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

**Catalog No. NR-2562**
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: L0508005  
Manufacturing Date: 10AUG2005

<table>
<thead>
<tr>
<th>TEST</th>
<th>SPECIFICATIONS</th>
<th>RESULTS</th>
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</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Colorless, clear to slightly opalescent</td>
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<tr>
<td>SDS-PAGE (Reduced; Coomassie Blue)</td>
<td>Major band at ~ 51 ± 5 kDa</td>
<td>Major band at ~ 51 kDa</td>
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<tr>
<td>Identification by Western Blot</td>
<td>Antibody to F1 protein</td>
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<td>SDS-PAGE (Reduced; Silver stain)</td>
<td>Report results</td>
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</table>

**SDS-PAGE (Reduced; SYPRO Ruby stain, Fluorometric Scan)**

- ≥ 95% fluorescence intensity at ~ 51 kDa

**Size-Exclusion HPLC**

- Monomer: ≥ 60%
- Dimer: Report results
- Multimer: Report results

**Concentration by Spectrophotometer at OD_{280}**

- Report results: 1.15 mg/mL

**Functional Activity**

- Western Blot
  - Antibody to F1 protein: Reactive
  - Antibody to V protein: Reactive
- Toxicity in murine *Y. pestis* model
  - Protective to ≥ 10^5 LD_{50}
    - 7 of 9 survived 10^7 LD_{50}
    - 4 of 8 survived 10^9 LD_{50}
  - Control subjects: 0 of 10 controls survived 10^7 LD_{50}

**Bioburden**

- 0 colony-forming units/mL

**Sterility**

- 0.2 µm filter sterilized

**Endotoxin Content (Limulus Amoebocyte Lysate assay)**

- ≤ 5 EU/mL
- 0.18 EU/mL

**Host Cell Genomic DNA (qPCR)**

- *Escherichia coli* ≤ 100 pg/mL
- 1.2 pg/mL

**pH (post-vialing)**

- 9.9 ± 0.4
- 9.3

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

2. 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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