

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

### **Catalog No. NR-2562**

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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: L0508005**

**Manufacturing Date: 10AUG2005**

TEST	SPECIFICATIONS	RESULTS
<b>Appearance</b>	Colorless, clear to slightly opalescent	Colorless, clear to slightly opalescent
<b>SDS-PAGE (Reduced; Coomassie Blue)</b>	Major band at ~ 51 ± 5 kDa	Major band at ~ 51 kDa
<b>Identification by Western Blot</b> 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
<b>SDS-PAGE (Reduced; Silver stain)</b>	Report results	Major band at ~ 51 kDa Trace dimer band at ~ 102 kDa Characteristic pattern below ~ 51 kDa
<b>SDS-PAGE (Reduced; SYPRO Ruby stain, Fluorometric Scan)</b>	≥ 95% fluorescence intensity at ~ 51 kDa	≥ 97% fluorescence intensity at ~ 51 kDa
<b>Size-Exclusion HPLC</b> Monomer Dimer Multimer	≥ 60% Report results Report results	69.1% 19.3% 11.6%
<b>Concentration by Spectrophotometer at OD<sub>280</sub></b>	Report results	1.15 mg/mL
<b>Functional Activity</b> Western Blot Antibody to F1 protein Antibody to V protein Toxicity in murine <i>Y. pestis</i> model <sup>1</sup>	Reactive Reactive Protective to ≥ 10 <sup>7</sup> LD <sub>50</sub>	Reactive Reactive Protective to ≥ 10 <sup>8</sup> LD <sub>50</sub> 7 of 9 survived 10 <sup>7</sup> LD <sub>50</sub> 8 of 10 survived 10 <sup>8</sup> LD <sub>50</sub> 4 of 8 survived 10 <sup>9</sup> LD <sub>50</sub> 0 of 10 controls survived 10 <sup>7</sup> LD <sub>50</sub>
<b>Bioburden</b>	0 colony-forming units/mL	0 colony-forming units/mL
<b>Sterility</b>	0.2 μm filter sterilized	0.2 μm filter sterilized
<b>Endotoxin Content (Limulus Amoebocyte Lysate assay)</b>	≤ 5 EU/mL	0.18 EU/mL
<b>Host Cell Genomic DNA (qPCR)</b> <i>Escherichia coli</i>	≤ 100 pg/mL	1.2pg/mL
<b>pH (post-vialing)</b>	9.9 ± 0.4	9.3 <sup>2</sup>

<sup>1</sup>After two-stage, 20-μg subcutaneous vaccination with Alhydrogel-absorbed F1-V intermediate bulk. Control subjects were given subcutaneous Alhydrogel alone.

<sup>2</sup>The pH of this lot decreased after vialing, likely due to solvation of atmospheric carbon dioxide.

**Date:** 24 April 2008

**Signature:** Signature on file

**Title:** Technical Manager, BEI Authentication or designee

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