

Product Data Sheet – Native Antigen

Name of product	Candida albicans Antigen
Order No.	BA117VS
Lot No.	Lot specific
Agent	Candida albicans (wild strain)
Culture system	Solid medium
Preparation	Organisms are washed, disrupted and subjected to an extraction process. The antigen consists of cytoplasmic and cell wall components, presented in alkaline pH glycine buffer.
Pathogen inactivation	Sterile filtration. 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.

2021-04-19

Analysis:

Test	Method	Specification
Protein concentration	Bradford assay (Bio-Rad) with BSA as reference standard	0.5 – 2 mg/mL
Immunoreactivity	SERION ELISA classic Candida albicans IgA (ESR117A), IgG (ESR117G) and IgM (ESR117M)	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