Herpes Simplex Virus Type 2 (HSV-2) IgM Rapid Test

（Colloidal Gold Chromatography）

【Introduction】

Although Herpes Simplex Virus type 1 and type 2 have many things in common, the HSV type 1 is the cause of most orofacial herpes and HSV encephalitis; type 2 is the primary cause of initial and recurrent genital herpes and neonatal HSV. In other word, genital herpes is most frequently caused by HSV-2 where it establishes latency in dorsal nerve root ganglia. Intermittent reactivation of virus occurs in most people who are infected with HSV-2. These reactivations cause genital lesions and the viral shedding on mucosal areas.

Genital HSV-2 infection may be sub-clinical, which means that a significant number of patients may not realize that they are infected and may unknowingly transmit the virus to sexual partners. Numerous studies report that, while infection with HSV-2 frequently results in periods of overt disease (expressing “typical” or “atypical” symptoms) followed by periods of viral latency with no overt disease, the disease does not self-cure. Neither can it be cured through medical intervention.

The detection of HSV-2 IgM antibody enables effective diagnosis of acute or recent CMV infection. The test is particularly useful for the follow-up of pregnant women, who were not previously exposed to HSV-2 and consequently are not protected against the virus. In addition, determination of specific IgM antibody in the newborn is useful for the diagnosis of congenital HSV-2 infection.

【Principle】

Based on the principle of Gold Immuno-chromatography Assay (GICA), anti-human HSV-2 IgM monoclonal antibody and recombinant HSV-2 IgM antigen are used to detect HSV-2 IgM with high sensitivity and specificity in serum specimen.

When the sample added contains HSV-2 IgM, this antibody will act with anti-human HSV-2 IgM monoclonal antibody in the membrane strip. These complexes move along the membrane strip chromatographically to the test region (T), where these complexes will be captured by the pre-coated recombinant HSV-2 antigen. A complex of double sandwich structure will form, ant a red or pink line will appear in the test region, indicating a positive result. The unbounded complex moves on to the control region (C), where they are captured by the anti-mouse antibody, and a red line will appear, indicating the assay is a valid one. In this way, the control line provides an inner quality control mechanism.

【Materials Provided】

Each test cassette is packed in a single aluminum pouch with silicon gel for long time storage, 25 cassettes per outer box;

Instruction for Use: One Copy.

【Specimen Collection & Preparation】

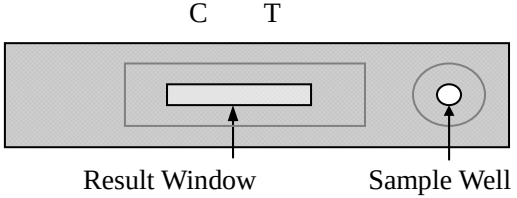
Collect the patient’s venous blood and let it contract in a natural way. Then centrifuge and collect the serum. Do not use haemolytic samples. Once the sample is collected, perform the assay as soon as possible.

If serum is not tested immediately, it should be refrigerated at 2-8 degrees Centigrade. For storage periods greater than three days, freezing is recommended. The specimen should be brought to room temperature prior to testing assay.

【Test Procedure】

Please read the *Instruction for Use* carefully before carrying out the test.

1. Let the sealed pouch and the samples come to room-temperature range of 15-30℃ before testing.
2. Open the aluminum foil pouch, take out the test cassette and put it on a flat and dry surface, with the sample well facing up.
3. Add two drops of serum（80μl）to the sample well, and read the result after 15 minutes but within 30 minutes. After 30 minutes, the result should be regarded as invalid.



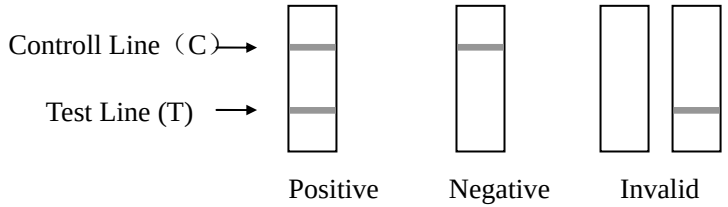
【Interpretation of Results】

Negative: Only one colored band appears on the control region. No apparent band on the test region.

Positive: Distinct color bands appear on both the control region and the test region. Both test line and control line indicate a positive result. Color intensity of the test bands may vary.

Invalid: A total absence of color in both (C) and (T) regions or no color band on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Diagram: Interpretation of Results



【Limitations of the test】

1. This HSV-2 IgM test is for in-vitro diagnostic test only.
2. This assay is only a qualitative screening test. For positive cases, more advanced quantitative testing method should be used before any clinical conclusion can be made.
3. If it is the first time for the patient to be infected, within 5 days, there is no detectable specific antibody in his/her serum. In this window period, the test will give a negative result when testing with this test cassette.
4. The HSV-2 IgM antibody of the mother will appear in the serum sample of a one-year old child, therefore it is improper to use independently the test result of a one-year old baby as the clinical proof either for its history of infection or for its immunization status.

【Storage, Carriage and Validity】

1. Store the test kits in a dry circumstance with a room-temperature range of 2～30℃.
2. Avoid direct sunlight and heat. Don’t freeze.
3. This reagent can be transported within a short period in a normal temperature range. In summer or winter when the environment is rough, some protective measures should be taken to avoid high temperature or freeze thawing.

【Manufacturer】

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