



United States Department of Agriculture  
Animal and Plant Health Inspection Service  
and  
National Institute of Food and Agriculture

A Proposal for a Revised Structure of the  
National Animal Health Laboratory Network  
(NAHLN)

October 2012

## Executive Summary

The National Animal Health Laboratory Network (NAHLN) is a nationally coordinated network and partnership of Federal, State, and university-associated animal health laboratories. NAHLN laboratories provide animal health diagnostic testing to detect biological threats to the nation's food animals, thus protecting animal health, public health, and the nation's food supply.

This paper:

1. Defines the NAHLN laboratory membership structure;
2. Recognizes NAHLN oversight by the U. S. Department of Agriculture (USDA);
3. Identifies the role of the NAHLN Coordinating Council;
4. Identifies the National Veterinary Service Laboratories (NVSL) as the reference laboratories for the NAHLN; and,
5. Affirms the opportunity for each State to have a NAHLN laboratory as long as State laboratories meet defined minimum criteria.

These actions will allow the NAHLN to achieve its original surveillance and response goals and expand its capability and capacity for detecting emerging and zoonotic disease to protect animal health, public health, and the nation's food supply. Moreover, codification of USDA oversight of the NAHLN, the existence of a NAHLN charter, and the outline of the network structure will give the NAHLN the flexibility to respond to future national animal health testing needs. The NAHLN will gain this flexibility through clearer designation of network members' roles and responsibilities, and through the ability to more easily expand or contract NAHLN testing capabilities and capacities. Other elements, such as the actual NAHLN charter

and the specific requirements for each level of laboratory participation, will be referenced in program standards and will allow the NAHLN to respond to the changing needs of animal agriculture.

## Introduction

The NAHLN is the result of mutual recognition by members of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) and Federal officials that a nationally coordinated network of animal health diagnostic laboratories is essential to protecting animal health, public health, and the nation's food supply from foreign animal and emerging diseases. In 2002, the USDA established a partnership with State and university-associated animal health diagnostic laboratories, with funding derived from appropriations authorized under Public Law 107-38 (Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States, codified at 50 U.S.C 414) to leverage and unite existing Federal and State animal health diagnostic resources. Funding continues through congressional appropriations to the USDA, and substantial support from State governments.

Originally composed of 12 laboratories, the NAHLN has grown to include 12 Core, 28 Member, and 9 Contract laboratories. Core laboratories are regionally distributed and capable of testing large numbers of samples that originate from food animal species. Member laboratories are more widely disseminated than Core laboratories, and facilitate greater geographic coverage. Contract laboratories provide diagnostic testing for specific disease agents. In addition, a small number of adjunct laboratories, such as Food Safety and Inspection Service (FSIS) laboratories,

contribute to NAHLN efforts by providing a specific but needed diagnostic capability.

The NAHLN is overseen and administered by the USDA, with operational oversight provided through the Animal and Plant Health Inspection Service (APHIS). Initially, a steering committee composed of staff from State and university-associated animal health laboratories, additional representatives from the AAVLD, a State veterinarian, and USDA staff was formed to provide input to NAHLN leadership. The steering committee was discontinued in 2009, and a NAHLN Coordinating Council was established to represent State regulatory and laboratory partners rather than professional or other organizations.

The Coordinating Council is composed of USDA representatives, State animal health officials, and State employee representatives of NAHLN laboratories. USDA established and approved a charter for the NAHLN Coordinating Council. This charter defines Federal oversight of the NAHLN and the roles and responsibilities of USDA agencies, the NAHLN Executive Committee, and the NAHLN Coordinating Council. The structure of the network was not changed.

## Proposed Changes

Recent feedback from a wide variety of stakeholders indicates that the NAHLN structure needs to change to fully meet original surveillance and response goals, and to expand detection of emerging and zoonotic diseases. While the current NAHLN structure of Core, Member, and Contract laboratories has served the stakeholders well, the changes proposed in this paper ensure that the NAHLN continues to meet current and future needs.

Founding principles that guided NAHLN development in preceding years remain intact. For each participating laboratory, these are:

- a. Operate within a quality management system that meets AAVLD, ISO 17025, or equivalent requirements;
- b. Establish and maintain competency of laboratory personnel;
- c. Use standardized protocols, reference materials, and equipment;
- d. Participate in communications and reporting systems established by the NAHLN;
- e. Use facilities with biosafety/biosecurity levels requisite for testing performed; and
- f. Evaluate preparedness (identify and prioritize gaps) through scenario testing.

The NAHLN structure described below is intended to ensure continuation of the founding principles while addressing changes necessary to allow for needed flexibility and added capacity to more completely address the current gaps in the nation's surveillance, detection, and response capability.

## Proposed NAHLN Structure

**Governance:** The proposed NAHLN structure preserves its current oversight, leadership, administrative structure, and roles and responsibilities as outlined in the USDA-approved NAHLN charter (appended). Specifically, the USDA will provide Federal oversight with APHIS being responsible for operational aspects of the NAHLN. An Executive Committee composed of USDA staff will continue to review and implement the NAHLN strategic and operational plans. The Coordinating Council, composed of USDA staff, State employee representatives of NAHLN laboratories, and State animal health

officials, will continue to provide a forum to discuss the NAHLN's current and future needs.

**Participation:** Under the proposed structure, each State can sponsor a publicly-funded NAHLN laboratory. However, participating laboratories must have sufficient laboratory-generated income, State resources, or other public funds to qualify for their level of participation (see below). Having State-based NAHLN laboratories allows for proximity to and linkages with producers and veterinarians critical to early detection of foreign animal and emerging diseases. Qualifying requirements are tiered, and based on current understandings of the needs of the overall network (see below). To maintain a NAHLN designation, qualifying laboratories will undergo annual reviews to demonstrate adherence to established NAHLN policies and procedures.

**Laboratory designations:** Participating laboratories will be designated as Levels 1, 2, 3, Affiliate, or Specialty laboratories. Level 1, 2, and 3 laboratories are publicly-funded State and university-associated animal health diagnostic laboratories. Affiliated laboratories are publicly-funded laboratories that may occasionally perform NAHLN-related testing, and currently include the FSIS, the National Wildlife Health Center (NWHC), and the Department of Defense, Fort Sam Houston laboratories. Specialty laboratories are private or commercial enterprises that provide diagnostic capabilities that do not exist at needed capacities within the NAHLN.

To participate in the NAHLN, specialty laboratories must have a written, USDA-approved plan that demonstrates the ability to avoid conflicts of interest in the testing they perform. USDA will have

responsibility for decisions regarding laboratory membership and tier designations in the NAHLN, with input on criteria from the NAHLN Coordinating Council and other NAHLN stakeholders. All NAHLN laboratories are subject to an annual accountability review with the designation of Level 1 laboratories reassessed at least every 5 years.

The principal difference between Level 1 and Level 2 laboratories is that Level 1 laboratories must meet each defined criterion, whereas Level 2 laboratories must only meet a subset of Level 1 criteria and have the option of meeting others as resources permit. Level 3, Affiliate, and Specialty laboratories need not be accredited, but will be required to have a USDA-approved quality management system. Affiliate and Specialty laboratories must also establish operational relationships with a designated NAHLN laboratory and with the State animal health official for the State in which the laboratory is located.

**Level 1 Laboratories:** Similar to current Core laboratories, Level 1 laboratories will have the capacity to perform tests on large numbers of samples that originate from U.S.-farmed food animals. Unlike the current Core laboratories, the number and identity of Level 1 laboratories may change by adding or removing laboratories depending on national need and available funding.

The decision to modify the number or location of Level 1 laboratories will be based on (1) overall national need, (2) population density of the food animals of interest, (3) geographic location, (4) testing capabilities, (5) personnel expertise, (6) facilities and other infrastructure, and (7) level of State support.

To be classified as a Level 1 NAHLN laboratory, a laboratory must:

- a. Maintain capacity to provide surge testing for disease agents of interest;
- b. As requested by the USDA, participate in surveillance testing;
- c. Be fully accredited by AAVLD, ISO 17025, or by another accrediting body with equivalent standards;
- d. Perform all work within a quality management system under the direction of a quality manager;
- e. Have staff members trained and proficiency tested in diseases of interest;
- f. Possess a functional laboratory information management system (LIMS);
- g. Have the capability to electronically send diagnostic test results to APHIS databases;
- h. Report test results within timeframes indicated in NAHLN standard operating procedures;
- i. Help further develop the NAHLN IT system;
- j. As requested by the USDA, help other laboratories develop and implement IT capabilities to permit them to communicate testing results with NAHLN;
- k. Provide and maintain biosafety level 3 laboratory space adequate for work performed;
- l. Possess ongoing State funding adequate to maintain equipment and laboratory space used for NAHLN purposes;
- m. As requested by the USDA, send staff members to other laboratories or field operation centers during emergency situations;
- n. As requested by the USDA, provide training for NAHLN test procedures;
- o. Accept samples that originate from other States affected by disease outbreaks,

especially those from Level 2 laboratories;

- p. Assist with NAHLN test development and validation;
- q. Participate in NAHLN-related activities (e.g. subcommittee and working group activities, development of training programs, scenario testing exercises, AAVLD/USAHA NAHLN Joint Committee, etc.);
- r. As requested by the USDA, participate in auditing NAHLN or prospective NAHLN laboratories;
- s. Have an acceptable periodic review conducted under the oversight of USDA.

**Level 2 Laboratories:** Similar to current Member laboratories, Level 2 laboratories provide greater geographic coverage and consequently more rapid disease detection. To be classified as a Level 2 NAHLN Laboratory, a laboratory must meet most of the requirements outlined above for Level 1 Laboratories, except that Level 2 Laboratories:

- a. Are not required to maintain capacity to provide for surge testing;
- b. May be provisionally accredited by AAVLD or by another accrediting body to World Organization for Animal health (OIE) standards, ISO 17025, or equivalent standards;
- c. Perform all work within a quality management system under the direction of a quality manager;

Have no requirement for biosafety level 3 laboratory space; and

- d. In reference to items i – q (except k – the biosafety requirement), participate as resources allow.

**Level 3 Laboratories:** These laboratories participate primarily in surveillance

activities. To be classified as a Level 3 NAHLN laboratory, a laboratory must:

- a. As requested by the USDA, participate in surveillance testing;
- b. Work under a NAHLN-approved quality management system overseen by a quality manager;
- c. Have staff members trained and proficiency tested in diseases of interest;
- d. Have a functional LIMS;
- e. Report test results within timeframes indicated in NAHLN standard operating procedures.

**Affiliate Laboratories:** These are publicly-funded laboratories that may occasionally perform NAHLN-related testing. To be classified as a NAHLN Affiliate laboratory, a laboratory must meet the requirements of a Level 3 laboratory, plus:

- a. Establish a memorandum of understanding with the USDA that defines the role and relationship of the laboratory within the NAHLN; and
- b. Establish operational relationships with a designated NAHLN laboratory and with the State animal health official of the State in which the laboratory is located.

**Specialty Laboratories:** These are private laboratories that have a specific, but needed, capability as determined by the USDA with input from the Coordinating Council. To be classified as a NAHLN Specialty laboratory, a laboratory must meet the requirements of a Level 3 laboratory, plus:

- a. Establish operational relationships with a designated NAHLN laboratory and with the State animal health official of the State in which the laboratory is located; and
- b. Have a written, USDA-approved plan that demonstrates the ability to avoid

conflicts of interest in the testing they perform.

**Reference Laboratories:** The NAHLN Reference laboratories are the NVSL. In fulfilling this role, NVSL personnel provide: (1) oversight on testing and reporting procedures; (2) assay development, validation, and deployment; (3) proficiency tests; (4) reference materials; and (5) procedure training.

## Summary

The proposed revisions to the structure of the NAHLN and codification of USDA oversight, the existence of a NAHLN charter, and the outline of the network structure will give the NAHLN flexibility to respond to future national animal health testing needs. The proposed changes clarify the roles and responsibilities of network members and provide the ability to more easily expand or contract NAHLN testing capabilities and capacities. Having the actual NAHLN charter and the specific requirements for each level of participation referenced in program standards but not codified allows the NAHLN to respond readily to the changing needs of animal agriculture.

The proposed changes will allow the NAHLN to achieve its original surveillance and response goals and to expand detection of emerging and zoonotic diseases to protect animal and public health as well as the nation's food supply.