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

Document Number: CVB-DAT-0070
Revision: 03

Previous Number: BBDAT0089.06

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 Biologies  
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.

<table>
<thead>
<tr>
<th>Initial dilution</th>
<th>Host dose</th>
<th>Additional Dilution</th>
<th>Final dilution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:10</td>
<td>1 mL</td>
<td>None</td>
<td>1:10</td>
</tr>
<tr>
<td>1:10</td>
<td>2 mL</td>
<td>1:2</td>
<td>1:20</td>
</tr>
<tr>
<td>1:10</td>
<td>4 mL</td>
<td>1:4</td>
<td>1:40</td>
</tr>
<tr>
<td>1:10</td>
<td>5 mL</td>
<td>1:5</td>
<td>1:50</td>
</tr>
</tbody>
</table>

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.

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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

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