

Product Data Sheet – Native Antigen

Name of product	Toxoplasma gondii Antigen
Order No.	BA110VS
Lot No.	Lot specific
Agent	Toxoplasma gondii, strain RH
Culture system	Vero cell culture
Preparation	Disrupted Toxoplasma 'ghosts' treated with detergent and further purified. The antigen is presented in cell culture medium containing n-octyl-β-D-glucopyranoside.
Pathogen inactivation	Disruption and 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.

2021-11-22

Analysis:

Test	Method	Specification
Protein concentration	Bradford assay (Bio-Rad) with BSA as reference standard	0.3 – 2 mg/mL
Identity / Purity	SDS-PAGE (reducing)	Major bands comparable to Reference Standard
Immunoreactivity	SERION ELISA classic Toxoplasma gondii IgG (ESR110G) and IgM (ESR110M)	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