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

Document Number: CVB-DAT-0069

Revision: 03

Previous Number: BBDAT0088.06

Vault: CVB-Released

Section/Area: CVB-DAT

Effective Date: 11 Jul 2022

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 Biologies
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**: March 31, 2027

**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.

<table>
<thead>
<tr>
<th>Host dose</th>
<th>Canine Use Dilution</th>
<th>Porcine and Bovine Use Dilution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mL</td>
<td>1:12</td>
<td>1:6</td>
</tr>
<tr>
<td>2 mL</td>
<td>1:24</td>
<td>1:12</td>
</tr>
<tr>
<td>4 mL</td>
<td>1:48</td>
<td>1:24</td>
</tr>
<tr>
<td>5 mL</td>
<td>1:60</td>
<td>1:48</td>
</tr>
</tbody>
</table>

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°C - 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.