

Product Data Sheet – Native Antigen

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| Name of product | Borrelia afzelii Antigen |
| Order No. | BA121VS |
| Lot No. | Lot specific |
| Agent | Borrelia afzelii, strain PKo |
| 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 |