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 C (beta) Antitoxin

2. Strain or Source: Not applicable

3. Lot Number: IRP 585-A

4. Fill Date: April 14, 2011

Expiration Date: No expiration date has been assigned to this product because *C. perfringens* type C (*beta*) 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 585-A serves as the standard antitoxin when conducting *C. perfringens* type C (*beta*) toxin-neutralization tests in mice.
- 7. Instructions for Use: *C. perfringens* type C (*beta*) antitoxin IRP 585-A contains 500 units of beta antitoxin per mL. A dilution of standard antitoxin containing 10 antitoxin units per mL (AU/mL) is used in the toxin-neutralization test as described in 9 CFR 113.111 and 9 CFR 113.454. The dilution is prepared by adding 0.5 mL of well mixed IRP 585-A to 4.5 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 1:10 dilution to 4.0 mL of diluent. The 1:10 dilution of antitoxin is stable when stored at -70°± 10°C and should be aliquoted for future testing.
- **8. Test of Reagent:** *Determination of antitoxin titer* The antitoxin titer was determined by injecting mice with 0.2-mL volume of diluted antitoxin mixed with 10 L+ toxin doses (the smallest amount of toxin which, when mixed with 10 units of antitoxin, causes death in at least 80% of the animals within 24 hours) and 10 Lo toxin doses (the largest amount of toxin which, when mixed with 10 units of antitoxin, causes no death in animals within 24 hours). The antitoxin titer of IRP 585-A was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 585-A possessing 10 beta antitoxin units per mL with the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of the WHO International Standard for *C. perfringens* Beta Antitoxin possessing 10 beta antitoxin units per mL.
- **9. Container Size, Type, Weight, or Volume:** Two-mL tube containing 0.7 mL of antitoxin.
- 10. Storage Conditions: Store at $-70^{\circ} \pm 10^{\circ}$ C.

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- **11. CVB Technical Contact:** Center for Veterinary Biologics, Bacteriology Section, (515) 337-6140 or FAX (515) 337-7673.
- 12. Origin and Passage History: Not applicable
- **13. Method of Preparation:** Goats with no history of *Clostridial* vaccinations and no detectable type A (alpha) antitoxin titer received multiple injections of purified *C. perfringens* type C beta 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 antitoxin was passed through a sterile Millipore filtration unit containing a 0.22-μm membrane. Sterile glycerol was added to a final concentration of 10% (v/v). No preservatives were added to the antitoxin.

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: https://www.aphis.usda.gov/library/forms/pdf/APHIS_2018.pdf

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