Herpes Simplex Virus Type 1 (HSV-1) IgG Rapid Test
（Colloidal Gold Chromatography）

【Introduction】

Herpes Simplex Virus Type 1 (HSV-1) and Herpes Simplex Virus Type 2 (HSV-2) are similar, sharing approximately 50% of their DNA and have over 80% of common antigens. Both types infect the body's mucosal surfaces, usually the mouth or genitals, and then establish latency in the nervous system. For both types, at least two-thirds of infected people have no symptoms, or symptoms too mild to notice. Both types can recur and spread even when no symptoms are present.

HSV-1 is the cause of most orofacial herpes and HSV encephalitis; HSV-2 is the primary cause of initial and recurrent genital herpes and neonatal HSV. Reactivation of latent HSV infection is a frequent complication of immunosuppression due to cancer, transplantation and AIDS. Asymptomatic genital shedding of HSV-2 is more common than HSV-1 and occurs more frequently during the first 3 months after acquisition of primary type 2 disease than during later periods. The presence of HSV-1 IgG antibody in serum is an indication of previous exposure. A significant increase in HSV IgG is an indication of reactivation, current or recent infection.

【Principle】

Based on the principle of Gold Immuno-chromatography Assay (GICA), anti-human HSV-1 IgG monoclonal antibody and recombinant HSV-1 IgG antigen are used to detect HSV-1 IgG with high sensitivity and specificity in serum specimen. When the sample added contains HSV-1 IgG, this antibody will act with anti-human HSV-1 IgG 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-1 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】

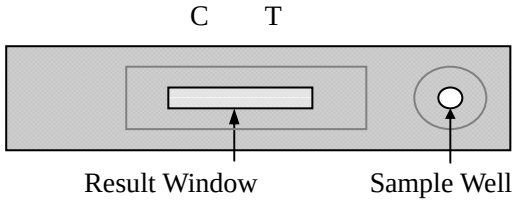
Collect the patient’s venous blood and let it contract in a natural way. Then centrifuge and collect the serum. Do not use haemolytic samples. Once the sample is collected, perform the assay as soon as possible.

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 making sure that there are no air bubbles and read the result after 15 minutes but within 20 minutes. **After 30 minutes, the result should be regarded as invalid.**



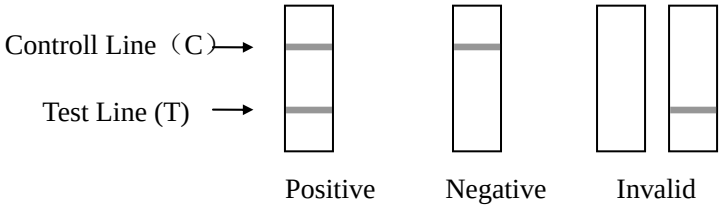
【Interpretation of Results】

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-1 IgG 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-1 IgG 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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