



## Product Information Sheet

**Product Name:** CMV grade 2 Antigen

**Catalogue Number:** EL-01-02

**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:** AD-169

**Cultured In:** MRC-5, a diploid cell line of human lung origin.

**Buffer:** Glycine buffered saline (GBS) pH 9.5

**Preparation:** MRC-5 monolayers are infected in a manner which will ensure that the full host of viral proteins is present upon harvest. Optimally infected tissue is collected and put into glycine buffered saline. The cells are disrupted to release cell phase CMV antigen. Cellular debris is removed by centrifugation.

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

**Description:** This preparation contains CMV antigens from all parts of the virus cycle of replication including early and late antigens, nuclear antigen, cytoplasmic antigen, structural and non-structural proteins. The antigen is in GBS without detergent or preservative. This preparation contains residual host cellular material.

**Recommendations for Use:** CMV antigen 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 and M capture formats.

## Quality Control Information

**Product Name:** CMV grade 2 Antigen

**Lot Number:** 01XXXXX

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.

### **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

**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 CMV 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](mailto: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.