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. NAHLN laboratories may be asked to conduct screening tests on samples collected during foreign animal disease investigations, in accordance with the current version of Veterinary Services Guidance (VSG) 12001.
4. 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.
5. Membership evaluation criteria for veterinary diagnostic laboratories are outlined in the *NAHLN Laboratory Qualification Checklist for Membership of a Veterinary Diagnostic Laboratory*. This checklist can be obtained by contacting the NAHLN Program Office by calling (515) 337-7731 or email (NAHLN@aphis.usda.gov).
6. Return the completed checklist to:
   National Animal Health Laboratory Network
   NVSL
   PO Box 844 (letter)
   1920 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. This is particularly important 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. These and other required criteria are defined in section A.1 (Evaluation Criteria).

A.1 Evaluation Criteria

The NAHLN Coordinating Council 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 with current regulations of the Federal Select Agent Program for the possession, use, and transfer of select agents and toxins in Title 9 Code of Federal Regulations (CFR) Part 121, 7 CFR Part 331, and 42 CFR Part 73) in the Federal Register (http://www.selectagents.gov/index.html), and Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition http://www.cdc.gov/biosafety/publications/bmbl5/index.htm, Appendix F or other superseding 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 5th (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 American Association of Veterinary Laboratory Diagnosticians (AAVLD) accredited laboratory or other public, not-for-profit, animal disease diagnostic laboratory with an established quality assurance system meeting OIE/ISO 17025 standards and selected by the USDA.
5. *Data and Information Security* - Core laboratories must have the capability to electronically message test results, to ensure accurate, consistent, secure, and timely transmission of data. Member laboratories are expected to actively work toward meeting this requirement; and Contract and Adjunct laboratories are encouraged to demonstrate progress toward developing the capability to electronically transmit the standardized test result data to the Laboratory Messaging Services (LMS, formally NAHLN repository) and/or State Animal Laboratory Messaging Services (SALMS). The laboratory must comply with current APHIS security and IT training requirements, and must restrict access to protocols, reagents, samples, and results only to those approved personnel.
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 International Air Transportation Association (IATA), Department of Transportation (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 bio-detection assays which are not intended for diagnostic use outside of the NAHLN defined testing parameters.
9. *Federal Acquisition Regulations (FAR)* - 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 as outlined in the appropriate policy, SOP, or other official NAHLN document.

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 NAHLN protocols and reagents only in accordance with published agent specific NAHLN surveillance and/or response plans when conducting NAHLN testing of suspected high consequence livestock pathogens unless an official request for deviation is submitted and approved prior to implementation of any deviation.
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 unless an official request for deviation is submitted and approved prior to implementation of any deviation.
3. Must agree to provide results of any and all testing performed with the NAHLN protocols and reagents to the State Animal Health Official and Federal District Director (DD) or Associate District Director (ADD) 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 the 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 Animal Health Official 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 parties in accordance with State and Federal disease-reporting requirements; must not release test results to any other parties.
7. May need to implement secure storage and chain-of-custody procedures meeting standards of evidence in the jurisdiction to support potential evidentiary requirements of the FBI. NAHLN laboratories are expected to have established communication with the state FBI Weapons of Mass Destruction Coordinator. If FBI assistance is needed and you do not have a local FBI contact, contact the FBI at (202) 324-3000 or http://www.fbi.gov/contact/fo/fo.htm.
8. Must agree to dissolution of the contract/cooperative agreement with USDA and the NAHLN with or 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.

C. Summary of Revisions

Policy-NAHLN-0001.03:

- Policy Statement #3 - Removed version number of VSG 12001.
- Section A.1.1 – updated web links to Federal Select Agent Program and BMBL sites.
  - Section A.1.5 – Modified to state ""~~Once in the Network,~~ ~~while~~ Core ~~and Member NAHLN~~ laboratories must have the capability to electronically message test results, to ensure accurate, consistent, secure, and timely transmission of data. Member laboratories are expected to actively work toward meeting this requirement;~~, all labs~~ and Contract, and Adjunct laboratories are encouraged to…"

Policy-NAHLN-0001.02:

- Section A.1.1 - REMOVAL of reference "Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and USA Patriot Act of 2001".
- Section A.1.1 - ADDITION of reference "with current regulations of the Federal Select Agent Program for the possession, use, and transfer of select agents and toxins in Title 9 Code of Federal Regulations (CFR) Part 121, 7 CFR Part 331, and 42 CFR Part 73) in the Federal Register"
- Section A.1.5 – ADDITION of phrase "while Core and Member NAHLN laboratories must work toward meeting this requirement, all labs are encouraged to demonstrate progress"
- Section A.1.5 – REMOVAL of phrase "previously approved for access to the secure NAHLN website."
- Section A.2.3 – REPLACED "AVIC" with "District Director (DD) or Associate District Director (ADD)".