



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Escherichia coli Anti-F41 Pilus Polyclonal Antibody (F41 PAb) - Lot ID IRP 693

Document Number: CVB-DAT-5167

Revision: 01

Previous Number:

Vault: CVB-Released

Section/Area: CVB-DAT

Effective Date: 01 Dec 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:** *Escherichia coli* Anti-F41 Pilus Polyclonal Antibody (F41 PAb)
2. **Strain or Source:** Not applicable
3. **Lot Number:** IRP 693
4. **Fill Date:** July 15, 2022
5. **Expiration Date:** November 30, 2027

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

6. **Intended Use:** For use in potency testing of *E. coli* biologicals containing the F41 pilus antigen, according to **Supplemental Assay Method (SAM) 623**.
7. **Instructions for Use:** Dilute the F41 PAb 1:1,000 in cold carbonate-bicarbonate coating buffer (0.05M, pH 9.6) and use immediately, according to **SAM 623**.
8. **Test of Reagent:** The F41 PAb was evaluated using enzyme-linked immunosorbent assay. The F41 PAb was shown to be specific for F41 pilus antigen, with negligible reactivity against other pilus types and non-piliated mutants of *E. coli*. It exhibits minimal nonspecific binding (background).
9. **Container Size, Type, Weight, or Volume:** 75 μ L aliquots in microfuge vials
10. **Storage Conditions:** -20 $^{\circ}$ to -80 $^{\circ}$ C for long term storage. Vial may be held at 2 $^{\circ}$ - 7 $^{\circ}$ C for several weeks.
11. **CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6100 or FAX (515) 337-7673.
12. **Origin and Passage History:** *E. coli* F41 NADC culture 1839 (IRP 677)

13. Method of Preparation: *E. coli* F41 PAb was produced in New Zealand White rabbits. Each rabbit received 5 intravenous doses of *E. coli* F41 NADC culture 1839 (IRP 677) given at 7-day intervals. The first 3 doses contained formalin-killed/partially formalin-killed *E. coli*, and the final 2 doses contained live *E. coli*. Serum was harvested, pooled, and adsorbed one time with non-piliated bacteria (NADC, *E. coli* strain 1839) to remove antibodies not directed against F41 pili. The F41 PAb was filter-sterilized and frozen at -70°C or lower.

14. Other:

Restrictions: For use only in potency tests conducted according to **SAM 623**.

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.

Signature Manifest**Document Number:** CVB-DAT-5167**Revision:** 01**Title:** Escherichia coli Anti-F41 Pilus Polyclonal Antibody (F41 PAb) - Lot ID IRP 693**Effective Date:** 01 Dec 2022

All dates and times are in Central Standard Time.

Escherichia coli Anti-F41 Pilus Polyclonal Antibody (F41 PAb) - Lot ID IRP 693**Review for Doc Format**

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	01 Dec 2022, 07:40:51 AM	Approved

Lab Supervisor Final Approval

Name/Signature	Title	Date	Meaning/Reason
RANDY ATCHISON (RGATCHISON)	Bacteriology Lab Supervisor	01 Dec 2022, 11:54:59 AM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	01 Dec 2022, 12:28:06 PM	Approved