Product Data Sheet - Native Antigen

Name of product	Bordetella pertussis whole-cell Antigen	
Order No.	BA120VS8	
Lot No.	Lot specific	
Agent	Bordetella pertussis, Strain Tohama I	
Culture system	Broth culture	
Preparation	Bordetella pertussis bacteria are harvested from broth culture, washed and inactivated by treatment with β -propiolactone. The antigen is presented in glycine buffer at alkaline pH.	
Pathogen inactivation	β-Propiolactone 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.	
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	2 – 5 mg/mL
Immunoreactivity	SERION ELISA classic Bordetella pertussis IgM (ESR120M)	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