



May 9, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-11

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team

FROM: Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Replacement Lots of the Center for Veterinary Biologics' Mycobacterium Tuberculosis Sensitinogen, *Escherichia coli* Anti-K99 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody, and *Clostridium tetani* Antitoxin 5.0 AU/mL (guinea pig origin)

I. PURPOSE

This Notice provides information on the availability of new lots of the Center for Veterinary Biologics' (CVB) Mycobacterium Tuberculosis Sensitinogen - MTS-3 1001; *Escherichia coli* Anti-K99 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody [K99-HRP Conjugate] – IRP 595; and *Clostridium tetani* Antitoxin 5.0 AU/mL (guinea pig origin) – IRP 466.

II. BACKGROUND

The CVB provides certain reagents, listed in Veterinary Services Memorandum (VSM) 800.97, for the testing of veterinary biologics. When existing lots of reagents are depleted, they are replaced with new lots of material.

A new lot of Mycobacterium Tuberculosis Sensitinogen is now available for distribution, Lot MTS-3 1001 will replace Lot MTS-3 0601. This reagent is used in tuberculin potency testing according to Title 9, Code of Federal Regulations (9 CFR), Part 113.406 and SAM 604.

A new lot of *Escherichia coli* Anti-K99 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody [K99-HRP Conjugate] is also available for distribution. Lot IRP 595 will replace Lot IRP 539. This reagent is used in *Escherichia coli* Bacterin potency testing according to SAM 620. This SAM describes a capture enzyme-linked immunosorbent assay (ELISA) for K99 pilus antigen. This reagent detects bound antigen.



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A new lot of *Clostridium tetani* Antitoxin 5.0 AU/mL (guinea pig origin) is available for distribution. Lot IRP 466 replaces Lot IRP 467A for use in the potency test described in 9 CFR 113.114 and SAM 217. This reagent is the positive control for an indirect ELISA.

III. ACTION

These new reagent lots may be received when these reagents are requested from the CVB. Please follow the procedures in VSM 800.97 for requesting these reagents.

IV. IMPLEMENTATION/ APPLICABILITY

Firms with supplies of the previous lots of the above reagents may continue to use their stocks. As additional reagent is requested from the CVB, the new lots will be supplied to meet these requests.