142.5mm 142.5mm

200mm

HSV-2 IgG Field Use Rapid Test Kit

(Whole Blood/Serum/Plasma)

INTRODUCTION

Herpes is among several inflammatory viral diseases of the skin or nervous system, especially herpes simplex, characterized by the formation of small watery blisters. There are two kinds of Herpes, Type 1 and Type 2.

Herpes Simplex Type 1 typically involves an infection of the mouth with what are commonly known as cold sores or fever blisters and is called oral herpes. Herpes Simplex Type 2, called genital herpes, is a sexually transmitted disease (STD) that usually affects the genital area with very similar blisters as is seen with Type 1. It is the second most common form of herpes. The herpes simplex virus can cause an individual to suffer from blisters or cold sores around the mouth and/or genitalia. These same sores can also be found in other areas of the body such as the hands, the eye, the central nervous system and the brain. It is also possible to have contracted genital herpes and to suffer no symptoms at all or to be asymptomatic. Both HSV-1 (which produces most cold sores) and HSV-2 (which produces most genital herpes) are ubiquitous and contagious. Transmission of herpes simplex most commonly occurs by direct contact with a blister or the body fluids, including saliva, semen, vaginal fluid or the fluid from herpetic blisters of another infected person. Herpes simplex virus (HSV)-2 is periodically shed in the human genital tract, most often asymptomatically, and most sexual transmissions occur during asymptomatic shedding.

iCARE HSV-2 IgG Field Use Rapid Test Kit is rapid test based on principle of immunoassay combined with conjugated colloid gold technology. This diagnostic device is a test for qualitative detection of anti-HSV-2 IgG in human whole blood, serum or plasma specimen.

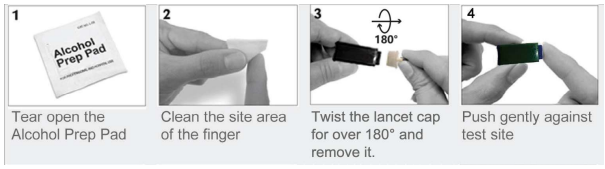
SUMMARY

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. This one step test is very sensitive and only takes about 15-20 minutes. Test results are read visually without any instrument.

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 closely as follows (from picture 1 to picture 4).
3. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile lancet.



Tear open the Alcohol Prep Pad | Clean the site area of the finger | Twist the lancet cap for over 180° and remove it. | Push gently against test site

Allow a new drop of blood to form. If blood flow is inadequate, the finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid milking the finger.

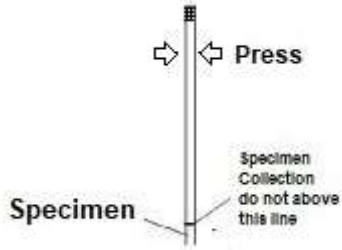
4. Use the 5 µL pipette (provided with the kit) to collect the blood until it is filled to the scale. Avoid air bubbles. Whole blood samples collected by fingerstick should be used immediately after collection.

Serum and Plasma:

For serum (or plasma), collect blood into a container without anticoagulant. If the specimen cannot be tested on the day of collection, store the serum (or plasma) specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing.

TEST PROCEDURE

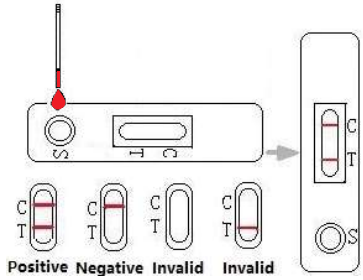
1. Open the pouch containing the test cassette, remove the cassette from the pouch and place it horizontally on the desk.



2. Draw **5 µL (please refer to the scale on the dropper)** of specimen and **touch the dropper onto the upper part of sample well** to transfer the specimen to the sample well.
3. Then draw **2 drops of buffer** into the sample well **immediately.**
4. Read the results within 15-20 minutes. Do not read results after 20 minutes.

INTERPRETATION OF RESULTS

Negative: Only one pink band appears on 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.



PRECAUTION

1. Please 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 expiry 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.

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.

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.

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Note: An extra lancet is provided in the package in case that the safety lancet is misused.