

**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:** January 31, 2026

**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* – Ten 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- $\mu$ m membrane, dispensed aseptically into sterile vials, and stored at  $-70^{\circ}\pm 5^{\circ}\text{C}$ . 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](mailto:VS.DB.CVB.Reagent.Requests@usda.gov)

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