

**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:** *Leptospira icterohaemorrhagiae* Reference Bacterin
2. **Strain or Source:** N/A
3. **Lot Number:** IRP 542 (06)
4. **Fill Date:** November 1, 2006
5. **Expiration Date:** The stability of this reagent will be evaluated over time by the CVB using hamster PD₅₀ values. Any changes in use dilutions will be communicated via CVB Notice.

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

6. **Intended Use:** To be used as a reference bacterin in accordance with **SAM 627** (Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serovar *icterohaemorrhagiae* Bacterins). **CAUTION:** This reference is to be used for canine, swine, and bovine vaccines as approved in Outlines of Production.
7. **Instructions for Use:** Make an initial dilution of 1:10 (1.0 mL bacterin + 9.0 mL 0.85% NaCl solution). Adjust final dilution (using 0.85% NaCl solution) based on host animal dosage per the following table. The final dilution is considered as **UNDILUTED** when entering data into the RelPot software program.

Initial dilution	Host dose	Additional Dilution	Final dilution
1:10	1 mL	None	1:10
1:10	2 mL	1:2	1:20
1:10	4 mL	1:4	1:40
1:10	5 mL	1:5	1:50

8. **Test of Reagent:** Tested satisfactory for sterility according to 9 CFR 113.26. Host animal (canine and porcine) efficacy studies conducted by Dr. Carole Bolin at Michigan State University. Data summary available upon request.

9. **Container Size, Type, Weight, or Volume:** 5-mL serum vials, nominal fill volume 1 mL
10. **Storage Conditions:** 2°- 7°C
11. **CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.
12. **Origin and Passage History:** Passage history not available.
13. **Method of Preparation:** This non-adjuvanted bacterin was produced by a licensee according to a confidential outline of production.
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

REVISED: 18Apr14 alb