



May 23, 2003

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-08

Marketing and
Regulatory
Programs

Animal and Plant
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Service

Veterinary Services

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Subject: Purpose of the Equine Infectious Anemia Weak Positive Serum Sample as Outlined in Veterinary Services Memorandum No. 555.16

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

The purpose of this notice is to inform interested parties of the intended function of the Equine Infectious Anemia (EIA) weak positive serum sample required in the testing procedures to be followed by approved EIA laboratories as outlined in Veterinary Services (VS) Memorandum No. 555.16.

According to VS Memorandum No. 555.16, a weak positive EIA serum sample is available from the National Veterinary Services Laboratories (NVSL). The NVSL EIA serum sample is intended to remind approved personnel of the expected weak positive precipitation lines obtained in an agar gel immunodiffusion (AGID) test. This serum sample does not represent a weak positive threshold sample as the sample has a higher antibody concentration. If manufacturers wish to evaluate the NVSL EIA serum, they may purchase the sample from the NVSL.

The NVSL EIA serum sample is not intended to be used by manufacturers of AGID Equine Infectious Anemia Virus Antibody Test Kits during the standardization of the antigen in individual serials. The Center for Veterinary Biologics-Policy, Evaluation, and Licensing (CVB-PEL) has available the current EIA weak positive threshold serum that manufacturers should use for antigen standardization of each AGID serial. The EIA threshold serum is available to manufacturers upon request to the CVB-PEL.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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(Voice/TTY/ASCII/Spanish)
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