

Product Name: Measles grade 2 Antigen

Catalogue Number: EL-04-02

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

Hazards: The product has been inactivated. No test method guarantees a product to be non-infectious. All products should be handled as if potentially infectious. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

Strain: Edmonston

Cultured In: Vero cells.

Buffer: MEM

Agent Description: Measles is part of the family Paramyxoviridae, Morbillivirus; It is a 300 nm diameter, enveloped; single-stranded RNA. Acute disease with prodromal fever, conjunctivitis, coryza, cough and Koplik spots on the buccal mucosa; red blotchy rash appears in 3 -7 days, beginning on the face and becoming generalized, lasting 4 - 7 days; leukopenia; more severe in infants and adults; bacterial superinfection.

Preparation: Optimally infected cells are disrupted in culture fluids. The suspension is clarified and concentrated by crossflow ultrafiltration.

Inactivation: Measles antigen is inactivated using gamma radiation. This procedure is effective primarily by damaging viral genetic material.

Description: The resulting antigen preparation contains a high concentration of virus and viral components as well as some cellular material suspended in MEM.

Recommendations for Use: This antigen preparation 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 or may be further purified to meet the needs of a particular assay format. Grade 2 antigen is widely used for both IgG and IgM detection in assays which include EIA with polystyrene and latex solid phases.

Quality Control Information

Product Name: Measles grade 2 Antigen

Lot Number: 04XXXXX

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:

Titre: This antigen preparation is titrated using a microtitre plate based ELISA. 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.

IgG Result: XXX %

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: XXX mg/mL

Inactivation Assay: The effectiveness of inactivation is tested by inoculating a BSC-1 monolayer with antigen. The culture is manipulated using the original optimal culture conditions used to manufacture the antigen. The culture is monitored for cytopathic effect for 5 days. If no sign of infection is observed the culture is passaged into a fresh monolayer. The second passage is monitored for a further 5 days. If no cytopathic effect is observed in either passage the antigen is considered inactivated.

Result: No growth detected

Quality Assurance Signature:

Date:



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.