

Product Data Sheet – Native Antigen

Name of product	Cytomegalovirus (CMV) Antigen
Order No.	BA109VS
Lot No.	Lot specific
Agent	Cytomegalovirus, strain Towne
Culture system	HEL 299 cell culture
Preparation	Infected cells are harvested, washed and virus extracted by alkaline treatment and sonication. The resulting antigen preparation consists of a high concentration of virus and viral components and contains residual host cell material. The antigen is presented in 100 mM glycine buffer, pH 9.5.
Pathogen inactivation	β -Propiolactone treatment. No specific biological hazards are known to be associated with this product. It should be handled with appropriate safety precautions for biological materials.
Storage	-65 °C or below. Avoid repeated freeze-thaw cycles. Sonicate before use.
Date of manufacture	Lot specific
Expiry	10 years from date of manufacture (when stored under recommended conditions)
Manufacturer	Institut Virion\Serion GmbH, Germany

For research or manufacturing use only. Not for use in diagnostic procedures.

2018-07-10

Analysis:

Test	Method	Specification
Protein concentration	Bradford assay (Bio-Rad) with BSA as reference standard	2 – 6 mg/mL
Immunoreactivity	SERION ELISA classic Cytomegalovirus	QC serum panel (multiple negative, borderline and positive sera) within defined reactivity range
Inactivation assay	Attempted pathogen recultivation under original culture conditions	No propagation observed
Bioburden	Membrane filtration test	\leq 100 cfu/mL