

## Product Data Sheet – Native Antigen

<b>Name of product</b>	Bordetella pertussis Filamentous Hemagglutinin (FHA)
<b>Order No.</b>	BA120VS3
<b>Lot No.</b>	Lot specific
<b>Agent</b>	Bordetella pertussis, Strain Tohama I
<b>Culture system</b>	Broth culture
<b>Preparation</b>	Filamentous hemagglutinin (FHA), highly purified from Bordetella pertussis culture supernatant. FHA is presented in buffer containing Tris/HCl pH 8.0, 500 mM NaCl and 50 % glycerol.
<b>Pathogen inactivation</b>	Whole B. pertussis organisms are removed by 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.
<b>Storage</b>	-65 °C or below. Avoid repeated freeze-thaw cycles.
<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.*

2022-10-13

### Analysis:

Test	Method	Specification
<b>Protein concentration</b>	UV absorption measurement (280 nm)	0.15 – 0.5 mg/mL
<b>Identity / Purity</b>	SDS-PAGE (reducing)	Major bands comparable to Reference Standard
<b>Identity</b>	Western Blot	Major bands comparable to Reference Standard
<b>Immunoreactivity</b>	SERION ELISA classic Bordetella pertussis IgA (ESR120A) and IgG (ESR120G)	QC serum panel (multiple negative, borderline and positive sera) within defined reactivity range
<b>Inactivation assay</b>	Absence of viable bacteria is confirmed by attempted growth under original culture conditions	No colonies observed
<b>Bioburden</b>	Membrane filtration test	≤ 100 cfu/mL