## 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 perfringens Type A (alpha) Antitoxin

2. Strain or Source: Not applicable.

**3. Lot Number:** IRP 538 (06)

**4. Fill Date:** February 16, 2006

**5. Expiration Date:** No expiration date has been assigned to this product because *C. perfringens* type A (alpha) antitoxin has demonstrated over time to be very stable if properly stored. The stability of this reagent will be routinely monitored by the Center for Veterinary Biologics.

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

- **6. Intended Use:** IRP 538 (06) serves as the standard antitoxin when conducting *C. perfringens* type A (alpha) toxin-neutralization (TN) tests in mice.
- **7. Instructions for Use:** IRP 538 (06) contains 6.0 International units of alpha antitoxin per mL. A dilution of standard antitoxin containing 1.0 antitoxin unit per mL (AU/mL) is used in the mouse assay. The dilution is prepared by adding 1.0 mL of IRP 538 (06) to 5.0 mL of peptone diluent (1.0% peptone, 0.25% sodium chloride, pH 7.2).

## 8. Test of Reagent:

Determination of antitoxin titer - The antitoxin titer of IRP 538 (06) was determined by injecting mice intravenously with 0.5 mL volumes of diluted antitoxin mixed with 1.0  $L_0$  dose of toxin (the largest amount of toxin which, when mixed with 1.0 unit of antitoxin, causes no deaths in animals within 48 hours), and 1.0  $L_+$  dose of toxin (the smallest amount of toxin which, when mixed with 1.0 unit of antitoxin causes death in at least 80% of the mice within 48 hours). The antitoxin titer of IRP 538 (06) was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 538 (06) possessing 1.0 AU/mL with the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of International *C. perfringens* alpha antitoxin possessing 1.0 AU/mL.

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

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- **9. Container Size, Type, Weight, or Volume.** 2-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:** *Clostridium perfringens* Type A (alpha) Antitoxin IRP 538 (06) was obtained from young adult goats immunized with antigen prepared from *C. perfringens* type A American Type Culture Collection (ATCC) no.13124.
- **13. Method of Preparation:** Goats with no history of Clostridial vaccinations received multiple injections of *C. perfringens* alpha toxoid and toxin during a 6-month period. Sera from the hyperimmunized goats were fractionated with ammonium sulfate and the immunoglobulin dialyzed against 0.015 M phosphate buffered saline, pH 7.4. The dialyzed material was passed through a sterile Millipore filtration unit containing a 0.22-μm membrane. No preservative was added to the product.
- 14. Other: None.

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

Reagent orders forms (APHIS 2018) are available from: http://www.aphis.usda.gov/animalhealth/cvb\_forms

**REVISED:** 18Apr14 alb

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