

Yersinia pestis* F1-V Fusion Protein, Monomer-Enriched Antigen, Recombinant from *Escherichia coli

Catalog No. NR-2561

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Product Description: Recombinant *Yersinia pestis* (*Y. pestis*) F1-V fusion protein, monomer-enriched antigen was purified from *Escherichia coli* and depleted of DNA and endotoxin.

Lot: L0604016

Manufacturing Date: 01JUN2006

TEST	SPECIFICATIONS	RESULTS
Appearance	Colorless, clear to slightly opalescent	Colorless, clear
SDS-PAGE (Reduced; Coomassie Blue)	Major band at ~ 51 ± 5 kDa	Major band at ~ 51 kDa
Identification by Western Blot Antibody to F1 protein Antibody to V protein	Major band at ~ 51 ± 5 kDa Major band at ~ 51 ± 5 kDa	Major band at ~ 51 kDa Major band at ~ 51 kDa
SDS-PAGE (Reduced; Silver stain)	Report results	Major band at ~ 51 kDa Trace dimer band at ~ 102 kDa
SDS-PAGE (Reduced; SYPRO Ruby Stain, Fluorometric Scan)	≥ 95% fluorescent intensity at ~ 51 kDa	98.4% fluorescent intensity at ~ 51 kDa
Size-Exclusion HPLC Monomer	≥ 60%	98.35%
Concentration by Spectrophotometer at OD₂₈₀ (ε₂₈₀, 1 mg/mL = 0.468)	≥ 1.35 mg/mL ¹	1.64 mg/mL
Functional Activity Western Blot Antibody to F1 protein Antibody to V protein Toxicity in murine <i>Y. pestis</i> model ²	Reactive Reactive Protective to ≥ 10 ⁷ LD ₅₀	Reactive Reactive Protective to 3.3 X 10 ⁸ LD ₅₀ 17 of 18 (94%) survived 10 ⁷ LD ₅₀ 12 of 18 (67%) survived 10 ⁸ LD ₅₀ 6 of 18 (33%) survived 10 ⁹ LD ₅₀
Bioburden	No growth	No growth
Sterility	0.2 μm filter sterilized	0.2 μm filter sterilized
Endotoxin Content (Limulus Amoebocyte Lysate assay)	≤ 5 EU/mL	< 0.05 EU/mL
Host Cell Genomic DNA (qPCR) <i>Escherichia coli</i>	≤ 100 pg/mL	0.7 pg/mL
pH (post-vialing)	9.9 ± 0.4	9.6

¹Manufacturing target concentration is 1.5 mg/mL.

²After two-stage, 20-μg subcutaneous vaccination with Alhydrogel-absorbed F1-V intermediate bulk. Control subjects were given subcutaneous Alhydrogel alone.

Date: 02 OCT 2008

Signature: Signature on File

Title: Technical Manager, BEI Authentication or designee

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