



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

*Product Name:*

## Dengue Type 2 Antigen

*Catalogue Number:* EL-22-02

*Storage:* Store this antigen preparation frozen at - 70 °C 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:* 16681

*Cultured In:* Vero

*Buffer:* Medium 199

*Preparation:* Dengue virus particles are concentrated from tissue culture supernatants by precipitation and ultracentrifugation. The antigen is then purified by sucrose density gradient centrifugation. Virus particles are separated from the sucrose containing buffer by ultracentrifugation and the antigen is resuspended in Medium 199.

*Inactivation:* Dengue virus is inactivated by room temperature incubation with formaldehyde. The formaldehyde is neutralized with the addition of sodium bisulphite.

*Description:* This antigen is a highly purified preparation of Dengue 2 virus particles.

*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 fax 905-361-8911, with any relevant data, to Microbix Technical Services. Your complete satisfaction with the performance of this product is important to us.

## Quality Control Information

*Product Name:* Dengue Type 2 Antigen

*Lot Number:* 22053A1

Microbix performs qualitative and quantitative tests on all developmental antigens. 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:*

*Activity:* This antigen preparation is titrated using a microtitre plate based ELISA. (This procedure may be found in Microbix Technical Bulletin number 93-1.) Antigens are tested for reactivity with IgG. The dilution of antigen which generates a signal of 1.0 O.D. unit in the immunoassay is compared to that of the standard approved antigen. The result of this comparison is expressed as a percentage of the reference.

*Result:* 224 % of reference

*Protein Concentration:* Protein is determined using the Biorad dye binding assay in the microassay format. The standard curve is generated with a known concentration of IgG.

*Result:* 0.89 mg/mL

*Inactivation Assay:* The formalin treated antigen is inoculated onto vero cell monolayers. Potentially infected monolayers are then overlaid with a semisolid medium. These are incubated 6 days and are overlaid with semisolid medium containing neutral red dye. On the seventh day, the monolayers are examined for plaques. One live virus particle is capable of developing a plaque. The preparation is considered inactivated when no plaques are observed at undiluted and all dilutions.

*Result:* No growth detected



Quality Assurance Signature:

31-May, 2011