



Product Name: Dengue Type 1 Antigen

Catalogue Number: EL-52-02

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

Hazards: The material is to be treated in accordance with local laws and best laboratory practices governing the use of hazardous biomaterial including Dengue virus. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

ICTV: 00.026.0.01.013.08.001

Strain: West Pacific 74

Cultured In: Vero cells.

Buffer: Potassium phosphate based buffer, pH 7.2

Preparation: Dengue virus 1 cultured in Vero cells is purified from tissue culture supernatant by chromatography. Following the chromatographic purification, the buffer is exchanged for potassium phosphate based buffer, pH 7.2 by dialysis.

Description: This antigen is a purified preparation of Dengue 1 virus particles. It is suitable for use in assays for detection of presence of antibodies against Dengue virus, and as a positive control for the presence of the Dengue virus antigens in a sample. The product is formulated in a buffer that should not interfere with conjugation chemistries that are typically used in immunoassay development.

Quality Control Information

Product Name: Dengue Type 1 Antigen

Lot Number: 52004A1

Microbix performs qualitative and quantitative tests on all 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.

Tests:

Quantitation by PCR: The product was analysed by PCR to determine quantity of viral RNA

Specification: > 10⁸ copies/mL

Result: 8.61 x 10⁹ copies/mL

ELISA Activity: ELISA activity of the product was evaluated in a sandwich ELISA using monoclonal against epitopes of E1 protein. The preparation showed that the material is suitable for immunoassay based tests.

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

Result: 0.79 mg/mL

Inactivation: The material is inactivated by gamma irradiation that damages nucleic acid. The effectiveness of the inactivation is assessed by the ability of Dengue virus to propagate in the cell culture based assay.

Result: No growth detected

Quality Assurance Signature:



Date: 02 September, 2016



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 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.