



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 cells.

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.

Quality Control Information

Product Name: Dengue Type 2 Antigen

Lot Number: 22093A2

Expiry date: 12 November, 2020

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.

Tests:

Specific Activity: This antigen preparation is titrated using a micro titre 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: 200 % of reference antigen

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: 1.1 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:



22 August, 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.