TORCH-IgM IgG Rapid test

Catalog No.:BG801C BG802C

INTENDED USE

The TORCH test is a panel of rapid qualitative lateral flow test designed for the qualitative detection of IgG/IgM antibodies to Toxoplasma gondii(TOXO), Cytomegalovirus (CMV), Rubella, Herpes Simplex virus (HSV-2) in human serum/plasma samples.

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SUMMARY AND CLINICAL SIGNIFICANCE for TOXO

T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution (1, 2). Serological data indicate that approximately 30% of the population of most industrialized nations is chronically infected with the organism (3). When a seronegative woman become infected T. gondii during pregnancy, the organism is often transmitted across the placenta to the fetus (1,4). The severity of infection in the fetus varies with the trimester during which the infection was acquired. Infection during the trimester may lead to spontaneous abortion, stillbirth or overt disease in the neonate. Approximately 75% of congenitally infected newborns are symptomatic. However, nearly all children born with subclinical toxoplasmosis will develop adverse ocular or neurologic sequelae later in life (4, 7). Approximately 80-85% develops chorioretinitis and some may also experience blindness or mental retardation.

A variety of serologic tests for antibodies to T. gondii have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. The more widely used test include the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorenscence, and ELISA (5, 6).

SUMMARY AND EXPLANATION OF THE TEST for CMV

Cytomegalovirus is a herpes virus and a leading biological factor causing congenital abnormalities and complications among those who receive massive blood transfusions and immunosuppressive therapy. About half of pregnant women who contract a primary infection spread the disease to their fetus. When acquired in- utero, the infection may cause mental retardation, blindness, and/or deafness.

Serological tests for detecting the presence of antibody to CMV can provide valuable information regarding the history of previous infection,

Diagnosis of active or recent infection, as well as in screening blood for transfusions in newborns and immuno- compromised recipients

SUMMARY AND EXPLANATION OF THE TEST for Rubella

Rubella is a herpes virus. Generally rubella is considered a mild adolescence disease. However a maternal infection could be transmitted through the placenta to the fetus, causing congenital rubella. Congenital rubella may result in chronic cardiac disease, growth retardation, hepatosplenomegaly, malformations and other severe anomalies. Children born asymptomatic may develop these abnormalities later in life.

To reduce risk of such severe complications, accurate serological methods must be performed to determine the serologic status of childbearing aged women. The presence of rubella specific IgG in the bloodstream attests immunity to rubella. A woman tested to be non-immune can be educated on the availability of vaccination. An increase in rubella IgG denotes an acute infection and differentiates rubella from other exanthematous diseases. Expecting women with current rubella infection should be counseled on the consequences of congenital infection.

SUMMARY AND EXPLANATION OF THE TEST for HSV-2

HSV-2 causes mostly gennital and neonatal infections (1, 2) however, the tissue specificity are not absolute (3). Infants infected with HSV appear normal at birth but almost invariably develop symptoms during the newborn period (1, 4, and 5). Neonatal HSV infection may remain localized or become disseminated. Localized infection may involve one or a combination of sites. These are skin, eyes, mouth or central nervous system. Disseminated infection is

manifested by pneumonitis, hepatitis, dissembinated intravascular coagulopathy and encephalitis. Of the infants with neonatal HSV, about one half of the serviving infants will develop severe neurological or ocular sequelae.

A number of serological procedures have been developed to detect antibodies to HSV. These include complement fixation, indirect immunoflorescent antibody, plaque neutralization, and ELISA (2, 4, and 6). Antibody of the IgM class is produced during the first 2-3 weeks of infection with HSV and exists only transiently

In most patients Serologic procedures which measure the presence of IgM antibodies help discriminate between primary and recurrent infections since IgM antibodies is rarely found in recurrent infections.

High affinity IgG antibodies to HSV, if presence in a sample, may interfere with the detection of IgM specific antibody (9). if present along with antigen specific IgG, may bind to IgG causing false positive IgM results. Both the problem can be eliminated by deactivating igG in the sample before testing for IgM.

Principles of the Tests

The quick one-step test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. If TORCH antibody is present in the sample in concentration above the detection, a labeled antibody-dye complex will be formed. This complex is then captured by antigen immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of TORCH antibody in the sample. On the other hand, a color band will always appear at the control zone ("C").

Kit Content

1. Test device.
2. Develop Buffer solution in a dropper bottle.

Precautions for User and General Safety Instructions

1. For In-vitro use only.
2. Do not use after expiration date
3. Do not use reagents from different kits.
4. Store reagents 4 - 30 degrees Centigrade. Do not freeze.
5. Devices should be kept dry in the recloseable foil pouch with desiccant. Allow the strips and pouch to equilibrate to room temperature before opening the pouch to avoid condensation of moisture onto the strips. Always reseal the foil pouch after use.
6. Do not smoke, eat or drink in areas where testing is conducted.
7. Do not mouth pipette Universal precautions should be practiced PVC gloves and proper protective eyewear and clothing should be worn. Wash hands thoroughly afterwards.
8. Infectious specimens and nonacid-containing spills should be wiped thoroughly with 5% sodium hypochlorite.
9. All waste materials should be properly disinfected before disposal. Liquid and solid wastes should be autoclaved for at least 1 hour at 121.5 degrees Centigrade.
10. Once the assay has been started, all subsequent steps should be completed without interruption and within the recommended time limits.

Specimen Collection and Preparation

This test can be performed on either serum or plasma. It is recommended that fresh samples be used if possible. If this is not possible, Samples should be stored in a refrigerator (2-8oC) before being analyzed. For long term storage, specimens should be frozen at –20oC.

Test Procedures

1. Dispense 5 ul of specimen into location of allow (between T line region and end edge of the view window). The T line region must be wetted by the sample added.
2. After 30 seconds, add 2 drops of Develop Buffer into each sample well.
3. Read time:

Torch-IgM Panel Test: 10 minutes

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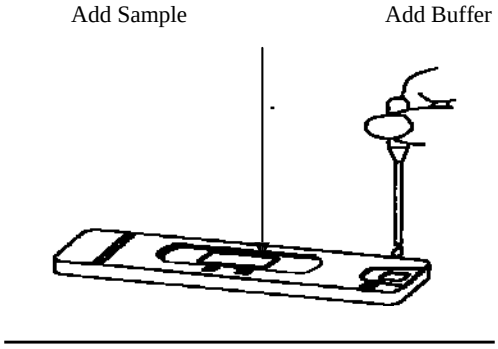
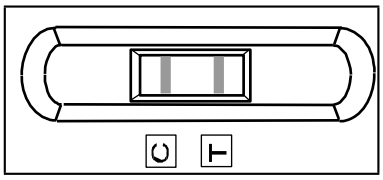
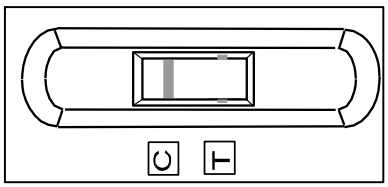


Interpretation of Results

Positive Result: If there is a rose-pink color band in the control region (marked with a "C"), and a rose-pink color band in the test region (marked with a "T"), TORCH antibody is present and the specimen is positive.



Negative Result: The absence of a color band in the test region next to the letter "T" indicates the absence of any detectable TORCH antibody.



Invalid Result: If a color band does not appear in the control region "C", the test results are invalid. The sample may have been added to the wrong window, or the Test Device may have deteriorated. This specimen should be re- tested using a new Test Device.

Limitations of the Procedure

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particulate that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult. (See remarks on Frozen Specimens).
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A repeatedly positive result in this test is presumptive evidence of the presence of antibodies to TORCH in the specimen. A negative result indicated the likely absence of detectable antibodies to TORCH in the specimen, but it does not exclude the possibility of exposure to or infection with TORCH.
4. False positive and negative results might be expected with a test kit. The proportions of false results will depend on the sensitivity and specificity of the test, and on the prevalence TORCH antibody in the population to be screened.
5. Caution should be used when interpreting results of this test with pro-diluted samples,