TORCH Panel Rapid test

The OnSite TORCH Panel Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of IgG and IgM antibodies to Toxoplasma gondii (T. gondii), rubella virus, cytomegalovirus (CMV), herpes simplex virus 1 (HSV-1), and herpes simplex virus 2 (HSV-2) in human serum, plasma, or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with T. gondii, rubella virus, CMV, HSV-1 and HSV-2.

SUMMARY AND EXPLANATION OF THE TEST

T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution1, 2. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism. Women initially infected with T. gondii during pregnancy possess a risk of transmission to their unborn child. Seronegative women should avoid risk factors for T. gondii transmission including owning cats, eating raw and undercooked meats, and gardening.

U. Rubella virus infection most often occurs during childhood and manifests with mild symptoms. However, ifa rubella virus infection occurs during pregnancy, the unborn child may develop a group of birth defects collectively known as congenital rubella syndrome (CRS), including congenital eye defects, deafness, congenital heart diseases, and mental retardation5. The presence of anti-rubella virus IgM or high titers of anti-rubella virus IgG (> 200 IU/mL) are suggestive of acute rubella infection6. Lower titers of anti-rubellavirus IgG (≥ 10-15 IU/mL) are suggestive of previous exposure and protective immunity. An individual with an anti-rubella virus IgG titer less than 10-15 IU/mL is considered to be at risk of acquiring a rubella virus infection.

. CMV infections are widespread and usually asymptomatic; however, the virus may persist as a latent or chronic infection . The majority of individuals that contract CMV infections remain asymptomatic . Congenital transmission of CMV can lead to hearing loss, mental retardation, or central nervous system motor disorders in infected

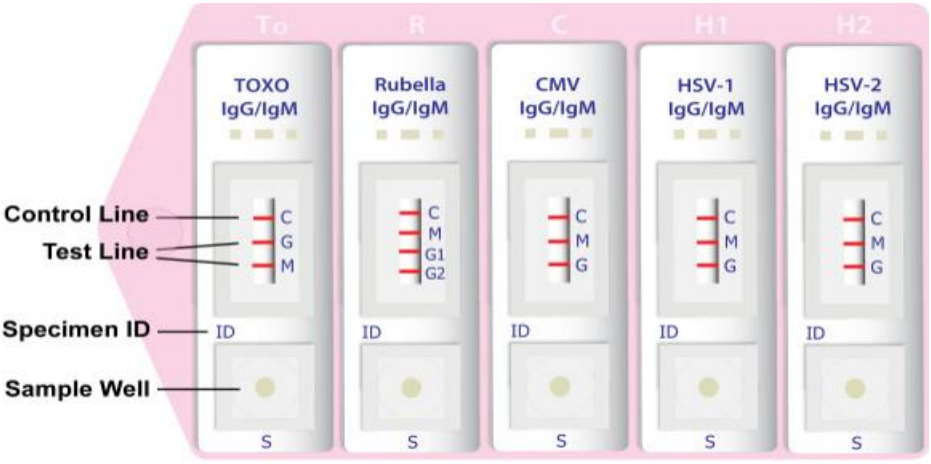
infants10. The presence of anti-CMV IgM is suggestive of primary infection.Differentiation of anti-CMV IgG and IgM can help discriminate between primary and recurrent infections since anti-CMV IgM is rarely found in recurrent infections..**Herpes simplex viruses** refer to two types of DNA viruses of the Herpesviridae family, HSV-1 and HSV-212. HSV-1 is generally acquired during childhood via non-sexual contact and affects mainly the orofacial area. HSV-2 is nearly always sexually transmitted and is the main cause of genital herpes. HSV-1 and HSV-2 can infect both the genital and orofacial areas12, however they have different prognoses.

TEST PRINCIPLE : The OnSite TORCH Panel Rapid Test is a lateral flow chromatographic immunoassay consisting of 5 panel strips assembled in one cassette. Each panel contains the following components, respectively:

Panel Conjugate Pad Test Line G Test Line M Toxo T. gondii antigen Anti-Human IgG Anti-Human IgM Rubella Rubella virus antigen Anti-Human IgG (G1, G2) Anti-Human IgM CMV CMV antigens Anti-Human IgG Anti-Human IgM HSV-1 HSV-1 specific glycoprotein G1 antigen Anti-Human IgG Anti-Human IgM HSV-2 HSV-2 specific glycoprotein G2 antigen Anti-Human IgG Anti-Human IgM When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. If present in the specimen, IgM antibodies bind to the target antigen conjugates. The immunocomplex is then captured on the membrane by the pre coated mouse anti-human IgM forming a colored M line, indicating an IgM positive result for that particular disease.

IgG antibodies, if present in the specimen, will bind to the target antigen conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a colored G line, indicating an IgG positive result for that particular disease. In the case of rubella, an anti-rubella virus IgG titer ≥15 IU/mL produces a colored G1 test line. An anti rubella virus IgG titer ≥250 IU/mL produces colored G1 and G2 test lines. Absence of any test lines (M, G, G1, or G2) suggests a negative result for that particular test strip. The strip in each cassette contains an internal control (C line) which should exhibit a colored line of the immunocomplex of

the control antibodies regardless of color development on any of the test lines. If the C line does not develop, the test result for that test strip is invalid, and the specimen must be retested with another device. Each test is read independently. One invalid test does not disqualify the results of other valid tests.



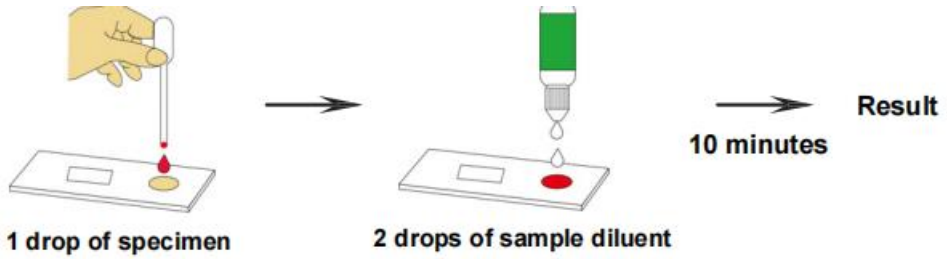
SPECIMEN COLLECTION AND HANDLING (Procedures)

Plasma/Serum Step 1: Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture. Step 2: To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube. Step 3: To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube. Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately. The specimens can be stored at 2-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Whole Blood

Step 1: Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a collection tube containing EDTA, citrate or heparin. Do not use hemolyzed blood for testing.Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection. ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.**Step 2:** When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface. **Step 3**: Be sure to label the device with specimen ID number. **Step 4**: Fill the plastic dropper with specimen. Holding the dropper vertically, dispense 1 drop (about 10 µL) of serum/plasma or 1 drop of whole blood (about 15 µL) into the center of the sample well in each panel making sure that there are no air bubbles. Immediately add 2 drops (about 60-80 µL) of sample diluent to the sample well in each panel with the bottle positioned vertically. **Step 5**: Set up the timer.**Step 6**: Read results at 10 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 15 minutes only. However, any results interpreted outside the 10-15 minute window should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.



INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C line develops, the test indicates that antibodies to the target infection are not detected in the specimen. The result is negative or non-reactive. 2. POSITIVE RESULT:2.1 IgM positive: In addition to the presence of the C line, if the M line develops in any of the five tests, it indicates the presence of IgM antibodies for that particular infection in the specimen. The result is IgM positive or

reactive..2 IgG positive: In addition to the presence of the C line, if the G line develops in any of the five tests, the test indicates the presence of IgG antibodies for that particular infection in the specimen. The result is IgG positive or reactive.

2.3 IgG and IgM positive: In addition to the presence of the C line, if both the M and G line develop in any of the five tests, the test indicates the presence of both IgM and IgG antibodies for that particular infection in the specimen. The result is IgM and IgG positive.

The clinical significant of this test

a. **Identification of High-Risk Pregnancies:** The TORCH panel helps identify pregnant women who may be at a higher risk of transmitting infections to their unborn child. This allows healthcare providers to closely monitor and manage these pregnancies to minimize potential complications.
b. **Prevention of Congenital Infections:** Congenital infections are infections that a baby acquires during pregnancy or childbirth. These infections can lead to serious and sometimes permanent health problems for the newborn. The TORCH panel aids in the early detection of infections so that appropriate interventions can be initiated to prevent or reduce the impact of congenital infections.
c. **Timely Treatment:** If a pregnant woman is found to have any of the TORCH infections, prompt treatment can be initiated to help prevent the transmission of the infection to the fetus or mitigate its effects.
d. **Counseling and Informed Decision-Making:** Knowledge of TORCH infection status allows healthcare providers to counsel pregnant women and their partners about potential risks, the importance of preventive measures, and the available treatment options.
e. **Monitoring Fetal Development:** Positive TORCH test results may prompt more frequent prenatal monitoring and additional imaging tests to assess the baby's growth and development.
f. **Preventive Measures:** In cases where the mother has a history of a previous TORCH infection, preventive measures can be taken to reduce the risk of reinfection during pregnancy.
g. **Neonatal Management:** Newborns born to mothers with positive TORCH test results may require specialized medical care and monitoring after birth to promptly address any potential complications.
h. It's important to note that while the TORCH panel is valuable in assessing potential risks during pregnancy, a positive result on the panel does not necessarily mean that the baby will be affected. Many pregnancies with positive TORCH results have favorable outcomes with appropriate monitoring and management.