



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Veterinary Rabies Reference Vaccine, killed virus, Lot 17-06

Document Number: CVB-DAT-5117

Revision: 01

Previous Number:

Vault: CVB-Released

Section/Area: CVB-DAT-RAB

Effective Date: 05 Feb 2020

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: Veterinary Rabies Reference Vaccine, killed virus**
2. **Strain or Source: Pitman-Moore**
3. **Lot Number: 17-06**
4. **Fill Date: January 22, 2018**
5. **Expiration Date: January 31, 2028**

Precautions: There are no known hazards associated with the use of this reagent.

6. **Intended Use:** For use as a reference vaccine in the title 9, *Code of Federal Regulations*, (9 CFR), part 113.209 testing.

7. **Instructions for Use:** Reference the current edition of the World Health Organization's Laboratory Techniques in Rabies; *The National Institute of Health's (NIH) Test for Potency*; or the Center for Veterinary Biologics (CVB) Supplemental Assay Method 308 for use and formulations.

Reconstitute 1 vial with 79.8 mL sterile distilled water, which is approximately 0.7 IU/mL. This reference vaccine is for use in the NIH test. Starting with 5-fold dilutions (1:5 through 1:3125) are made in phosphate buffered saline and these dilutions of the reference are used to vaccinate mice. Freeze the remaining reconstituted reference vaccine at -70°C for use in the 2nd vaccination.

8. **Test of Reagent:** Lot 17-06 was negative for viable rabies virus by intracerebral inoculation of mice and rabbits by 9 CFR 113.209(d)(2)(i). The vaccine was found to be free of mycoplasma and bacteria by 9 CFR 113.26 and 113.28 testing. The residual moisture content of the vaccine was equal to 0.5% by 9 CFR 113.29. The initial dilution value was determined by calibrating against the 6th International Rabies Reference vaccine in the NIH test.

9. **Container Size, Type, Weight, or Volume:** 5 mL (lyophilized) in a 20-mL glass serum bottle.

10. **Storage Conditions:** Store at -20°± 4°C.

11. **CVB Technical Contact:** Virology Section, Center for Veterinary Biologics, (515) 337-6100.

12. Origin and Passage History: The virus is the Pitman-Moore strain.

13. Method of Preparation: Lot 17-06 was grown in hamster kidney cells. Following 5 days of incubation, the virus was inactivated with beta-propiolactone. The vaccine was tested for purity and inactivation. The reference was bottled, lyophilized, sealed, and stored at -20°C.

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@aphis.usda.gov

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