

**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 tetani* Antitoxin 5.0 AU/mL (guinea pig origin)
2. **Strain or Source:** Not applicable
3. **Lot Number:** IRP 466
4. **Fill Date:** August 10, 2010
5. **Expiration Date:** No expiration date has been assigned to this product because *Clostridium tetani* 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:** To serve as the positive control serum when determining the antitoxin titer of guinea pig serum by ELISA, as outlined in **Supplemental Assay Method (SAM) 217**.
7. **Instructions for Use:** Use according to **SAM 217**.
8. **Test of Reagent:** The antitoxin titer of IRP 466 was quantitated by ELISA and the guinea pig toxin-antitoxin neutralization test as described in **SAM 217**, and title 9, *Code of Federal Regulations* (9 CFR), section 113.451, respectively. The serum contains 5.0 American antitoxin units per mL (AU/mL). The serum has been tested for the presence of viable bacteria and fungi as described in 9 CFR 113.26. No viable bacteria or fungi were found in the test vials.
9. **Container Size, Type, Weight, or Volume:** 0.5 mL microcentrifuge tubes containing 240 µL.
10. **Storage Conditions:** Store IRP 466 at -20°C or lower. After thawing, store at 2°- 7°C. Repeated freezing and thawing is not recommended.
11. **CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.

12. Origin and Passage History: The serum was obtained from 350- to 550-gram female Hartley guinea pigs immunized with tetanus toxoid. The animals were purchased from Charles River Breeding Laboratories, Wilmington, Massachusetts.

13. Method of Preparation: Serum collected from immunized guinea pigs was mixed with serum from non-immunized guinea pigs using a ratio that provided 5 AU/mL. The serum mixture was filtered through a Millipore filtration unit containing a 0.22- μ m membrane, dispensed aseptically into sterile vials, and stored at -50° to -90C. No preservatives were added to the serum.

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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