



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 NO. 20-08

**TO:** Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics  
Veterinary Services Leadership Team  
American Veterinary Medical Association

**FROM:** Byron Rippke  
Director

**SUBJECT:** Update to Equine Parvovirus Extraneous Agent Testing  
Requirement for Equine-Origin Antibody, Antitoxin, Antivenin,  
Serum, and Plasma Biological Products Regulated by APHIS

### I. PURPOSE

The purpose of this notice is to inform interested parties of updated testing and reporting requirements for donor horses and serials of Animal and Plant Health Inspection Service (APHIS)-regulated antibody, antitoxin, serum, and plasma products of equine origin for freedom from equine parvovirus-hepatitis (EPV-H).

Additionally, this notice announces procedures for extending the implementation period of the testing requirements for donor horses and serials of APHIS-regulated products of equine origin for freedom from EPV-H. The implementation will now be extended through April 30, 2021, to allow firms to comply due to unforeseen events related to the COVID-19 global pandemic.

Further, this notice informs interested parties that APHIS-regulated products derived from donor horses includes antivenin biological products regulated by APHIS. The labeling requirements, as stated in the Center for Veterinary Biologics (CVB) Notice 19-03, will also apply to antivenin products of equine origin.

### II. BACKGROUND

CVB Notice 19-03, published April 5, 2019, informed permittees and licensees of new labeling requirements for equine donor horse products. Additionally, the notice required that donor herds and serials of APHIS-regulated equine origin antibody, antitoxin, serum, or plasma biological products be tested for EPV-H by methods acceptable to APHIS. The labeling requirements were to be met within 6 months of publication of the notice, while the testing requirements were to be met within 18 months of the publication date. The testing requirement was implemented based on published research describing EPV-H as a probable cause of equine serum hepatitis<sup>1-4</sup>. An additional research study has been published<sup>5</sup> indicating that the virus is present in, and can be spread by, administration of equine serum and/or

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plasma. The presence of the EPV-H in licensed veterinary biologicals poses a newly identified and unacceptable risk, requiring regulatory action.

### III. ACTION

#### A. ASSAY TESTING AGAINST EPV-H

EPV-H must be detected by an assay acceptable to APHIS. Licensees and permittees may develop an assay to detect EPV-H or use a contract laboratory for testing. Licensees and permittees should contact CVB regarding their testing preference prior to initiation of testing.

For licensees and permittees that will develop an assay, the assay must be validated, and the limit of detection for the assay must be established. Interested parties must also satisfactorily complete testing of a quality assessment panel available from CVB. Upon satisfactory acceptance of the assay validation data and quality assessment panel results by CVB, the assay may be used for testing donor horses and final product serials.

#### B. Update of the Outline of Production (OP)

1. After CVB acceptance of the validation data and quality assessment panel results, Section I.B.1 of the OP must be revised to include annual EPV-H testing and testing of replacement donor horses.
2. Section V.B.1 of the OP must be revised to include serial testing of final product. Include the following: name of laboratory performing the testing; assay test procedure; validity criteria for testing; and acceptance criteria for a satisfactory test including conditions for retesting. A Special Outline may be used to document the conduct of an assay performed by the licensee or permittee.

### IV. IMPLEMENTATION/ APPLICABILITY

Product labeling per CVB Notice 19-03 and Outlines of Production, Sections I.B and V.B must be in compliance by April 30, 2021.

### V. REFERENCES

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of equine biologic product administration: A prospective study (2014-2018). *J Vet Intern Med.* 2019: Jan;33(1) 258-265.

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