

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, 1.3 AU/mL
2. **Strain or Source:** Equine origin
3. **Lot Number:** IRP 528
4. **Fill Date:** August 14, 2014
5. **Expiration Date:** July 31, 2028

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

6. **Intended Use:** Equine tetanus antitoxin IRP 528 serves as the positive control serum when assaying the potency of equine tetanus antitoxin as outlined in title 9, *Code of Federal Regulations* (9 CFR), part 113.451 and **Supplemental Assay Method (SAM) 206**.
7. **Instructions for Use:** Use according to **SAM 206**.
8. **Test of Reagent:**

Determination of antitoxin titer - The antitoxin titer of IRP 528 was determined by the guinea pig toxin neutralization test as described in 9 CFR part 113.451. The serum was found to contain 1.3 American antitoxin units (AU) per mL.

Sterility test – 10 vials of IRP 528 were tested for sterility by inoculating them in sterile fluid thioglycollate medium with beef and soybean-casein digest medium. No detectable growth appeared in any tubes of medium.
9. **Container Size, Type, Weight, or Volume:** 4 mL glass screw-cap 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.
12. **Origin and Passage History:** N/A

- 13. Method of Preparation:** Equine serum containing at least 50 units of tetanus antitoxin per mL was mixed with serum from non-immunized horses using a ratio that provided 1.3 AU per mL. The serum mixture was filtered through a Millipore filtration unit containing a 0.22 μm membrane, dispensed aseptically into sterile vials, and stored at $-70^{\circ}\text{C} \pm 5^{\circ}\text{C}$. 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: VS.DB.CVB.Reagent.Requests@usda.gov

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