## CONTROLLED//PROPIN//BASIC

## 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 637

4. Fill Date: December 7, 2016

**5. Expiration Date:** February 28, 2029

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

- **6. Intended Use:** IRP 637 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 637 contains 550 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 title 9, *Code of Federal Regulations* (9 CFR), part 113.111 and 9 CFR 113.454. The dilution is prepared by adding 0.5 mL of well mixed IRP 637 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 4.5 mL of diluent. The 1:10 dilution of antitoxin is stable when stored at -50° to -80°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 637 was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 637 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.

Sterility test - IRP 637 was tested for sterility according to 9 CFR 113.26.

## CONTROLLED//PROPIN//BASIC

- 9. Container Size, Type, Weight, or Volume: Freestanding micro tubes (1.5 mL) containing 0.6 mL of antitoxin.
- 10. Storage Conditions: Store at -50° to -80°C.
- **11. CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6100.
- 12. Origin and Passage History: Not applicable
- **13. Method of Preparation:** Goats received multiple injections of a *C. perfringens* type C beta commercially prepared toxoid, CVB prepared toxoid and toxin during a 3-month period. The antitoxin was passed through a sterile Sartorius filtration unit containing a 0.1-μm membrane. 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: <u>VS.DB.CVB.Reagent.Requests@usda.gov</u>

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

CVB-DAT-0140.05 Page 2 of 2