Certificate of Analysis for NR-2561

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

Catalog No. NR-2561
This reagent is the tangible property of the U.S. Government.

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: L0508003 **Manufacturing Date: 10AUG2005**

TEST	SPECIFICATIONS	RESULTS
Appearance	Colorless, clear to slightly opalescent	Colorless, clear to slightly opalescent
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 Characteristic pattern below ~ 51 kDa
SDS-PAGE (Reduced; SYPRO Ruby stain, Fluorometric Scan)	≥ 95% fluorescence intensity at ~ 51 kDa	≥ 97% fluorescence intensity at ~ 51 kDa
Size-Exclusion HPLC Monomer Dimer Multimer	 ≥ 60% Report results Report results	 69.8% 19.4% 10.8%
Concentration by Spectrophotometer at OD_{280}	1.5 mg/mL ± 0.15 mg/mL	1.51 mg/mL
Functional Activity Western Blot Antibody to F1 protein Antibody to V protein Toxicity in murine *Y. pestis* model[1]	 Reactive Reactive Protective to ≥ 10^7 LD_{50}	 Reactive Reactive Protective to ≥ 10^8 LD_{50} 7 of 9 survived 10^7 LD_{50} 8 of 10 survived 10^8 LD_{50} 4 of 8 survived 10^9 LD_{50} 0 of 10 controls survived 10^7 LD_{50}
Bioburden	0 colony-forming units/mL	0 colony-forming units/mL
Sterility	0.2 μm filter sterilized	0.2 μm filter sterilized
Endotoxin Content (Limulus Amoebocyte Lysate assay)	≤ 5 EU/mL	0.44 EU/mL
Host Cell Genomic DNA (qPCR) *Escherichia coli*	 ≤ 100 pg/mL	 1.8 pg/mL
pH (post-vialing)	9.9 ± 0.4	9.52

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

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Manassas, VA 20108-4137 USA
www.beiresources.org
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Date: 24 April 2008 **Signature:** Signature on file

Title: Technical Manager, BEI Authentication or designee

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Manassas, VA 20108-4137 USA
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