Veterinary Services
Safeguarding Animal Health

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

Clostridium novyi Type B (alpha) Antitoxin - Lot ID IRP 507 (04)

Document Number: **CVB-DAT-0056** **Revision:** **02**

Previous Number: BBDAT0065.09

Author: APJMWILSON

Section/Area: CVB-DAT

Release Date: 09 Apr 2019

Notes: *Strain or Source: C novyi Type B Strain CN 234.3 was used to produce the immunizing antigen, Fill date: June 24, 2004*

United States Department of Agriculture
Animal and Plant Health Inspection Service
Center for Veterinary Biologics
P. O. Box 844
Ames, IA 50010

1. Reagent Name: *Clostridium novyi* type B (alpha) Antitoxin

2. Strain or Source: *C. novyi* Type B Strain CN 234.3 was used to produce the immunizing antigen.

3. Lot Number: IRP 507 (04)

4. Fill Date: June 24, 2004

5. Expiration Date: March, 30 2024

Precautions: There are no known hazards associated with the use of this reagent.

6. Intended Use: IRP 507 (04) serves as the standard antitoxin when evaluating the potency of *C. novyi* alpha antitoxin.

7. Instructions for Use: IRP 507 (04) contains 140 alpha antitoxin units per mL (AU/mL). A dilution of standard antitoxin containing 0.1 AU/mL is used in the alpha toxin-neutralization test as described in title 9, *Code of Federal Regulations* (9 CFR), section 113.108. The dilution may be prepared by adding 1.0 mL of well mixed IRP 507 (04) to 13 mL of peptone diluent (1.0% peptone, 0.25% sodium chloride, pH 7.2). The antitoxin is further diluted by adding 1.0 mL of the solution containing 10 AU/mL to 9.0 mL of diluent. The final dilution, containing 0.1 AU/mL, is prepared by adding 1.0 mL of the solution containing 1.0 AU/mL to 9.0 mL of diluent. The antitoxin diluted 1:14 is stable when stored at -70°C or lower.

8. Test of Reagent:

Determination of antitoxin titer - The antitoxin titer was determined by injecting mice intravenously with 0.2 mL of diluted antitoxin mixed with 0.1 L_+ dose of toxin (the smallest amount of toxin which, when mixed with 0.1 unit of antitoxin, causes death in at least 80% of the animals within 72 hours) and 0.1 L_o toxin dose (the largest amount of toxin which, when mixed with 0.1 unit of antitoxin, causes no deaths in animals within 72 hours). The antitoxin titer of IRP 507 (04) was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures that contained 1.0 mL of IRP 507 (04) diluted 1:1400 to the results of mice injected with toxin-antitoxin mixtures that contained 1.0 mL of *C. novyi* International standard antitoxin possessing 0.1 AU/mL.

Sterility test - The antitoxin was tested for sterility and found to be free of viable bacteria and fungi according to procedures outlined in 9 CFR 113.26.

9. Container Size, Type, Weight, or Volume: Two-mL glass vials containing 1.3 mL of antitoxin.

10. Storage Conditions: Store at -70°C or lower.

11. CVB Technical Contact: Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.

12. Origin and Passage History: N/A

13. Method of Preparation: Goats with no history of clostridial vaccinations received multiple injections of *C. novyi* alpha toxoid and toxin during a 10-month period. Sera from the hyperimmunized goats were fractionated with ammonium sulfate and the immunoglobulin dialyzed against 0.01 M phosphate buffered saline, pH 7.2. The antitoxin was passed through a sterile Millipore filtration unit containing a 0.22-µm membrane, and mixed with 15% v/v of sterile glycerol. No other preservative was added.

14. Other: None

Reagent orders and feedback should be sent *including phone number* to the following email address: VS.DB.CVB.Reagent.Requests@aphis.usda.gov

Reagent orders forms (APHIS Form 2018) can be found on the CVB website.