



Microbix Biosystems Inc.

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Product Name:

Mumps grade 2 Antigen

Catalogue Number: EL-06-02

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: Enders

Cultured In: BSC-1

Buffer: 1969B

Agent Description: Mumps virus is a member of the Paramyxoviridae family. There is only one serotype. The virion is pleomorphic with a roughly spherical shape and a diameter of 85 to 300 µm. The nucleocapsid is composed of a continuous linear molecule of single-stranded RNA that is tightly coiled in a helical formation and a capsid protein with RNA polymerase activity. The nucleocapsid is surrounded by a lipid envelope composed of three layers. The inner surface is a protein that supports the outer layers, the middle is a lipid bilayer acquired as the virion buds from the host cell, and the external layer is studded with glycoproteins that carry receptor-destroying, hemagglutinating and cell fusion activity. The hemagglutinating protein binds to sialic acid residues on target cells to initiate infection. The cell fusion protein is responsible for the fusion of lipid bilayers that enables penetration of the virus and cell-to-cell spread of infection.

Preparation: Optimally infected cells are harvested, disrupted by sonication in culture medium and then subjected to low speed centrifugation. The supernatant from the infected culture is concentrated using crossflow ultrafiltration.

Inactivation: Mumps 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 1969B.

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.

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.

Quality Control Information

Product Name: Mumps grade 2 Antigen

Lot Number: 06017A3

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:

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: 192.0%

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: 2.26 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:

30-August, 2010