



Laboratory Membership

- In 2002, Animal and Plant Health Inspection Service and National Institute of Food and Agriculture (formerly the Cooperative State Research Education and Extension Service) initiated the Network by entering into cooperative agreements with 12 State and university veterinary diagnostic laboratories. These were funded by Homeland Security appropriations.
- APHIS has since contracted with additional State and university diagnostic laboratories to assist with testing and surveillance. These contracts are with 56 State/university laboratories; the Department of Interior (DOI) laboratory in Madison, Wisconsin; the USDA, Food Safety and Inspection Service (FSIS) laboratory in Athens, Georgia; and the National Veterinary Services Laboratories (NVSL) in Ames, IA and Plum Island, NY locations, for a total of 60 laboratories in 43 States.
- NVSL trains and proficiency tests the NAHLN member laboratories either annually or semi-annually. Tests include standardized screening methods for the currently targeted diseases in the NAHLN. These laboratories perform screening assays and forward any suspect or positive samples to the appropriate section of the NVSL for confirmatory testing.

Movement to Member Laboratory Designation

The NAHLN is comprised of four laboratory designations: Adjunct, Contract Member, Member, and Core Member Laboratory. In 2009, the list of requirements was updated to further define each laboratory designation's roles and responsibilities within the Network. In 2010, cooperative agreements were established with 12 AAVLD-accredited laboratories to move them from Contract Member to Member Laboratory status. Funding has been provided to support their quality management system and their capability to electronically transmit the standardized test result data to the NAHLN information technology (IT) system. The following laboratories are participating: AR, CT, GA- Tifton, IL-Urbana, KY-Lexington, MO, MT, ND, OK, PA-Kennett Square, PA-University Park, and SC.

Revisions to VS Memo 580.4

Veterinary Services (VS) Memorandum 580.4 provides the procedures for investigating a suspected foreign animal or emerging disease incident. The memo was revised and finalized in October 2008 with inclusion of NAHLN laboratories testing in FAD investigations in specific situations. Due to the complicated nature of the communications involved in the memo, flow charts were developed in 2010 with the National Center for Animal Health Emergency Management (NCAHEM) and distributed to NAHLN laboratories and State animal health officials.

NAHLN Methods Technical Working Group

The NAHLN Methods Technical Working Group (MTWG), established in July 2006, consists of personnel from NAHLN laboratories and NVSL as well as DOI, FSIS, and the National Center for Foreign Animal Disease in Winnipeg, Manitoba. The working group provides input on various aspects of methods validation and approval of methods. For example, a Dossier Review Team, consisting of members of the NAHLN MTWG met to evaluate data on a number of potential influenza assays to detect the novel 2009 H1N1. The Dossier Review Team reviewed the data generated by the NVSL's Diagnostic Virology Laboratory and recommended the testing algorithm currently used by the NAHLN laboratories. The methods comparison processes



developed by the group have been used to evaluate several studies. The processes and training materials were discussed at an International Atomic Energy Agency (IAEA)/World Organization for Animal Health (OIE)-sponsored meeting on test validation in October 2010 and will be used by OIE as a model for OIE training.

NAHLN Newsletter

The first issue of *The NAHLN Quarterly*, an electronic newsletter with the purpose of increasing communication with stakeholders, was provided to NAHLN laboratory directors in February 2009. Since that time, eight issues have been released and subscriptions have increased to over 1300. Subscribers include NAHLN laboratory directors, State animal health officials, APHIS program staff, animal industry representatives, and other State, Federal, and international representatives. In order to continue to provide readers with the information that they need, a Readers' Review was conducted in summer of 2010. Results of the review, as well as other feedback received, demonstrated that the subscribers view the newsletter as relevant and valuable as an effective tool to disseminate important information regarding activities related to the Network.

NAHLN Laboratory Review Process

NAHLN program staff collaborated with AAVLD to establish a review process for NAHLN laboratories, ensuring the development and implementation of a quality system consistent with AAVLD, OIE, and ISO standards. Standardized reports detailing non-conformances and requirements to maintain NAHLN status are provided to each audited laboratory. A summary report was prepared which details the site visits conducted in 2009, the issues found, and the program goals for 2010. The 2010 goals are now being compared to the 2010 laboratory review accomplishments and will be used to develop goals for 2011.

NAHLN Information Technology (IT) System

Currently, there are 38 NAHLN laboratories approved for CSF testing and 21 laboratories that are receiving surveillance samples; 13 of those are sending CSF surveillance testing results electronically. In addition, 53 NAHLN laboratories are approved for avian influenza surveillance testing and 35 of the avian influenza(AI)-approved laboratories are participating in Wildlife Services' (WS) Wild Bird AI Surveillance. At present, 12 laboratories are messaging into the NAHLN IT system, with several more in the testing phase. Current messaging efforts include CSF, and AI; a message for SIV is in development .

FMD Table-top Exercises

The NAHLN, in collaboration with the National Agriculture Biosecurity Center (NABC) at Kansas State University (KSU) and the CNA Corporation, coordinated a series of foot-and-mouth (FMD) table-top exercises based on recommendations from the highly pathogenic avian influenza table-top exercise series in 2008. In April 2010, representatives from multiple Veterinary Services (VS) program units participated in the first component of these exercises-- a policy-level workshop with the objectives to: identify existing policies related to laboratories, NAHLN activation and sample shipping during an FMD outbreak; determine roles and responsibilities of individual units related to laboratory decisions prior, during and following an FMD outbreak; and clearly define gaps and processes for VS to address prior and during the subsequent exercises. The second component of the exercise series involved a simulated FMD



outbreak in Kansas and Iowa in order to examine early-, mid-, and late-response laboratory activities regarding the decision-making process for NAHLN activation and deactivation; testing capacity at each of the State's NAHLN laboratories; surveillance sample collection protocols; testing algorithms; integration of surveillance and testing results; and communication and coordination processes. The third component of the exercises consisted of 15 follow-up exercises in NAHLN laboratories across the country, each involving single or multiple States. These exercises were designed to practice policy implementation, decision-making, and communication identified in the first two components of the series with laboratory, and VS and State field personnel. Individual exercise reports will be shared with participants. An overall summary report, including findings and recommendations, will be generated and shared with stakeholders. Additional exercises will be held internal to the NVSL to increase our internal preparedness with focus on decision-making, primary and support role activities, interaction and support of NAHLN laboratories, collaboration, and communication. A wrap-up VS policy workshop will be held in late spring 2011 to complete the policy matrix, which will include findings and any existing gaps in VS policy, from the first phase of the exercise series.

Negative Cohort Studies

NAHLN is coordinating negative cohort studies for foot-and-mouth disease (FMD), African swine fever (ASF), and rinderpest as an important component to the validation of the real time PCR assays for these diseases. NAHLN has been working closely with the Proficiency and Validation Services and Diagnostic Services Sections at FADDL on the training, development and review of proficiency tests for 11 participating NAHLN laboratories. Further, we have focused on coordinated communication with VS' National Center for Animal Health Emergency Management (NCAHEM), VS' Regional staff, the participating NAHLN laboratories, and State animal health officials on the purpose of the negative cohort, expectations of false positive results, and processes for sharing the negative cohort testing results. The studies will be completed by April 2011.

Training on the Quality Management Systems

The NAHLN Program Office collaborated with members of the AAVLD Accreditation Committee and NVSL personnel to develop and deliver a Quality Management System (QMS) Training Program. The QMS Training Program was held August 3-5, 2010 at the National Centers for Animal Health in Ames, Iowa. The training program provided an interactive class environment that included training on quality system requirements, the accreditation process, document control, internal auditing, and root cause analysis. In addition, a wet laboratory provided the opportunity for participants to conduct an audit, recognize non-conformances, analyze the root cause, and write corrective actions. A total of 87 participants representing 53 laboratories attended the training; including 40 NAHLN laboratories, 8 prospective laboratories, 4 Federal laboratories (NVSL in Ames, Iowa; NVSL's Foreign Animal Disease Diagnostic Laboratory in Plum Island, New York; USDA laboratory in Topeka, Kansas; Plant Protection and Quarantine), and one guest from the University of Montreal. A summary report will be prepared and will include options for further deliveries and possible expansion.

NAHLN Coordinating Council

On June 15-16, 2010 the National Centers for Animal Health in Ames, Iowa hosted the first meeting of the NAHLN Coordinating Council. The Council Co-Chairs, Beth Lautner,



Veterinary Services (VS); Muquarrab Qureshi, National Institute for Food and Agriculture (NIFA); and Gary Anderson, Kansas State University, welcomed the members and facilitated the meeting. John Clifford, Deputy Administrator of VS, and Merle Broussard, Deputy Administrator of Plant and Animal Systems, NIFA, thanked the members of the Coordinating Council for their participation and stated that they are looking forward to feedback from the group as we look to move the NAHLN forward. They also highlighted some of the NAHLN accomplishments over the past few years.

The agenda for the meeting focused on the activities of the Coordinating Council as outlined in the Charter and included the following:

- The goals, strategic plan, and operational objectives of NAHLN
- The specific criteria that defines a NAHLN laboratory
- The policies that relate to the NAHLN
- New areas for the NAHLN

The notes from the Coordinating Council meeting have been posted on the NAHLN website. The next meeting has been scheduled for February 2011.

NAHLN Portal

FoodShield is being used to develop a NAHLN portal that initially will be comprised of the following modules:

- A secure mechanism to electronically comment on and release SOPs.
- A laboratory directory that includes information on physical space, personnel, and equipment.
- A mechanism to monitor assay performance and report proficiency test results.
- A mechanism to train others in the validation process.
- Work Group space to post documents and schedule meetings and calls.

Capacity Estimation Program

The Department of Homeland Security's National Center for Foreign Animal and Zoonotic Disease Defense (FAZD) located in College Station, Texas will be working with NAHLN program staff and NAHLN laboratories to develop a diagnostic testing capacity estimation program. The software program will include multiple technologies and can be personalized for individual laboratories. In addition, it will aid in the identification of rate limiting processes and help maximize efficiency as laboratories annually update their information. NAHLN laboratories will have the opportunity to participate in the requirements as well as user acceptance testing. It is anticipated that the prototype could be available within 9 months.