

Product Name: Varicella Zoster grade 2 Antigen

Catalogue Number: EL-03-02

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: VZ-10

Cultured In: MRC-5.

Buffer: EMEM

Agent Description Varicella Zoster virus (VZV) belongs to the herpesvirus family. VZV is a large virus with a diameter of about 180 - 200 nm; its dense core is 100 nm in diameter and is covered by an icosahedral capsid composed of 162 tubular capsomers, in turn covered by a lipid bilayer envelope. The core contains linear double-stranded DNA with a molecular weight of about 10^8 Daltons. VZV infections induces the production of specific proteins and glycoproteins by the host cell.

Preparation: Optimally infected monolayers are harvested, resuspended in a small volume of tissue culture fluid and disrupted by sonication. The suspension is subjected to low speed centrifugation and the resulting supernatant constitutes the antigen preparation.

Inactivation: Varicella Zoster 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 EMEM with some serum proteins.

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: Varicella Zoster grade 2 Antigen

Lot Number: 03XXXXX

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 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.

IgG Result: XXX% 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: XXX mg/mL

Inactivation Assay: The effectiveness of inactivation is tested by inoculating a MRC-5 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 3 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.