



October 28, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-22

**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 Leadership Team

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

SUBJECT: Routine Distribution and Replacement of the Center for Veterinary
Biologics' Bacterial Testing Reagents

I. PURPOSE

The purpose of this Notice is to inform interested parties that new lots of the following reagents are available and are routinely being distributed:

Leptospira canicola Polyclonal Antibody (LC PAb), IRP 491

Leptospira icterohaemorrhagiae Polyclonal Antibody (LI PAb), IRP 04-481

Leptospira pomona Polyclonal Antibody (LP PAb), IRP 04-482

Clostridium perfringens Type C (*beta*) Antitoxin, IRP 585-A

Erysipelothrix rhusiopathiae Challenge Culture, IRP 592

Clostridium tetani Toxin, IRP 588

It also provides general information on updating of lots of bacterial reagents prepared by the Center for Veterinary Biologics (CVB).

II. BACKGROUND

The CVB provides certain reagents, listed in Veterinary Services Memorandum (VSM) 800.97, for the testing of veterinary biologics. As quantities of particular lots are depleted, they are replaced with new lots of the material. The bacterial reagents listed above are among those offered for testing purposes.



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In the case of LC PAb, LI PAb, and LP PAb, they may be used in enzyme-linked immunosorbent assay (ELISA) systems or the respective microagglutination tests. The ELISA tests designed by the CVB are described in Supplemental Assay Methods (SAM) 625, 627, and 624. These SAMs use a sandwich ELISA to measure the relative potency of bacterins containing the indicated *Leptospira spp.* fractions.

In the case of *Clostridium perfringens* Type C (*beta*) Antitoxin, it is used as the standard antitoxin in the toxin neutralization test (TNT) used to measure the potency of Clostridium Perfringens Type C Toxoid and Clostridium Perfringens Type C Bacterin-Toxoid in accordance with Title 9, Code of Federal Regulations (9 CFR), Part 113.111 and described in SAM 201. It is also used to test Clostridium Perfringens Type C Antitoxin in accordance with 9 CFR 113.454 and as described in SAM 202.

In the case of *Erysipelothrix rhusiopathiae* Challenge Culture, it is used in SAM 611 which tests the potency of biological products containing *Erysipelothrix rhusiopathiae*, as prescribed in 9 CFR, Part 113.119. It may also be used in swine efficacy studies.

In the case of *Clostridium tetani* Toxin, it is used to coat the plates in the indirect ELISA described in SAM 217 for the testing of Tetanus Toxoid in accordance with 9 CFR 113.114 and for the comparative toxin-antitoxin neutralization test described in SAM 206 for the testing Tetanus Antitoxins in accordance with 9 CFR 113.451.

III. POLICY

New lots of these three leptospira polyclonal antibodies, Lots IRP 491, IRP 04-481, and IRP 04-482, have been prepared and are being distributed currently. Replacement lots of *Clostridium perfringens* Type C (*beta*) Antitoxin, Lot IRP 585-A; *Erysipelothrix rhusiopathiae* Challenge Culture, Lot IRP 592; and *Clostridium tetani* Toxin, Lot IRP 588 have been prepared and are being distributed. Details regarding the use of all these reagents are supplied in the reagent data sheet provided with the material.

IV. IMPLEMENTATION/APPLICABILITY

In the case of the leptospira polyclonal antibodies, Lots IRP 491, IRP 04-481, and IRP 04-482, they are now being distributed currently for routine use under VSM 800.97.

In the case of *Clostridium perfringens* Type C (*beta*) Antitoxin, Lot IRP 585-A replaces Lot IRP 585. Firms with supplies of Lot IRP 585 may continue to use this material. As additional reagent requests are received, Lot IRP 585-A has been supplied.

In the case of *Erysipelothrix rhusiopathiae* Challenge Culture, Lot IRP 592 replaces Lot IRP ERC Serial 4. Firms with supplies of Lot IRP ERC Serial 4 may continue to use this material. As additional reagent requests are received, Lot IRP 592 has been supplied.

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In the case of *Clostridium tetani* Toxin, Lot IRP 588 replaces Lot IRP 568. Firms with supplies of Lot IRP 568 may continue to use this material. As additional reagent requests are received, Lot IRP 588 has begun to be supplied.

New lots of bacterial reagents will be announced on our web site or in catalogues supplied upon request.