

Product Data Sheet – Native Antigen

Name of product	Borrelia garinii Antigen
Order No.	BA121GVS
Lot No.	Lot specific
Agent	Borrelia garinii, strain CIP 103362
Culture system	Broth culture
Preparation	Harvested bacteria are washed and detergent solubilised to produce a cytoplasmic extract enriched with lipoproteins and outer surface proteins (OSPs). The antigen is presented in phosphate buffered saline containing 1 % n-octyl- β -D-glucopyranoside.
Pathogen inactivation	Detergent 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.

2023-03-01

Analysis:

Test	Method	Specification
Protein concentration	Bradford assay (Bio-Rad) with BSA as reference standard	1 – 5 mg/mL
Immunoreactivity	SERION ELISA classic Borrelia burgdorferi IgG (ESR121G) and IgM (ESR121M)	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, sterility assurance level (SAL) $\leq 10^{-6}$
Bioburden	Membrane filtration test	≤ 100 cfu/mL