Product Data Sheet - Native Antigen

Name of product	Mumps Virus Antigen	
Order No.	BA103VS	
Lot No.	Lot specific	
Agent	Mumps virus, strain Enders	
Culture system	Vero cell culture	
Preparation	Mumps virus infected cells are harvested and virus is extracted by alkaline treatment and sonication. Following clarification, the suspension is purified and concentrated by ultracentrifugation. The resulting antigen preparation consists of a high concentration of virus and viral components and contains residual host cell material. The antigen is suspended 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.

2018-01-15

Analysis:

Test	Method	Specification
Protein concentration	Bradford assay (Bio-Rad) with BSA as reference standard	2 – 5 mg/mL
Immunoreactivity	SERION ELISA classic Mumps Virus IgG (ESR103G) and IgM (ESR103M)	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	≤ 100 cfu/mL