



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

Veterinary Rabies Reference Vaccine, killed virus - Lot ID 08-14

Document Number: CVB-DAT-0418

Revision: 05

Previous Number: VIRDAT1212.08

Vault: CVB-Released

Section/Area: CVB-DAT

Effective Date: 18 Jan 2023

Notes: *Strain/Source: Pasteur Virus, Fill Date: November 24, 2008*

**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:** January 31, 2020

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.DB.CVB.Reagent.Requests@usda.gov

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

Signature Manifest**Document Number:** CVB-DAT-0418**Revision:** 05**Title:** Veterinary Rabies Reference Vaccine, killed virus - Lot ID 08-14**Effective Date:** 18 Jan 2023

All dates and times are in Central Standard Time.

CVB-DAT-0418 Veterinary Rabies Reference Vaccine, killed virus - Lot ID 08-14**Review for Doc Format**

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	13 Dec 2022, 09:54:02 AM	Approved

Lab Supervisor Final Approval

Name/Signature	Title	Date	Meaning/Reason
ALETHEA FRY (AFRY)	Supvy Micro	13 Dec 2022, 01:29:34 PM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	18 Jan 2023, 05:11:54 PM	Approved