

Colonization Factor Antigen I (CFA/I) from Enterotoxigenic *Escherichia coli*

Catalog No. NR-49109

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Product Description: NR-49109 is a preparation of colonization factor antigen I (CFA/I) purified from enterotoxigenic *Escherichia coli* (*E. coli*) (ETEC). CFA/I was obtained from *E. coli*, strain 1933D, grown in DME/F-12 (Dulbecco's Modified Eagle's medium and F-12 serum-free medium) broth in a fermenter under cGMP conditions. The protein was purified from the culture supernatant by ammonium sulfate precipitation and tangential flow filtration and stored as a bulk preparation, at approximately -80°C, until it was vialled.

Lot¹: 06202014-1

Manufacturing Date: JUN2003

TEST	SPECIFICATIONS	RESULTS
Appearance	Report results	Clear
SDS-PAGE (GelCode [®] Blue Stain Reagent)	15 kDa band represents > 95% of total staining intensity above background	15 kDa band represents > 95% of total staining intensity above background (Figure 1)
Confirmation of Identity by Western Blot ² CFA/I (NR-49109)	Reactive	Reactive (Figure 2)
Concentration by Bicinchoninic Acid Protein Assay	Report results	1 mg/mL
Endotoxin Content ³	Report results	0.077 EU/μg protein
Sterility	0.22 μm filter sterilized	0.22 μm filter sterilized
Post-Purification Viability ⁴	No growth	No growth

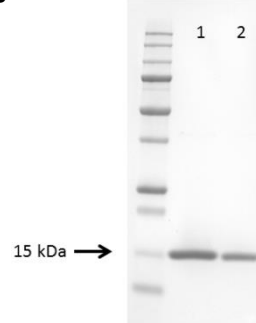
¹Production and quality control completed by Department of Subunit Enteric Vaccines and Immunology (SEVI), Bacterial Diseases Branch, Walter Reed Army Institute of Research, Silver Spring, Maryland, USA. The bulk material was thawed and vialled 20JUN2014. Quality control testing was completed at the time of vialing.

²Using rabbit anti-CFA/I serum

³Endosafe[®] LAL Assay from Charles River

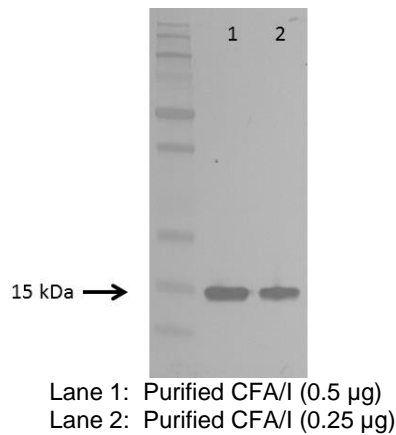
⁴Presence of bacteria was tested by plating 100 μL of purified protein onto a Tryptic Soy agar plate which was incubated in an aerobic atmosphere at 37°C for 24 hours, in triplicate.

Figure 1 — SDS-PAGE of CFA/I



Lane 1: Purified CFA/I (5 μg)
Lane 2: Purified CFA/I (2.5 μg)

Figure 2 — Western Blot of CFA/I



Date: 13 JAN 2015

Signature:

Title:

Technical Manager, BEI Authentication or designee

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