called oral herpes, typically involves an infection of the mouth, causing painful blisters known as cold sores or fever blisters. Herpes simplex virus 2 is a sexually transmitted disease (STD) that mainly affects the genital area with very similar blisters as seen in herpes simplex virus 1. It is the second most common form of herpes. It is also possible to have contracted genital herpes and have no symptoms at all. Both HSV-1 and HSV-2 are ubiquitous and highly contagious. Transmission of herpes simplex most commonly occurs by direct contact with the fluids of herpes sores or other body fluids, including saliva, semen and vaginal fluids of an infected person. Herpes simplex virus 2 is periodically shed in the human genital tract, most often asymptomatically, and most sexual transmissions occur during asymptomatic shedding.

The Herpes-2 Rapid Screen Test is a screening tool based on the principle of immunoassay combined with conjugated colloid gold technology. This diagnostic device is a test for the qualitative detection of anti-HSV-2 IgG in human whole blood, serum, or plasma specimens.

HOW THE HERPES-2 RAPID SCREEN TEST WORKS
Purified recombinant antigens of HSV-2 are precoated onto a membrane as a capture reagent on the test band region. If anti-HSV-2 IgG is present in the sample in concentrations above the labeled anti-human IgG, a dye complex will be formed. This complex is then captured by antigens immobilized in the Test Zone of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of the anti-HSV-2 IgG present in the sample. The Herpes-2 Rapid Screen Test has a high sensitivity and is able to give a result in 10-15 minutes. Test results are read visually without any instrument.

PRECAUTIONS
1. Use fresh specimen and avoid repetitive freezing, otherwise the result will be invalid.
2. Discard after first use. The test kit cannot be used more than once.
3. Do not use the test kit beyond the expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep the test kit out of reach of children.
6. DISPOSAL OF THE DIAGNOSTIC: A used-device may carry the risk of infection. The process of disposing the diagnostic must follow the local laws of disposal of infectious equipment or laboratory regulations.
7. The package containing the test kit should not be opened until it reaches room temperature if it is taken out from the refrigerator. Use the test kit as soon as possible but within 1 hour after removal from the pouch, especially if the room temperature is more than 30°C and in a high humidity environment.
8. Old serum cannot be used. If the serum is thick, it can be used only after being separated.

CONTENTS OF HERPES-2 RAPID SCREEN TEST
Each Kit Contains:
• Herpes-2 test card individually foil pouched with a desiccant
• Plastic dropper
• Sample diluent
• Safety lancet
• Alcohol swab
• Package insert

Material Required But Not Provided:
Timer

STORAGE AND STABILITY
The test kit can be stored at room temperature (18 to 30°C) in the sealed pouch until the date of expiry. The test kit should be kept away from direct sunlight, moisture and heat.
**SPECIMEN COLLECTION**

Whole blood collected by fingerstick:
1. Bring the test card, sample buffer, alcohol swab, safety lancet, and plastic dropper to room temperature.
2. Follow the steps below, from picture 1 to picture 8. When collecting the specimen, apply gentle pressure beside the point of the puncture. Do not squeeze (‘milking’) the finger to make it bleed. Wipe away the first drop of blood with a sterile alcohol pad. Allow a new drop of blood to form. Avoid air bubbles.

Whole blood samples collected by fingerstick should be used immediately after collection.

**INTERPRETATION OF THE RESULTS**

Negative: Only one pink band appears on the control region of the cassette. This indicates that there is no detectable anti-HSV-2 IgG in the specimen.
Positive: Two pink bands appear on the results window of the cassette – one band in the test region and one band in the control region. This indicates that the specimen contains detectable amounts of anti-HSV-2 IgG.
Invalid: If no colored bands appear, this indicates either an error in the test procedure or a fault in the test kit. The test should be repeated using a new test kit.

**LIMITATIONS**

1. The test is for in-vitro diagnostic use only.
2. The test is a qualitative filter detection test, it cannot be used as a final test for blood donors.

**BIBLIOGRAPHY**