Product Information Sheet

Microbix Biosystems Inc.
265Watline Avenue
Mississauga, Ontario Canada L4Z 1P3
Tel 905-361-8910 Fax 905-361-8911

Product Name:

Toxoplasma gondii Antigen, IgM Grade

Catalogue Number: EL-18-08

Storage: Store this antigen preparation frozen at - 70 to - 100 °C. Repeated freezing and thawing should be avoided.

Hazards: We are aware of no specific hazards associated with this product. The reagent has been inactivated and should contain no infectious material. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

Strain: RH

Cultured In: Vero Cells

*Buffer:*2% N-octyl-β-D-glucopyranoside (OGP) in Phosphate Buffered Saline pH 7.4

Disease Description: Toxoplasma in healthy individuals is most often asymptomatic. When symptomatic disease occurs it often resembles mononucleosis or may be limited to an ocular infection. Subclinical infections may surface some years after infection when the individual becomes immunocompromised. In these patients the result is often cerebral infection. Congenital infections are the primary area of concern as the symptoms may involve severe defects of the central nervous system and eyes which is often fatal.

Preparation: Confluent cultures of Vero cells are infected with Toxoplasma and the infection is allowed to proceed. Cells are harvested and disrupted to harvest tachyzoites, which are washed and the concentration adjusted. Tachyzoities are then disrupted and purified using a method designed to enrich membrane fractions, including the apical complex which is thought to be associated with active motility during parasite invasion and is reactive with IgM antibodies. The material is inactivated and standardized based on the ELISA results compared to a reference antigen. This antigen preparation contains a high concentration of disrupted tachyzoites in phosphate buffered saline.

Inactivation: Detergent treatment.

Recommendations for Use: This preparation may be used as is in a variety of immunoassay formats where high purity Toxoplasma antigens are required, particularly when clear differentiation is required between IgM positive and IgM negative sera.

Assistance: If you have any questions regarding the production, testing or use of this antigen, please send them by email to customer.service@microbix.com or call +1-905-361-8910 with any relevant data. Your complete satisfaction with the performance of this product is important to us.

Quality Control Information

Product Name: Toxoplasma gondii Antigen, IgM Grade *Lot Number:* 18104A1

Microbix performs quality control tests to ensure each batch meets in-house specifications. Test results are provided with each lot of antigen shipped. Antigen users require this information for a number of reasons:

- to maintain a record for good manufacturing purposes,
- to correlate user results with Microbix results and
- for use as a starting point for those just starting with either a new antigen or developing a new assay.

It is important that each user perform titrations of antigen using their own assay as each assay format and serum release panel makes different performance demands on the antigen. Often, use of an antigen may be optimized by making adjustments to concentrations of other assay reagents such as conjugate. Once this is complete, the result is cost effective use of the antigen and optimal assay performance.

Test:

Protein Concentration: Protein is determined using the BCA assay using a BSA standard curve.

Result: 0.65 mg/mL

Serum detection: Antigen is screened by ELISA using sera known positive and negative for the relevant immunoglobulin. Result must be within 20% of the reference antigen.

Result: Pass

Inactivation Assay: The effectiveness of inactivation is tested by attempting culture in Vero cells under optimal conditions for 7 days. If no growth is detected, the preparation is considered inactivated.

Result: No growth detected

Expiry Date: No expiry is required if the antigen is stored at -70 to -100 °C. The antigen is stable for 28 days at 4°C.

Quality Assurance Signature 05 June, 2015