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

Document Number: CVB-DAT-0072           Revision: 03

Previous Number: BBDAT0092.06

Vault: CVB-Released

Section/Area: CVB-DAT

Effective Date: 06 May 2022

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

<table>
<thead>
<tr>
<th>Host dose</th>
<th>Use Dilution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mL</td>
<td>1:20</td>
</tr>
<tr>
<td>2 mL</td>
<td>1:40</td>
</tr>
<tr>
<td>4 mL</td>
<td>1:80</td>
</tr>
<tr>
<td>5 mL</td>
<td>1:100</td>
</tr>
</tbody>
</table>

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:** 2º- 7ºC
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.