

Product Data Sheet – Native Antigen

Name of product	Brucella abortus Antigen
Order No.	BA116VS
Lot No.	Lot specific
Agent	Brucella abortus, strain S99 - Weybridge
Culture system	Fermentation
Preparation	Bacterial lysate in glycine buffer (pH 9.5) containing n-octyl-β-D-glucopyranoside.
Pathogen inactivation	The pathogen raw material used in this product has been treated with heat (1 hour, 65 °C), phenol (0.5 %, w/w) and detergent and has passed sterility testing in quality control. 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.
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	0.15 – 1 mg/mL
Immunoreactivity	SERION ELISA classic Brucella IgA (ESR116A), IgG (ESR116G) and IgM (ESR116M)	QC serum panel (multiple negative, borderline and positive sera) within defined reactivity range
Bioburden	Membrane filtration test	≤ 10 cfu/mL