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-K99 Pilus Monoclonal Antibody (K99 MAb)

2. Strain or Source: Hybridoma 2BD4E4

3. Lot Number: IRP 629

4. Fill Date: December 12, 2013

5. Expiration Date: Not Applicable.

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

6. Intended Use: For use in potency testing of *E. coli* biologicals containing the K99 antigen, according to **Supplemental Assay Method (SAM) 620**.

7. Instructions for Use: Dilute the K99 MAb 1:2,000 (or as optimized in specific titration studies) in cold carbonate-bicarbonate coating buffer (0.05M, pH 9.6) and use immediately according to **SAM 620**.

8. Test of Reagent: The K99 MAb was shown to be specific for K99 pilus antigen, and it demonstrated minimal nonspecific binding (background) in assays performed according to **SAM 620**.

9. Container Size, Type, Weight, or Volume: 50 µL aliquots in 0.5-mL microfuge vials.

10. Storage Conditions: -20° to -80°C for long-term storage. A vial may be held at 2°- 7°C for several months.

11. CVB Technical Contact: Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.

12. Origin and Passage History: The hybridoma cell line secreting anti-K99 antibody was obtained from ATCC.

13. Method of Preparation: The hybridoma cell line was propagated in a bioreactor to produce supernatant fluid containing K99 MAb. The 500 mL harvest was originally frozen at -70°C or lower on December 23, 2002. The antibody was thawed in December of 2013; 35 mL was mixed with an equal part glycerol and aliquoted.

14. Other:

Restrictions: This reagent is to be used only in conjunction with biological potency testing according to SAM 620.

Reagent orders and feedback should be sent *including phone number* to the following email address: CVB@aphis.usda.gov

Reagent orders forms (APHIS 2018) are available from:
https://www.aphis.usda.gov/library/forms/pdf/APHIS_2018.pdf

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