



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

Leptospira grippotyphosa Reference Bacterin - Lot ID IRP 523 (05)

Document Number: CVB-DAT-0069

Revision: 02

Previous Number: BB DAT0088.06

Vault: CVB-Released

Section/Area: CVB-DAT

Effective Date: 01 Apr 2020

Notes: *Strain or Source: N/A, Fill date: June 15, 2005*

**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 grippotyphosa* Reference Bacterin
2. **Strain or Source:** N/A
3. **Lot Number:** IRP 523 (05)
4. **Fill Date:** June 15, 2005
5. **Expiration Date:** May 31, 2022

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 626** (Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serogroup *grippotyphosa* Bacterins). **CAUTION:** This reference is to be used for canine, swine, and bovine vaccines as approved in Outlines of Production. Host use dilutions vary.
7. **Instructions for Use:** Reconstitute lyophilized bacterin with 1.0 mL of sterile water. 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.

Host dose	Canine Use Dilution	Porcine and Bovine Use Dilution
1 mL	1:12	1:6
2 mL	1:24	1:12
4 mL	1:48	1:24
5 mL	1:60	1:48

8. **Test of Reagent:** Tested satisfactory for sterility according to title 9, *Code of Federal Regulations* (9 CFR), section 113.26. Host animal (canine and porcine) studies conducted by Dr. Carole Bolin at Michigan State University.

9. **Container Size, Type, Weight, or Volume:** 2-mL serum vials (lyophilized).
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: VS.DB.CVB.Reagent.Requests@usda.gov

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