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: Equine Negative Serum

2. Strain or Source: Not applicable.

3. Lot Number: IRP 319

4. Fill Date: November 3, 2004

Expiration Date: No expiration date has been assigned to this product because it has demonstrated over time to be very stable if properly stored. 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:** Equine negative serum IRP 319 serves as the negative control serum when assaying the potency of equine tetanus antitoxin by competitive enzyme-linked immunosorbent assay (CELISA) as described in Bacteriology Standard Operating Procedure (BBSOP) 0091.
- 7. **Instructions for Use:** Use according to **BBSOP0091**.

8. Test of Reagent:

Determination of absorbance values - Absorbance values of 1.5-1.8 were recorded when IRP 319 was tested by CELISA according to **BBSOP0091**.

In-vivo antitoxin test - IRP 319 was found to contain less than 0.1 unit per mL of tetanus antitoxin when tested by the comparative toxin-antitoxin neutralizations test in guinea pigs as described in 9 CFR 113.451.

Sterility test – IRP 319 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: Two-mL glass vials containing 1.3 mL of serum.

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- **10. Storage Conditions:** Store at -20°C or lower.
- **11. CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.
- 12. Origin and Passage History: Not applicable.
- 13. Method of Preparation: Blood collected from an adult horse with no history of being vaccinated with tetanus toxoid was allowed to stand overnight at room temperature for clot formation. The serum was poured from the clot, centrifuged, and passed through a sterile Millipore filtration unit containing a 0.22-µm membrane. No preservative was added to the serum. The serum was dispensed into sterile vials and stored at -70°C or lower.

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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