



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE 17-10

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

FROM: Byron E. Rippke
Director

SUBJECT: Discontinued Availability of Diagnostic Test Kit Serial Release Panels
Obtained from the Center for Veterinary Biologics (CVB)

I. PURPOSE

The purpose of the document is to notify veterinary biologics manufacturers that the CVB distribution of Serial Release Panels for the following diagnostic test kits will be discontinued:

- Anaplasma Antibody Test Kit
- Bluetongue Virus Antibody Test Kit
- Bovine Leukemia Virus Antibody Test Kit
- Caprine Arthritis-Encephalitis-Ovine Progressive Pneumonia (CAE-OPP) Virus Antibody Test Kit
- Equine Infectious Anemia Virus Antibody Test Kit
- Porcine Reproductive and Respiratory Syndrome Virus Antibody Test Kit
- Pseudorabies Virus Antibody Test Kit (including gB and gI)

The Poultry Antibody Specificity Panel utilized in development and quality control of some avian products will also be discontinued by the CVB.

II. BACKGROUND

For the purpose of this Notice, a Serial Release Panel refers to a collection of samples used to assess a diagnostic test kit.

The CVB laboratory has routinely provided Serial Release Panels to veterinary biologics manufacturers. Due to reduced resources, the CVB is discontinuing these reagents. All Serial Release Panels above, except for the CAE-OPP and Poultry Antibody Specificity Panel, are available for a fee from the National Veterinary Services Laboratories (NVSL) as proficiency test panels (check tests). See NVSL's [Proficiency Test Panel web page](#) for details.

III. ACTION

The Outline of Production, Section V.C, must include information regarding the specific panel or samples used for serial release testing. Firms may use an NVSL panel without additional justification. If a firm does not use an NVSL panel, lot/serial numbers for the samples must be included in the Outline of Production. These samples must be well characterized. This information must be approved by CVB-PEL prior to use.

Firms may use the appropriate panel, past or present, produced by the NVSL for serial release testing. The most current panel supplied by the NVSL is not required. The APHIS Form 2008 should specify the NVSL panel used to test an individual serial, including the year of panel release. For a Serial to be satisfactory, all samples within a panel must be identified correctly. The NVSL panel used by the CVB for prelicense and routine confirmatory testing may not match the panel listed on the APHIS Form 2008.

Individual control and panel member results should be reported on the APHIS Form 2008 to be evaluated by CVB-Inspection and Compliance.

IV. IMPLEMENTATION/APPLICABILITY

This change is effective immediately. Necessary Outline of Production changes should be completed prior to releasing a serial tested by a new Serial Release Panel, or by the next annual review, whichever comes first.