TORCH Antigens Sample Kit (Catalog 9281)  
– contains antigens to develop a high sensitivity TORCH panel assay

Meridian Life Science, Inc. (MLS) has developed a convenient TORCH sample kit that includes commercially important antigens which are used in approved diagnostic assays around the world. These antigens are exclusively manufactured by MLS using proprietary methods for viral extraction and purification. The TORCH Antigen Sample Kit (Catalog 9281) contains a selection of popular antigens which are used by the world’s top diagnostic companies. In addition, MLS provides variations of these antigens and antibodies suitable for a range of applications.

INTRODUCTION

TORCH is an acronym for a group of infections that can cause significant birth defects and even fetal death.
- Toxoplasmosis
- Other: syphilis, hepatitis B, Coxsackie virus, Epstein–Barr virus (EBV), human parvovirus, and varicella zoster
- Rubella
- Cytomegalovirus (CMV)
- Herpes simplex virus (HSV)

Between 2-3% of all congenital anomalies are attributed to perinatal infections, of which the TORCH agents are the most common cause of infection. The TORCH organisms typically are asymptomatic or cause only mild infections in the mother; however, there are much more serious consequences for infection to the fetus. In addition, TORCH infections pose a greater risk to the fetus and neonate if the mother is actively infected during pregnancy. Primary infections (newly acquired during pregnancy) are generally more damaging than secondary or reactivated infections. For example in the case of Rubella, infection to the mother during the first 12 weeks of gestation leads to congenital rubella syndrome in 80% of fetus and poor outcome; however, congenital infection during the second half of pregnancy has minimal risk to the fetus. For *T. gondii*, although the risk of maternal transmission is lowest in the first trimester, congenital disease is the most severe during this phase and often results in fetal death. CMV, which is the most common cause of congenital infectious disease, has a much higher rate of transmission (10% vs. 1%) for mothers with a primary infection compared to a reactivation.

For most TORCH organisms, the initial screening test is based on detection of antibodies to the organism. Assays are commercially available for the detection of IgG antibodies, IgM antibodies, or both IgG and IgM antibodies. In most cases, IgG reactivity in the absence of IgM reactivity is indicative of a past infection, while IgM reactivity in the absence of IgG reactivity indicates a current infection. However, for toxoplasmosis and CMV infections, IgG avidity has recently been found to be useful for identifying primary infections. Since IgM antibodies can be produced following reactivation or re-infection in some individuals, a positive IgM is not necessarily indicative of a primary, active infection. In addition, it has been demonstrated that IgG antibody produced in the first few months following an initial infection has a lower avidity than IgG antibody produced several months or years later; consequently, low-avidity antibody can be used to specifically identify high-risk mothers with a primary infection. Overall to protect a fetus from TORCH infection, early diagnosis through first trimester screening is critical. Most TORCH infections are asymptomatic for the mother but can lead to serious birth defects or death for the fetus if left untreated.

KIT COMPONENTS

**TOXOPLASMA GONDII**

Toxoplasmosis is caused by the protozoan parasite *Toxoplasma gondii*. Transmission of *T. gondii* to the fetus can result in serious health problems, including mental retardation, seizures, blindness, and death. The risk of congenital disease is lowest (10 - 25%) when maternal infection occurs during the first trimester and highest (60 – 90%) when maternal infection occurs during the third trimester. However, congenital disease is more severe when infection is acquired in the first trimester. The overall risk of congenital infection from acute *T. gondii* infection during pregnancy ranges from approximately 20 - 50%. Toxoplasmosis usually is diagnosed on the basis of antibody detection and in acute infections, as IgG and IgM antibody levels generally rise within 1-2 weeks of infection. Specifically, the detection of *T. gondii*–specific IgM antibodies has been used as an aid in determining the time of infection: a negative IgM test result with a positive IgG result...
generally indicates a past infection (six months or more). It is important to note however, that the interpretation of *T. gondii*–specific IgM-positive results is complicated by the persistence of IgM antibodies up to 18 months after infection and by false-positive reactions in commercial tests.

Meridian Life Science manufactures a variety of Toxoplasma antigens in different purities and in commercial quantities. All Toxo antigens are propagated in HeLa cells and display both IgG and IgM immunoreactivity. All antigens are inactivated and tested for infectivity prior to final quality release. Depending on the antigen grade, purified toxoplasma antigens vary from >60-90% Tachyzoite protein.

**Toxoplasma gondii Antigen Grade II**

Catalog: EV9519
- Native Antigen
- 1 vial = 0.2mL
- Protein concentration: 0.8-1.2 mg/mL by BCA
- Buffer: Phosphate buffered saline. 0.15M NaCl, 0.05% NP40, pH 7.5 ± 0.2
- Ideal for IgM assay development
- Partially purified antigen containing NP40 for good dispersion of antigens.
- Inactivated and tested for infectivity prior to final quality release

**Toxoplasma gondii Antigen grade III**

Catalog: EV8131
- Native Antigen
- >90% viral protein
- 1 vial = 0.2mL
- Protein concentration: ≥0.5 mg/mL by BCA
- Buffer: Phosphate buffered saline. 0.15M NaCl, pH 7.5 ± 0.2
- Ideal for IgM assay development
- Highly enriched toxoplasma antigen. Purified by membrane enrichment and extraction.
- Inactivated and tested for infectivity prior to final quality release

**NOTE:** Sonicate for 1 second, 3 times at 10% amplitude before use. Avoid repeated freeze thaws. Store at ≤-65°C.

**RUBELLA VIRUS**

Rubella is a viral illness caused by a togavirus of the genus *Rubivirus* and is characterized by a mild, maculopapular rash. Rubella infection in the first trimester of pregnancy often results in spontaneous abortion or severe fetal defects associated with Congenital Rubella Syndrome, including heart, brain, ear or eye malformations, deafness, microcephaly, and mental retardation. Aggressive immunization of pre-school children has greatly reduced the incidence of rubella epidemics, but a need still exists for accurate monitoring of the immune status, especially for women of child-bearing age. Rubella-specific IgM can usually be detected 4–30 days after onset of illness. However, false-positive serum rubella IgM tests can occur due to the presence of rheumatoid factors, cross-reacting IgM, or infection with other viruses such as human parvovirus.

Meridian’s Rubella virus antigen is prepared by the concentration of cell culture fluid from cells infected with Rubella virus strain HPV77. The rubella virus is then purified by a proprietary method. This antigen is very sensitive with low backgrounds in ELISA and other solid phase immunoassays.

**Rubella virus Antigen Grade IV**

Catalog: 6076
- Native Antigen
- 1 vial = 0.2mL
- Protein concentration: 0.5 mg/mL by OD 260/280nm
- >90% pure, highly purified antigen
- Ideal preparation for IgM antibody testing
- Buffer: 10mM Tris, 150mM NaCl, 1.0 mM EDTA, pH 8.0-8.4
- Inactivated and tested for infectivity prior to final quality release

**NOTE:** Sonicate for 1 second, 3 times at 10% amplitude before use.
Avoid repeated freeze thaws. Store at ≤-65°C.
**CYTOMEGALOVIRUS**

Cytomegalovirus (CMV) is one of the herpesviruses. This group of viruses includes the herpes simplex viruses, varicella-zoster virus, and Epstein-Barr virus. CMV is the leading cause of congenital viral infection and the virus can be transmitted to the fetus during pregnancy after maternal primary infection or eventually the recurrence of a latent virus. Transmission generally results in severe complications (hepatosplenomegaly, microcephaly, hydrocephaly, low birth weight, prematurity, and mental retardation) and 1 of every 5 children born with congenital CMV infection will develop permanent problems (such as hearing loss or developmental disabilities).

Meridian Life Science, Inc. manufactures a variety of Cytomegalovirus (CMV) antigens with key protein mixtures, concentrations, and purities. CMV antigens are propagated in human fibroblast cells and infected with the same viral strain, AD169. At least 30 proteins form the complete infectious particle of CMV. Key immuno-diagnostic antigens of CMV infection include: pp65 & p52 (IgM associated), glycoprotein gB, pp150 (IgM & IgG associated), and others.

**CMV IgM Concentrate Antigen**

**Catalog: 7511**

- Native Antigen
- 1 vial = 0.2mL
- Protein concentration: 0.8 mg/mL by OD 260/280nm
- Buffer: 0.1M glycine buffer, pH 9.3 - 9.7
- Strain: AD169
- Partially Purified
- Ideal preparation for IgG and IgM antibody testing
- Process extracts antigens primarily from the nucleus and endoplasmic reticulum of the infected cells to enhance the amount of antigens reacting with the early IgM antibody
- Inactivated and tested for infectivity prior to final quality release

**NOTE:** Sonicate for 1 second, 3 times at 10% amplitude before use. Avoid repeated freeze thaws. Store at ≤-65°C.

**HERPES SIMPLEX VIRUS**

Herpes simplex virus (HSV) types 1 and 2 are members of the *Herpesviridae* family and produce infections that range from mild stomatitis to disseminated and fatal disease. Neonates are particularly vulnerable to HSV-1 and HSV-2 infections and in most cases, the infection is the result of vertical transmission during the peripartum period, and more rarely in utero or postpartum. Women with primary infections are 10 to 20 times more likely to transmit the virus to their infants than women with recurrent infections. Without prompt initiation of treatment, more than 70% of infected infants will progress to disseminated or central nervous system diseases. Serological assays that are able to differentiate between HSV-1 and HSV-2 are useful for HSV diagnosis and usually require detection of the IgG-class antibodies to type-specific HSV glycoprotein G (gG).

**HSV-1 Antigen**

**Catalog: 7305**

- Native antigen
- 1 vial = 0.4mL
- Partially purified whole cell lysate
- Protein concentration: 0.25 – 0.35 mg/mL by OD 260/280nm
- Buffer: 0.1M glycine buffer, pH 9.3 - 9.7
- Inactivated and tested for infectivity prior to final quality release

**HSV-2 Antigen**

**Catalog: 7705**

- Native antigen
- 1 vial = 0.4mL
- Partially purified whole cell lysate
- Protein concentration: 0.2 – 0.4 mg/mL by OD 260/280nm
- Buffer: 0.1M glycine buffer, pH 9.3 - 9.7
- Inactivated and tested for infectivity prior to final quality release

**NOTE:** Sonicate for 1 second, 3 times at 10% amplitude before use. Avoid repeated freeze thaws. Store at ≤-65°C.
HSV-1 gG Antigen
Catalog VTI520

- Recombinant antigen
- Produced in *Saccharomyces cerevisiae*
- 1 vial = 0.2mL
- Protein concentration: 1.7 mg/mL by BCA
- Buffer: 0.5M Malonate, 6M Urea, pH 5.2 ± 0.2
- Detects the glycoprotein G N-terminal region (amino acids 1-190).

NOTE: Sonicate for 1 second, 3 times at 10% amplitude before use. Avoid repeated freeze thaws. Store at ≤-65°C.

HSV-2 gG Antigen
Catalog VTI530

- Recombinant antigen
- produced in *Saccharomyces cerevisiae*
- 1 vial = 0.2mL
- Protein concentration: 1.0-3.0 mg/mL by BCA
- Buffer: 50mM Sodium Phosphate, 160nM KCl, 5mM DTT, pH 7.0 ± 0.1
- Detects the glycoprotein gG-specific and unique sequences (amino acids Leu343-Asp649), not present in HSV-1

OTHER ANTIGENS FOR THE TORCH PANEL ARE AVAILABLE IN ADDITION TO SAMPLES INCLUDED IN THIS KIT. PLEASE VISIT US AT WWW.MERIDIANLIFESCIENCE.COM TO LEARN ABOUT OTHER PRODUCTS.

SHIPPING & STORAGE
Ship in dry ice, Store at ≤-65°C

References:

FOR RESEARCH OR FURTHER MANUFACTURING USE

Meridian Life Science, Inc.
5171 Wilfong Rd. / Memphis, TN 38134
www.meridianlifescience.com
Orders/Inquiries: info@meridianlifescience.com
Tel: 901.382.8716 / Fax: 901.333.8223