

**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:** Pasteur Virus
3. **Lot Number:** 08-14
4. **Fill Date:** November 24, 2008
5. **Expiration Date:** November 2018

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 13 mL sterile distilled water. This reference vaccine is for use in the NIH test. Starting with undilute, 5-fold dilutions (1:1 through 1:625) are made in phosphate buffered saline and these dilutions of the reference are used to vaccinate mice. Discard the remaining reconstituted reference.

For the second vaccination, reconstitute a new vial of reference with 13 mL sterile distilled water. Prepare 5-fold dilutions as described previously and immunize mice. Discard the remaining reconstituted reference.

8. **Test of Reagent:** Lot 08-14 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 3.9% 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:** Alethea Fry (515) 337-7460, Virology Section, Center for Veterinary Biologics.
- 12. Origin and Passage History:** The virus is the Pasteur Virus strain.
- 13. Method of Preparation:** Lot 08-14 was grown in baby hamster kidney (BHK-21) 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.STAS.CVB.Reagent.Requests@aphis.usda.gov

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

REVISED: 02July18 pap