



National Animal Health Laboratory Network (NAHLN) Update

Laboratory Membership

- In 2002, the Animal and Plant Health Inspection Service and the National Institute of Food and Agriculture 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 partnered with additional Federal, State and university diagnostic laboratories to assist with testing and surveillance. The NAHLN currently consists of 60 laboratories in 41 States. The National Veterinary Services Laboratories (NVSL) in Ames, IA and Plum Island, NY locations are the national reference laboratories providing all confirmatory testing as well as training and proficiency testing of NAHLN personnel on an annual or semi-annual basis.
- The tests that NAHLN laboratories conduct 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 laboratory within NVSL for confirmatory testing.

NAHLN Concept Paper published in the Federal Register and comments received

The NAHLN Concept paper that reflects a revised NAHLN structure was published for public comment in the Federal Register in April 2013 for a 60-day comment period. Forty-two (42) official comments were received from many stakeholders including: NAHLN laboratories, AAVLD representatives, non-NAHLN laboratories, State Animal Health Officials, industry representatives, private laboratories, academia and several concerned individuals. The comments were overall supportive of the proposed network structure. The next steps include providing responses to all comments and incorporating the feedback as we move forward with Code of Federal Regulations writing and development of NAHLN program standards. The input will also be considered as the NAHLN strategic plan is updated.

NAHLN Methods Technical Working Group (MTWG)

The NAHLN MTWG welcomed the two new co-chairs: Dr. Bruce Akey (NAHLN Coordinating Council and Laboratory Director Representative) and Dr. Sarah Tomlinson (NAHLN Coordinator) this year. The group held two face-to-face meetings and one 2-day webinar in FY2013. In addition to continuing to provide input on multiple ongoing assay development and validation projects, the group also focused on development of a standardized process for De Novo PCR method development and helping to define NAHLN's role in emerging disease detection. The group proposed several short and long-term actions to be taken by NAHLN to enhance the network's ability to detect emerging diseases. The group also reviewed a pilot proposal for FAD testing in wildlife, providing feedback on the technical aspect of the proposal for the NAHLN Coordinating Council and Veterinary Services to consider, in addition to the policy impact and communication needs of the project. The MTWG will also be reviewing several dossiers before the end of 2013.

Training on Quality Management Systems (QMS)

While the original QMS course in 2010 was developed to assist the NAHLN laboratories in implementing and continually improving quality management systems, it has expanded to assist other laboratory networks and international colleagues. In August 2013, the NAHLN program office,



International Services, Veterinary Services' Professional Development Staff, and AAVLD trainers offered the annual Quality Management System training course. Thirty-six participants from inside the U.S. and 25 participants representing 17 countries participated in the training. The three-and-a-half day training provided an interactive class environment that included topics such as quality management system requirements, document control, internal auditing, corrective actions, root cause analysis, and a mock audit. Additionally, development and expanded use of the on-line QMS training-- a collaboration between AAVLD, Washington Animal Disease Diagnostic Laboratory and NAHLN--continued in FY13 and will be on-going in the next year.

NAHLN Surveillance Activities

The NAHLN continues to collaborate with other groups in APHIS, such as NVSL, Wildlife Services, National Surveillance Unit, National Center for Animal Health Programs, and the National Center for Animal Health Emergency Management to implement surveillance programs. In FY12, NAHLN laboratories participated in surveillance programs for bovine spongiform encephalopathy (BSE), classical swine fever (CSF), chronic wasting disease (CWD), influenza A virus in swine ((IAV-S); referred to as swine influenza virus), pseudorabies virus (PRV), and scrapie.

<i>Disease/Agent</i>	<i>FY11</i>	<i>FY12</i>	<i># of NAHLN Laboratories Currently Approved for Testing</i>
	<i>Samples or Animals Tested</i>		
AI	*	*	55
BSE	39,041	40,088	6
CSF	5,889	6,771	40
CWD	15,337	7,749**	20
IAV-S	5,460	9,382	39
PRV	27,809	23,928	12
SCRAPIE	37,367	40,414	20

* The wildbird AI surveillance was discontinued in March 2011. Therefore, FY2011 data are not reported here.

** The NAHLN laboratories participated in CWD surveillance through 1st quarter of FY12 only.

NAHLN Portal

The NAHLN Portal is a web application created to provide a secure collaboration and communication system for members of NAHLN. This secure network provides NAHLN program staff and management with capability, capacity, and readiness data for the network member laboratories as well as a collaboration capability through the workgroup and webinar functionalities. Development on the NAHLN Portal began in spring 2011 with initial launch late 2011. Since that time, several updates have been made which include ongoing maintenance and core expansion to the NAHLN Portal laboratory directory. The equipment inventory, proficiency testing, standard operating procedure, accreditation, analyte, and assay performance sections will be released by the end of 2013. Further maintenance to the overall functionality and core expansion to the proficiency testing section is planned for FY 14.



Laboratory Messaging

In FY2013, the NAHLN IT system has undergone a number of modifications and updates to now become a Laboratory Messaging Service (LMS). The LMS uses the same Health Level 7 (HL7) standards that the NAHLN IT system has used historically, but with a more general approach to accommodate messaging of any test results much more quickly. The first success metric of LMS was to electronically message Swine Influenza Virus (SIV) testing results. Messaging of SIV has been tested successfully and is now in production. This same model will be followed for pseudorabies virus surveillance results. The next phase of LMS will be integration with other Veterinary Services IT systems. An additional success this year has been NVSL's development of HL7 messaging capabilities, which will continue to expand over the next year.

Validation Studies in the NAHLN

Collaborative inter-laboratory comparison and negative cohort studies have become a routine function in NAHLN as a part of diagnostic assay validation. Overall, these studies provide data needed to determine if and how the assays should be used for a specific purpose (fit for purpose) and how the assay performs on the U.S.' negative population. Inter-laboratory comparison studies provide data about reproducibility and robustness of assay, while negative cohort studies provide specificity parameters and identify cross reactivity with other agents. The studies are designed to meet OIE guidelines in terms of sample size numbers and geographic distribution representative of US livestock populations. The process for implementing these studies includes open communication with the stakeholders and approval by each participating State's Animal Health Official.

- ***Real time RT-PCR for Foot and Mouth Disease (FMD) virus in bulk tank milk:*** A collaboration between NVSL's Foreign Animal Disease Diagnostic Laboratory (FADDL), the Foreign Animal and Zoonotic Disease Center (FAZD), Pirbright, Wisconsin Veterinary Diagnostic and the California Animal Health and Food Safety Laboratories. Five NAHLN laboratories in major dairy States participated, testing approximately 2000 samples. The inter-laboratory comparison and negative cohort studies are complete. The dossier will be reviewed by the NAHLN MTWG this fall.
- ***FMD Penside Antigen assay (Lateral Flow Device):*** A collaboration with FAZD and FADDL. This was a follow-up to a pilot study that was conducted in 2012 with 2 NAHLN laboratories. In the larger study, 7 laboratories elected to participate, collecting and testing a total of 500 samples on cattle, swine, and small ruminants. The negative cohort has been completed and the dossier will be reviewed by the NAHLN MTWG this fall.
- ***Real time RT-PCRs for Contagious Bovine Pleuropneumonia (CBPP) and Lumpy Skin Disease (LSD):*** A collaboration with FADDL that included 8 participating NAHLN laboratories. The inter-laboratory comparison and negative cohort studies are complete. The laboratories tested a total of 1400 CBPP and 1000 LSD samples from cattle. The dossiers are currently being prepared and will be reviewed in early 2014.
- ***Upcoming studies:*** Include FMD 3 ABC ELISA inter-laboratory and negative cohort studies, in which 13 laboratories will participate by testing cattle, swine, and small ruminants. Additionally, an inter-laboratory comparison for a "pan-H7" multiplex PCR is being planned for late fall 2013.



NAHLN Preparedness Activities

- ***Laboratory Capacity Estimation Model (LCEM)*** was developed in partnership with the Foreign Animal and Zoonotic Disease Center (FAZD) and deployed to NAHLN laboratories in 2012. The web-based software program provides the ability for laboratories to define resources dedicated to each element of the accessioning and testing process for any diagnostic assay. This allows on the local level for the laboratories to determine throughput under various scenarios; identify rate limiting processes; and maximize their efficiency. Additionally, LCEM provides the ability for the NAHLN Coordinators to view an individual laboratory's current and maximum throughput for the various assays to guide decision-making for appropriate direction of samples in an outbreak situation. The second enhanced version of LCEM has been finalized and is ready to deploy. Version 2 includes integration with the NAHLN portal and enhancements to include limited accounting capabilities and for reagent and supply inventory tracking.
- ***NAHLN Exercises and Drills Working Group*** provided and/or sponsored several informational webinars on relevant topics such as LCEM, VS Guidance 12001.1 and the FAD investigation manual, and personal protective equipment for diagnosticians this year. The group is developing an exercise program for NAHLN labs that includes regular drills and utilization of virtual tools such as LCEM and the NAHLN Portal to train and prepare laboratories.