

## Product Data Sheet – Native Antigen

<b>Name of product</b>	Helicobacter pylori Antigen
<b>Order No.</b>	BA118VS
<b>Lot No.</b>	Lot specific
<b>Agent</b>	Helicobacter pylori, strain NCTC 11637
<b>Culture system</b>	Solid medium
<b>Preparation</b>	Bacteria are harvested, washed and solubilised. The antigen is partially purified by detergent extraction and centrifugation. It is presented in a 1 % non-ionic detergent solution.
<b>Pathogen inactivation</b>	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.
<b>Storage</b>	-65 °C or below. Avoid repeated freeze-thaw cycles. Sonicate before use.
<b>Date of manufacture</b>	Lot specific
<b>Expiry</b>	10 years from date of manufacture (when stored under recommended conditions)
<b>Manufacturer</b>	Institut Virion\Serion GmbH, Germany

*For research or manufacturing use only. Not for use in diagnostic procedures.*

2019-03-25

### Analysis:

Test	Method	Specification
<b>Protein concentration</b>	Bradford assay (Bio-Rad) with BSA as reference standard	3 – 6 mg/mL
<b>Identity / Purity</b>	SDS-PAGE (reducing)	Major bands comparable to Reference Standard
<b>Immunoreactivity</b>	SERION ELISA classic Helicobacter pylori IgA (ESR118A), IgG (ESR118G) and IgM (ESR118M)	QC serum panel (multiple negative, borderline and positive sera) within defined reactivity range
<b>Inactivation assay</b>	Attempted pathogen recultivation under original culture conditions	No propagation observed