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## 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 septicum* Antitoxin
- 2. Strain or Source: Not Applicable
- **3.** Lot Number: IRP 687
- 4. **Fill Date:** October 27, 2021
- 5. **Expiration Date:** February 28, 2029

**Precautions:** This reagent does not present a hazard to laboratory personnel who manipulate the antitoxin provided standard laboratory practices are followed.

**6. Intended Use:** IRP 687 serves as the standard antitoxin when determining *C. septicum* alpha antitoxin values using a toxin neutralization (TN) test in mice.

7. Instructions for Use: *C. septicum* antitoxin IRP 687 contains 180 units of antitoxin. One mL of standard antitoxin containing 1.0 antitoxin unit per mL (AU/mL) is used when determining the antitoxin content of serum from animals vaccinated with product containing *C. septicum* toxoid.

To conduct toxin neutralization (TN) tests in mice at the 1 AU/mL level, dilute IRP 687 1:180. Prepare the dilution by transferring 1.0 mL of IRP 687 to 9.0 mL of diluent and transferring 1.0 mL of the 1:10 dilution to 17.0 mL of diluent.

### 8. Test of Reagent:

*Determination of antitoxin titer* – The antitoxin titer of IRP 687 was determined by injecting mice intravenously with 0.5 mL of diluted antitoxin mixed with 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 animals within 72 hours) and 1.0 Lo dose of toxin (the largest amount of toxin which, when mixed with 1.0 unit of antitoxin, causes no deaths in any of the animals within 72 hours). The antitoxin titer was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 687 possessing 1.0 unit of antitoxin to the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 687 possessing 1.0 mL of *C. septicum* International antitoxin possessing 1.0 AU/mL.

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*Sterility test* – Ten vials of IRP 687 were tested for sterility according to 9 CFR 113.26. The antitoxin was found to be free of viable bacteria and fungi.

**9.** Container Size, Type, Weight, or Volume: 4 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) 337-6100 or FAX (515) 337-7673.

12. Origin and Passage History: Not applicable.

13. Method of Preparation: The ponies used for antitoxin preparation tested negative on serological tests for Equine Infectious Anemia. These ponies received multiple injections of *C*. *septicum* toxoid and toxin. The harvested serum was passed through a sterile Nalgene<sup>TM</sup> Rapid-Flow<sup>TM</sup> filtration unit containing a 0.2-µm membrane.

# 14. Other:

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.