



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## **Leptospira icterohaemorrhagiae Reference Bacterin - Lot ID IRP 542 (06)**

**Document Number: CVB-DAT-0070**

**Revision: 03**

**Previous Number: BB DAT0089.06**

**Vault: CVB-Released**

**Section/Area: CVB-DAT**

**Effective Date: 12 Jul 2022**

**Notes: *Strain or Source: N/A, Fill date: November 1, 2006***

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:** July 31, 2026

**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* Serogroup *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 software to estimate relative potency.

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.

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) 337-6100 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: [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.