



**Microbix Biosystems Inc.**

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*Product Name:*

## Toxoplasma gondii Antigen

*Catalogue Number:* EL-18-07

*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:* 1% Triton x-100, 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. 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. Some residual biological components from cell culture, as well as detergent are present in the final product.

*Inactivation:* Detergent treatment

*Recommendations for Use:* Toxoplasma gondii antigen should be sonicated immediately prior to use to ensure that the preparation is uniform. This preparation may be used as is, in a variety of immunoassay formats where a high titre, multi-protein Toxoplasma preparation is ideal such as solid phase IgG ELISA.

*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](mailto: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

*Lot Number:* 18103A1

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 with a BSA standard curve.

*Result:* 1.177 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