

Product Name: Hepatitis A Antigen

Catalogue Number: EL-25-01

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: HM-175

Cultured In: FRhK₄, an established cell line from foetal Rhesus Monkey kidney.

Buffer: Glycine pH 9.5

Agent Description: Hepatitis A virus is a non-enveloped, icosahedral virion with a single stranded RNA genome. Only one serotype of HAV is known and it does not cross react with Hepatitis B virus. The virus contains four proteins VP1, VP2, VP3 and VP4.

Preparation: Cells which have been infected with HAV are collected by centrifugation. Pelleted cells are resuspended in glycine buffer and the cells are disrupted releasing the viral particles. Cellular debris is removed by centrifugation and the antigen preparation is further purified by extraction with Galden Perfluorosolv. The final concentration of HAV antigen is adjusted to meet specifications by dilution.

Inactivation: HAV grade 2 Antigen is inactivated by incubating with formaldehyde for 96 hours.

Description: This preparation contains a high concentration of viral antigen. Its predominant form is as whole virions. The material contains no detergent and a low concentration of formaldehyde with some residual host cellular material.

Recommendations for Use: HAV antigens 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 manipulated to purify virions or extract individual viral proteins.

Quality Control Information

Product Name: Hepatitis A grade 2 Antigen

Lot Number: 25XXXXX

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.

This product is not suitable for use as a molecular control in nucleic acid testing.

Tests:

Antigen Activity: This antigen preparation is titrated using an antigen capture EIA. 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.

Result: XXX % of reference antigen (lot 25033A1)

Protein Concentration: Protein is determined using the Bradford (Bio-Rad) assay. The standard curve is generated with a known concentration of Bovine IgG.

Result: XXX mg/mL

Inactivation Assay: The effectiveness of inactivation is tested by inoculating a FRhK₄ monolayer with antigen. The infection is done in such a way that the effect of residual formaldehyde is negated. The culture is manipulated using the original optimal culture conditions used to manufacture the antigen. The culture is monitored for HAV 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.