Product Data Sheet - Native Antigen

Name of product	Varicella Zoster Virus (VZV) Antigen	
Order No.	BA104VS	
Lot No.	Lot specific	
Agent	Varicella zoster virus, strain Ellen	
Culture system	HEL 299 cell culture	
Preparation	VZV infected cells are harvested and virus is extracted by alkaline treatment and sonication. The preparation is purified by ultracentrifugation through a sucrose cushion. The resulting antigen consists of a high concentration of virus and viral components, it may contain residual host cell material. The antigen is suspended in 100 mM glycine buffer, pH 9.5.	
Pathogen inactivation	Physical inactivation. 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.

2018-01-1

Analysis:

Test	Method	Specification
Protein concentration	Bradford assay (Bio-Rad) with BSA as reference standard	4-8 mg/mL
Immunoreactivity	SERION ELISA classic Varicella Zoster Virus IgM (ESR104M)	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