Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

1920 Dayton Avenue
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Ames, IA 50010

(515) 337-6100

Leptospira pomona Master Reference Bacterin - Lot ID IRP 524 (05)

Document Number: **CVB-DAT-0072** **Revision:** **02**

Previous Number: BBDAT0092.06

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 pomona* Master Reference Bacterin

2. **Strain or Source:** N/A

3. **Lot Number:** IRP 524 (05)

4. **Fill Date:** June 15, 2005

5. **Expiration Date:** April 30, 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 624** (Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serogroup *pomona* Bacterins). **CAUTION:** This reference is to be used for canine, swine, and bovine vaccines as approved in Outlines of Production.

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	Use Dilution
1 mL	1:20
2 mL	1:40
4 mL	1:80
5 mL	1:100

8. **Test of Reagent:** Tested satisfactory for sterility according to 9 CFR 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

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Controlled by: APHIS Center for Veterinary Biologics, 515-337-6100

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.