

**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 (Hond Utrecht Strain)
3. **Lot Number:** IRP 699
4. **Fill Date:** March 5, 2024
5. **Expiration Date:** April 30,2029

Precautions: Caution – contains Thimerosal at 0.00042%

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:** Make an initial dilution of 1:10 (1.0 mL bacterin + 9.0 mL 0.85% NaCl solution of 0.01M phosphate buffered saline). Adjust final dilution (using 0.85% NaCl solution or phosphate buffered saline) 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 title 9, *Code of Federal Regulations* (9 CFR), part 113.26. Tested in comparison to old reference IRP 555 for validity and use dilution.

9. **Container Size, Type, Weight, or Volume:** 2ml cryovials with ~1ml liquid reference.

10. **Storage Conditions:** 2° – 7°C for long-term storage. Avoid freeze thawing this product.

11. **CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6100.
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 0.01M phosphate buffered saline solution as diluent.
14. **Other:** None

Restrictions: (optional)

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.