

Policy Regarding Evaluation of Veterinary Diagnostic Laboratories for Membership in the National Animal Health Laboratory Network

Policy statement:

1. It is the policy of the National Animal Health Laboratory Network (NAHLN) to strengthen and provide direct support for a coordinated national effort to prepare for and respond to foreign animal disease outbreaks, to acts of bioterrorism or to other animal and public health emergencies.
2. Veterinary diagnostic laboratories provide the capability to routinely diagnose high consequence livestock pathogens and toxins and select agents in animals, food, and environmental samples, and to do so at the confirmatory level. They are likely to be the first-line laboratories for recognition of an intentionally or accidentally introduced agent in animals.
3. A veterinary diagnostic laboratory may become a part of the testing network of the NAHLN only if specific criteria in A.1 and A.2 below are met by the state and by the proposed laboratory.
4. Membership evaluation criteria for veterinary diagnostic laboratories are outlined in the *Laboratory Qualification Checklist*. This checklist can be obtained by contacting Barbara M. Martin, NAHLN Coordinator, by calling (515) 663-7731 or email (Barbara.M.Martin@aphis.usda.gov).
5. Return the completed checklist to:
Barbara M. Martin
NVSL
PO Box 844 (letter)
1800 Dayton Av. (packages)
Ames, IA 50010

A. Analysis of Specimens

The mission of the NAHLN can best be served when the security and appropriate use of its resources (including protocols, reagents, and communications systems) is assured. Expansion of the NAHLN to include additional veterinary diagnostic laboratories is appropriate and essential to meet state and federal needs for increased laboratory capability and/or capacity, particularly for analysis of high consequence livestock pathogens and toxins and overlap select agents in samples of animal (including food) and environmental origin. Most veterinary diagnostic laboratories do not routinely handle, and in some cases are restricted from handling, human samples.

Required specimen handling, packing, shipping, processing and chain-of-custody procedures must be strictly adhered to by participating laboratories, and the challenges of assuring the safety of the laboratory worker must be fully understood and addressed.

A.1 Evaluation Criteria

The NAHLN Steering Committee develops criteria for entry into and maintenance of all veterinary diagnostic laboratories in the NAHLN. If a decision is made to introduce a

laboratory into the NAHLN in a state, the laboratory must first meet the following criteria:

1. *Facility and personnel security*: Must conform to existing requirements of the Select Agent Rule, USA PATRIOT Act of 2001, and BMBL 4th edition, Appendix F or other superceding document.
2. *Reagent Controls* - per NAHLN policy, there will be no distribution of any NAHLN assets or materials outside of the receiving facility to which the NAHLN originally supplied the material.
3. *Worker safety*: Must conform to BMBL 4th (or current) edition facility and practice criteria recommended for the agent(s) to be tested, including vaccination of workers when appropriate.
4. *Licensure/ certification*: Must be an AAVLD accredited laboratory or other public, not-for-profit, animal disease diagnostic laboratory selected by the USDA.
5. *Data and Information Security*: Once in the Network, the laboratory must have or develop the capacity to electronically transmit the standardize test result data to the NAHLN repository and must restrict access to protocols, reagents, samples, and results only to those personnel previously approved for access to the secure NAHLN Website.
6. *Proficiency*: Must agree to participate in APHIS-sponsored proficiency training and testing, and demonstrate proficiency.
7. *Specimen Handling*: Must have sample transport and chain-of-custody procedures in place that conform to IATA, DOT, State regulatory and law enforcement requirements.
8. *Regulatory Restrictions* - Must understand and accept the regulatory restrictions and liability on the use of specialized animal health biodetection assays which are not intended for diagnostic use outside of NAHLN defined testing parameters.
9. *Federal Acquisition Regulations*: Must comply with existing guidelines and restrictions related to the use of federal funds under the FAR, especially when a contractual (funded) relationship is required

A.2 Contractual Obligations

A detailed operational plan, including defined roles and responsibilities, must be developed and approved by mutual agreement between the USDA and the director of the laboratory under consideration. As a general guideline, NAHLN resources (including protocols, reagents, and proficiency testing) must only be used by the laboratory by explicit request.

In order to maintain the security of the NAHLN, prior to admitting an additional laboratory into the NAHLN the written consent of a responsible party attesting to the compliance of the laboratory with the following must be provided:

1. Must agree to use only NAHLN protocols and reagents when conducting testing of suspected high consequence livestock pathogens.
2. Must agree to use NAHLN reagents only for testing of suspected high consequence livestock pathogens, not for research, development, or private, for-profit testing.
3. Must agree to provide results of any and all testing performed with NAHLN protocols and reagents to the State Veterinarian and Federal AVIC of the state of sample origin, and/or to the National Veterinary Services Laboratories as appropriate and required by state and federal regulations.

4. Must agree to limit copying and distribution of NAHLN protocols to those parties who will actually conduct testing during a foreign animal disease or other high consequence livestock pathogen event and who were previously approved for access to the secure NAHLN Website.
5. Must agree to provide 24/7 services when requested by the State Veterinarian or APHIS during a foreign animal disease or other high consequence livestock pathogen event, and when funded accordingly.
6. Must immediately report positive and suspect results to the legally responsible party in accordance with State and Federal disease-reporting requirements; must not release test results to any other parties.
7. Must implement chain-of-custody procedures meeting standards of evidence in the jurisdiction when a terrorist event is suspected. These will be established and reviewed in consultation with the state FBI Weapons of Mass Destruction Coordinator. Must be willing to provide expert witness testimony concerning tests conducted during a terrorist event.
8. Must agree to dissolution of the contract/cooperative agreement with USDA and the NAHLN without cause, immediately upon notice, and to surrender any and all NAHLN reagent stocks and protocols immediately should this dissolution occur.

B. Analysis of Environmental and Food Specimens

Terrorism-related environmental samples present even greater concerns for worker safety than do clinical specimens. Veterinary diagnostic laboratories should expect that samples delivered by law enforcement or HazMat teams may contain multiple hazards.

Laboratory Directors are urged to consider the unique hazards accompanying a laboratory response to terrorism, and to carefully consider their ability to manage these risks. Sample handling, packing, shipping, processing and chain-of-custody procedures must take this into account and the challenges of assuring worker safety must not be taken lightly.

Summary of Revisions

Version .02 to reflect removal of David Kinker as Acting NAHLN Coordinator and replacing with Barbara Martin as the NAHLN Coordinator.

Version .03 to reflect change to page 2, number 4, “full service” changed to “public, not-for-profit” for clarification.

Version .03 to reflect change to page 2, number 5, by inserting “the laboratory must have or develop the capacity to electronically transmit the standardize test result data to the NAHLN repository” prior to “and must restrict access...”