TORCH IgG Rapid Test
(Colloidal Gold Chromatography)
For the Qualitative Detection of TORCH IgG Antibodies in Serum

【Intended Use】

TORCH test panel is a rapid qualitative lateral flow test designed for the qualitative detection of the IgG antibodies to the following viruses:

- Toxoplasma gondii (Toxoplasmosis) (TOXO);
- Cytomegalovirus (CMV);
- Rubella Virus (RV);
- Herpes Simplex Virus Type 1 (HSV-1);
- Herpes Simplex Virus Type 2 (HSV-2).

【INTRODUCTION】

The acronym TORCH was introduced in 1971 by Nahmias et al. to highlight a group of viral diseases which affect the foetus and newborn, namely Toxoplasma gondii, rubella virus, cytomegalovirus (CMV), and herpes simplex virus (HSV). These diseases often lead to a similar clinical picture which include one or more of the following clinical signs: low birth weight, prematurity, purpura, jaundice, anemia, microcephaly, hydrocephaly, cerebral calcification, chorioretinitis, cataracts, microphthalmia, and pneumonitis. TORCH screening is now widely requested by clinicians investigating infants and pregnant women for congenital, perinatal and neonatal infections.

Toxoplasmosis (TOXO) is a systemic disease, caused by the protozoa *Toxoplasma gondii*. Infection in Immuno-compromised patients and in the developing fetus can lead to serious consequences. Opportunistic toxoplasmosis infection or reactivation of a subclinical infection in Immuno-compromised patients may cause encephalitis, pneumonitis and myocarditis. In the congenitally infected fetus the infection may spread to the central nervous system. Abortion and stillbirth may occur when infection takes place during the first trimester of pregnancy, and irreversible neurological damages in case of infection during the second or third trimester.

Cytomegalovirus (CMV) infection is mainly asymptomatic. But primary infection during early pregnancy may also lead to congenital abnormalities in the fetus, and infection in immuno-deficient patients is the most common infectious cause of mortality. Screening for IgG antibodies to CMV is useful to establish previous exposure to CMV. Determination of the CMV IgG antibody level at weekly or biweekly intervals also enables diagnosis of acute infection through the demonstration of a significant rise in antibody titer.

Rubella (also called German measles or 3-day measles) is a disease caused by the rubella virus. Although rubella can strike people of all ages, it poses the greatest danger to unborn babies. Congenital rubella syndrome (CRS) occurs when the rubella virus attacks a developing fetus. Up to 85% of infants infected during the first trimester will be born with birth defects, including deafness, blindness, heart defects, and mental retardation. Miscarriages are also common. Growth retardation and diabetes mellitus have also been associated with late complications of congenital rubella. Screening for IgG antibodies to rubella virus is a useful tool for diagnosis of the disease, and for determination of the immune status. Serial determination of the rubella IgG antibody level in the infant, therefore, will assist in the differentiation between congenital rubella (plateau level) or neonatal rubella (increase in titer).

Herpes Simplex Virus Type 1 (HSV-1) and Herpes Simplex Virus Type 2 (HSV-2) are similar. 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. The presence of HSV-1 IgG antibody or HSV-2 antibody in serum is an indication of previous exposure. A significant increase in HSV-1 or HSV-2 IgG antibody is an indication of reactivation of the respective Herpes Simplex Virus current or recent infection.

【Principle】

The one-step TORCH IgG rapid test is an immuno-chromatographic assay, based on the principle of Gold Immuno-chromatography Assay (GICA) principle. Recombinant antigens of the five viruses and anti-human IgG antibodies to the five viruses are respectively used to detect the specific antibodies in the human serum or plasma samples.

When the samples are added to the sample wells on the test panel, the antibody, say TOXO IgG antibody, will react with the anti-human TOXO IgG antibody in the membrane strip, and complexes will emerge. These complexes move along the membrane strip chromatographically to the test region (T), where these complexes will be captured by the pre-coated recombinant TOXO antigen. Then a red or pink line will appear, 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. So the control line provides an inner quality control mechanism.

The test principle of all the other four antibodies is the same as that of the TOXO IgM testing. The color intensity is in accordance with the concentration of the respective antibody to the related TORCH virus in the samples.

【Materials Provided】

Each test panel with five membrane strips is packed in a single aluminum pouch with silicon gel for long time storage;

20 panels are packed in one outer box;

A pipette used to add samples to the sample wells on the test panel;

Instructions for use: One Copy.

【Specimen Collection & Preparation】

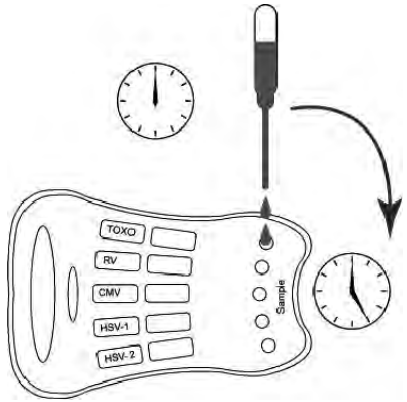
Collect the patient's venous blood and let it contract in a natural way. Then centrifuge and collect the serum. Do not use haemolytic samples. Once the sample is collected, perform the assay as soon as possible.

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 panel and put it on a flat and dry surface, with the sample wells facing up.
3. Add two to three drops of serum（80-120μl）to each sample well, and start the timer.
4. After 15 minutes but within 30 minutes, read the results in the result windows. After 30 minutes, the result should be regarded as invalid.



【Interpretation of Results】

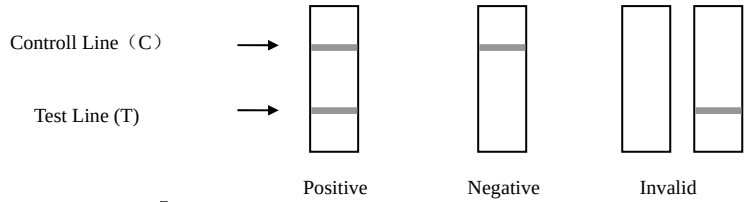
There are five result windows altogether, which indicates the testing result of TOX, RV, CMV, HSV-I and HSV-II respectively. After applying samples, either one line or two lines will appear in each result window. The interpretation of the result is as follow:

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 TORCH IgG test is for In-Vitro Diagnostic Test only.
2. This assay is only a qualitative screening test. For positive cases, more complicated 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 with any of the five diseases, within 5 days, there is no detectable specific antibody in his/her serum. In this window period, the test will give a negative result.
4. The TORCH IgG antibodies of the mother may appear in the serum sample of a child less than one year old, 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 4～30℃.
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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