



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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***Leptospira canicola* Master Reference Bacterin - Lot ID IRP 682**

Document Number: CVB-DAT-5151

Revision: 02

Previous Number:

Vault: CVB-Released

Section/Area: CVB-DAT

Effective Date: 05 Jan 2023

Notes:

**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 canicola* Master Reference Bacterin
2. **Strain or Source:** Lot 0367A00701
3. **Lot Number:** IRP 682
4. **Fill Date:** Sep 10, 2021
5. **Expiration Date:** October 31, 2026

Precautions: Caution – contains Thimerosal at 0.00067%

6. **Intended Use:** To be used as a reference bacterin in accordance with **SAM 625** (Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serogroup *canicola* 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 the lyophilized vial in 1.6mL of sterile water. 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. This dilution is used as the Working Reference bacterin for ELISA testing. The final dilution is considered as **UNDILUTED** when entering data into the software to estimate relative potency.

Initial dilution	Host dose	Additional Dilution	Final dilution
1:10	1 mL	None	1:10
1:10	2 mL	1:2	1:20
1:10	4 mL	1:4	1:40
1:10	5 mL	1:5	1:50

8. **Test of Reagent:** Tested satisfactory for sterility according to 9 CFR 113.26. Tested in comparison to old reference IRP 555 for validity and use dilution.
9. **Container Size, Type, Weight, or Volume:** 2-mL serum vials with ~1mL lyophilized
10. **Storage Conditions:** 2° – 7°C for long-term storage (lyophilized). When reconstituted with 1.6 mL of sterile water, up to 14 days at 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 bulk reagent was provided by a licensed establishment. Bacterin was diluted prior to bottling using 0.85% NaCl solution as diluent.
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.

Signature Manifest**Document Number:** CVB-DAT-5151**Revision:** 02**Title:** Leptospira canicola Master Reference Bacterin - Lot ID IRP 682**Effective Date:** 05 Jan 2023

All dates and times are in Central Standard Time.

Leptospira canicola Master Reference Bacterin - Lot ID IRP 682**Review for Doc Format**

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	14 Dec 2022, 01:26:25 PM	Approved

Lab Supervisor Final Approval

Name/Signature	Title	Date	Meaning/Reason
RANDY ATCHISON (RGATCHISON)	Bacteriology Lab Supervisor	14 Dec 2022, 01:33:11 PM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	05 Jan 2023, 07:06:08 AM	Approved