## CONTROLLED//PROPIN//BASIC

## 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-K88 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody (K88-HRP Conjugate)

2. Strain or Source: Hybridoma 21BA1-1H1

3. Lot Number: IRP 597

**4. Fill Date:** April 8, 2011

**5. Expiration Date:** March 31, 2026

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

- **6. Intended Use:** For use in potency testing of *E. coli* biologics containing the K88 pilus antigen, according to Supplemental Assay Method (SAM) 621.
- 7. Instructions for Use: Dilute the K88-HRP conjugate 1:6,000 in phosphate-buffered saline supplemented with 0.05% Tween 20 and 1% ovalbumin and use immediately, according to SAM 621.
- **8. Test of Reagent:** The K88-HRP conjugate was shown to be specific for the "a" subunit of the K88 pilus antigen. It exhibits minimal nonspecific binding (background) in assays performed according to **SAM 621**. The optimal use dilution was determined by titration, using the assay described in **SAM 621**.
- 9. Container Size, Type, Weight, or Volume: Approximately 50-μL aliquots in microfuge vials.
- **10. Storage Conditions:** Maintain at or below -70°C for long-term storage. The conjugate may be stored at 4 C up to two weeks.
- **11. CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6100.
- 12. Origin and Passage History: Raw ascites fluid was purchased from Molecular Genetics Inc., Minnetonka, Minnesota. Hybridoma 21BA1-1H1, secreting anti-K88 antibody specific for a common "a" epitope of all three K88 antigenic variants, was produced from a fusion of pili-

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immunized BALB/c mouse splenocytes with mouse plasmacytoma cells (NS-1) on September 29, 1983, at Molecular Genetics.

**13. Method of Preparation:** Raw ascites fluid was purchased from Molecular Genetics Inc. The anti-K88 ascites fluid was labeled with horseradish peroxidase, filter-sterilized, and stored at -70°C or lower.

## 14. Other:

**Restrictions:** To be used only in conjunction with biological potency testing according to SAM 621.

Reagent orders and feedback should be sent *including phone number* to the following email address: <u>VS.DB.CVB.Reagent.Requests@usda.gov</u>

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

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