

Product Name: HSV type 2 grade 2 Antigen

Catalogue Number: EL-23-02

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: MS

Cultured In: BSC-1, a cell line derived from African Green Monkey kidney

Buffer: Tissue culture medium

Agent Description: Herpes simplex virus (HSV) is a double stranded DNA, enveloped virus, 110 nm to 120 nm in diameter. The icosahedral viral capsid is assembled in the host cell nucleus followed by the virus acquiring its envelope by budding through the nuclear membrane at sites modified by the addition of viral protein. The HSV genome encodes over 50 polypeptides, including 9 glycoproteins (gB to gJ), at least 6 capsid proteins, viral protein kinase and DNA polymerase. There are two serotypes, HSV type 1 and HSV type 2 that can be differentiated on the basis of antigenicity of glycoprotein gG. The serotypes have approximately 40% homology leading to antigenic cross reactivity.

Preparation: HSV type 2 grade 2 antigen is collected from both the cell and supernatant phases of tissue culture. Harvest of antigen is carried out by disrupting optimally infected monolayers into the tissue culture medium. Cellular debris is removed by centrifugation.

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

Description: Grade 2 antigen contains a high concentration of virus particles and components in tissue culture medium containing a low concentration of bovine serum. The preparation contains no preservative or detergent. Some residual host cellular material is present.

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: HSV type 2 grade 2 Antigen

Lot Number: 23XXXXX

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 %

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.