



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: 02

Previous Number:

Vault: CVB-Released

Section/Area: CVB-DAT-RAB

Effective Date: 07 Feb 2022

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.

CVB Reference Lot 17-06 has been assigned a unitage of 55.8 International Units (IU) of rabies vaccine per vial. 55.8 IU/vial i.e., 55.8 IU/mL when reconstituted as directed in 1mL distilled water.

For use in *in vivo* NIH tests reconstitute the contents of each vial in 5 mL sterile distilled water (DI) Further dilute 1:11.16 with DI for a final dilution of 1:55.8 which is approximately 1 IU/mL. Use 1 IU/mL of rabies reference vaccine to prepare 5-fold dilutions (1:5 to 1:3125) in phosphate buffered saline. Vaccinate mice with dilutions (1:5 to 1:3125) of rabies reference vaccine. Freeze the remaining contents of the reconstituted rabies reference vaccine (5 mL vial) at -70°C for use in the second vaccination of the NIH test. Repeat the dilution process described above beginning with 1:11.16 dilution for use in the second 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 $-20^{\circ}\pm 4^{\circ}\text{C}$.
- 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.