



Microbix Biosystems Inc.

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Product Name:

Parainfluenza 3 grade 2 Antigen

Catalogue Number: EL-10-02

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: C243

Cultured In: Vero

Buffer: Tissue Culture Media

Disease and Agent Description: Parainfluenza viruses causes lower respiratory tract infections in children. Parainfluenza viruses are membrane-bound single-stranded RNA viruses and part of the family Paramyxoviridae. Four serotypes, designated 1, 2, 3 and 4 are recognized. Types 1 and 2 generally induce laryngotracheobronchitis but occasionally cause pneumonitis.

Preparation: Optimally infected monolayers are harvested, disrupted by sonication and then subjected to low speed centrifugation. The clarified cell lysate is pooled with supernatant from the infected culture and concentrated using crossflow ultrafiltration.

Inactivation: Gamma radiation inactivation

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

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: Parainfluenza 3 grade 2 Antigen

Lot Number: 10014A2

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:

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: 1.58 mg/ml

ELISA Activity: 164.4% of reference.

Inactivation Assay: The effectiveness of inactivation is tested by inoculating a Vero 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:

04-March, 2010