



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-08

TO: Biologics Licensees, Permittees, and Applicants

FROM: Dr. Geetha B. Srinivas
Director, Center for Veterinary Biologics

SUBJECT: National Animal Health Laboratory Network (NAHLN)
Requirements for Veterinary Biologics Manufacturers to Meet for
Diagnostic Products Detecting Transboundary and Foreign Animal
Diseases to be Used in the NAHLN

I. PURPOSE

The purpose of this document is to notify veterinary biologics manufacturers where National Animal Health Laboratory Network requirements can be found for diagnostic products detecting transboundary and foreign animal diseases (FADs) if manufacturers would like their products to be considered for use by the NAHLN.

II. BACKGROUND

The Center for Veterinary Biologics (CVB) regulates the licensing of veterinary biologics, including diagnostic products. CVB has specific requirements that domestic veterinary biologics manufacturers must meet for their products to be licensed or for foreign manufactured veterinary biologics to be permitted for sale and distribution within the United States. These licensing or permitting requirements assure consistency in manufacturing and that the products are safe, pure, potent, and efficacious.

The NAHLN is a network of university, State, and Federal animal health laboratories coordinated by the Animal and Plant Health Inspection Service Veterinary Services to support early detection, rapid response, and appropriate recovery from high-consequence animal diseases. Diagnostic products used within the NAHLN meet NAHLN-based requirements, use standardized procedures, and can range from in-house developed tests to commercially developed platforms.

Licensure of diagnostic products by CVB does not guarantee the use of these products within the NAHLN. However, the NAHLN prefers that diagnostic products used within their network be licensed or permitted by CVB. The NAHLN has requirements in addition to CVB licensing or permitting that must be met in order for a product to be considered for use in NAHLN laboratories. The NAHLN testing requirements for commercially available products can be found at the

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following link: [Requirements for NAHLN Deployment of New Diagnostic Assays \(usda.gov\)](#)

For questions regarding the NAHLN approval process contact the NAHLN Program Office at NAHLN@usda.gov. For information on test panel availability contact the National Veterinary Services Laboratories at NVSL.info@usda.gov.

III. ACTION

Veterinary biologics manufacturers should consult the NAHLN website regarding the requirements for diagnostic products detecting transboundary and FADs to be considered for use by the NAHLN. Contact the reviewer assigned to your firm if interested in obtaining additional information.