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 sordellii* antitoxin

2. Strain or Source: Not applicable

3. Lot Number: IRP 501 (04)

4. Fill Date: August 5, 2004

5. Expiration Date: February 28, 2029

6. Intended Use: IRP 501 (04) serves as the standard antitoxin when conducting *C. sordellii* toxin neutralization tests in mice.

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

7. Instructions for Use: *C. sordellii* antitoxin IRP 501 (04) contains 170 antitoxin units per mL (AU/mL). A dilution of standard antitoxin containing 1.0 AU/mL is used in the toxin neutralization test as described in title 9, *Code of Federal Regulations* (9 CFR), section 113.109. The dilution is prepared by adding 1.0 mL of well mixed IRP 501 (04) to 9.0 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 17 au/mL to 16 mL of diluent. The antitoxin diluted 1:10 is stable if stored at -70°C or lower.

8. Test of Reagent:

Determination of antitoxin titer - The antitoxin titer of IRP 501 (04) was determined by injecting mice intravenously with 0.2 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 L_o dose of toxin (the largest amount of toxin which, when mixed with 1.0 unit of antitoxin, causes no deaths in animals within 72 hours). The antitoxin titer of IRP 501 (04) was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of IRP 501 (04) possessing 1.0 unit of antitoxin to the results of mice injected with toxin-antitoxin mixtures containing 1.0 mL of *C. sordellii* International antitoxin possessing 1.0 unit of antitoxin.

Sterility test – IRP 501 (04) 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: Four-mL glass vacules 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: N/A

13. Method of Preparation: Young adult goats with no history of Clostridial vaccinations received multiple injections of *C. sordellii* toxoid and toxin during an 8-month period. Serum from the hyper-immunized goats was precipitated with ammonium sulfate; the precipitate resuspended in deionized water and dialyzed against 0.015 M phosphate buffered saline (PBS), pH 7.4. The dialyzate was passed through a sterile Millipore filtration unit containing a 0.22-µm membrane. Sterile glycerol was added to the antitoxin at a final concentration of 15% v/v. No preservative was added to the antitoxin.

14. Other: None

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

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