

National Animal Health Laboratory Network (NAHLN) Operational and Emergency Activation Plan

The National Animal Health Laboratory Network (NAHLN) is a cooperative effort among two federal agencies—Animal and Plant Health Inspection Agency (APHIS), the National Institute of Food and Agriculture (NIFA); State, Federal and university diagnostic laboratories; and the American Association of Veterinary Laboratory Diagnosticians (AAVLD) that ensures standardized surveillance and increased national capacity for early detection of foreign animal and emerging diseases, a better response to animal health emergencies, and standardized surveillance to assist in assessing the Nation's animal health status. The APHIS Veterinary Services, National Veterinary Services Laboratories (NVSL) serves as the national reference laboratory and provides confirmatory testing as well as reference materials training and proficiency testing. The NAHLN is always active at some level from its day-to-day activities of providing monitoring and surveillance for livestock and poultry diseases in the U.S. to a full blown activation of all member laboratories surging to provide testing support to a multi-state foreign animal disease (FAD) outbreak.

Key Elements of NAHLN Operations

Qualifications

Laboratories annually submit a NAHLN Laboratory Qualification Checklist expressing their qualifications and interest in participating in specific disease testing; approved laboratories are utilized as needed by APHIS programs.

- Signing of the NAHLN Laboratory Qualification Checklist by the NAHLN laboratory director, State Animal Health Official (SAHO), and responsible VS officials in the State indicates agreement to follow the requirements set forth in the Checklist by the NAHLN program and NVSL.
- Participating labs are determined by surveillance needs, as well as States' needs and desires to have testing capability.
- NAHLN laboratories must have a functional Quality Management System consistent with AAVLD and international standards.
- Current approved NAHLN laboratories and the diseases for which they test are listed on the NAHLN website: <u>NAHLN Laboratories</u>

Training and Proficiency Testing

The NAHLN Program staff coordinates with the appropriate NVSL reference laboratories to ensure NAHLN laboratories have reference materials; receive training, and complete proficiency testing for each disease for which the laboratory is approved.

Method Development

The NAHLN Methods Technical Working Group (MTWG) evaluates and recommends new testing algorithms and diagnostic methodology for implementation in the NAHLN.

Surveillance

NAHLN works in concert with the Surveillance, Design and Analysis (SDA) Unit, Surveillance Preparedness and Response (SPRS) staff, and the NVSL reference laboratories to develop the national surveillance plans.



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- For each disease/agent, the NAHLN laboratories receive a procedure manual that outlines testing protocols, communications procedures, and other key elements of the surveillance efforts; periodic updates for these manuals are provided.
- Surveillance data are reported to NAHLN for epidemiological analysis by SDA and SPRS staffs.
- The NAHLN Program staff establishes and manages financial agreements with NAHLN laboratories to reimburse for testing conducted under the NAHLN umbrella.
- NAHLN laboratories have the responsibility to communicate positive results to their SAHOs and appropriate VS staff.
- Some samples may cross State lines as coordinated with SPRS for efficiency.
- NAHLN coordinates with National Import Export Services to ensure member laboratories receive appropriate permits for the diagnostic reference materials and diagnostic specimens sample shipping to test for FADs.

Emergency Preparedness Recommendations for NAHLN Labs and States

- Completed annual NAHLN laboratory checklist
- Up-to-date information for each laboratory in the NAHLN portal
- Updated scenarios in NAHLN Laboratory Capacity Estimation Model to estimate all phases of laboratory capacity
- Familiarity with VS Guidance documents including VS Guidance 12001, FAD Prep documents and Redbook
- Participation in NAHLN preparedness exercises
- Laboratory Emergency Preparedness Plan
- Current procedures manual for each disease being tested
- State FAD testing Standard Operating Procedures
- Laboratory annex to State-level FAD plan and annual discussion-based exercise to test State Annex
- Semi-annual training with Foreign Animal Disease Diagnosticians (FADDs) within the State on FAD SOP
- Lab performance requirements- including trained and proficiency tested personnel

Operational Modes of the NAHLN

Monitoring and Surveillance Mode

This is the day-to-day steady operations of the system. The NAHLN is in **Monitoring and Surveillance** mode with all laboratories testing for endemic and emerging diseases. This includes routine surveillance testing, screening samples for FADs and available to receive duplicate FAD sample submissions for rapid diagnostic results for State-level decision makers. This testing is funded through various APHIS programs.

Routine monitoring and surveillance efforts in the NAHLN encompass four main goals:

Routine surveillance for endemic diseases:

NAHLN laboratories conduct surveillance for diseases such as: LPAI, IAV-S, ISA, PRV, Scrapie, and VHS.

Surveillance for emerging diseases:

The NAHLN system actively tests for emerging diseases such as SECD.

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Targeted surveillance testing for FADs

Includes surveillance programs for ASF, BSE, CSF, FMD and VSV.

FAD investigation screening—testing duplicate samples

- VS Guidance 12001 allows for the collection of duplicate samples in a FAD investigation for the purpose of sending one set of samples to the local NAHLN laboratory for rapid screening and the other to the appropriate NVSL laboratory for confirmatory testing.
- The SAHO and VS District Director (DD) or Assistant Director (AD) jointly make this decision in every investigation.
- The FADD will need to determine which NVSL facility -- Ames or the Foreign Animal Disease Diagnostic Laboratory at Plum Island (FADDL) and NAHLN laboratory is appropriate to send samples and send the correct samples immediately.
- As submission procedures for duplicate FAD sample submission will vary by State, each NAHLN laboratory is encouraged to coordinate with their SAHO and DD to outline how the entire process will be accomplished, in accordance with VS Guidance 12001 such as:
 - Which tests are available
 - What samples are needed
 - Shipping instructions
 - o Contact numbers for after hours
 - o What would be the turn-around time for each test
 - Will lab pick up samples in an emergency
 - o BSL2 or BSL3 facility requirements
 - o Coordination of interstate movement of samples
- Certain operational considerations for the NAHLN laboratory while in individual Activation mode, such as expectations for throughput, chain of custody, processes for transportation of the samples to the NAHLN lab, and reimbursement should be agreed upon ahead of time by the laboratory director and SAHO (see lab annex to state FAD plan template).

Emergency Activation Modes

Individual Laboratory Activation

A presumptive positive result of an FAD at a NAHLN laboratory may trigger Individual laboratory activation in the affected State. If an FAD investigation sample tests positive and is consistent with clinical signs, it may trigger the individual laboratory's surge procedures--preparation and expectation of increased sample volume for FAD screening tests on suspect and trace samples (aka surge procedures).

- Individual laboratory activation will be jointly agreed upon by SAHO, DD/AD, NAHLN laboratory director, NVSL director, and NAHLN Coordinator based on the diagnostic test results, clinical presentation of suspect animals, known epidemiology and disease situation
- If primary FAD investigation samples are tested only at NVSL and are positive, the NAHLN laboratory in the affected State may also be activated by decision of the above parties.
- Notifications by the NAHLN laboratory regarding a presumptive positive result should include:
 - NVSL Director, NAHLN Coordinator, NVSL section head to receive samples for confirmatory testing (or their respective designees).
 - VS District or Assistant Director
 - SAHO of NAHLN laboratory State and State of origin of samples (if different).

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Partial Activation of the Network

Partial activation of the network occurs when the *affected State/NAHLN laboratory is officially activated for testing samples associated with a disease outbreak* <u>and/or</u> additional NAHLN *laboratories (most likely within the affected region) have been activated,* <u>and/or</u> trained personnel from other NAHLN laboratories are deployed to activated laboratories. Activated laboratories will test samples from the infected zone, surveillance samples, re-routed routine samples or samples from nonsusceptible species from infected States.

- Select NAHLN laboratories in unaffected or less-affected States are activated by the NAHLN Coordinator in concert with Incident Commander, involved SAHOs and NAHLN laboratory directors. However, the final decision for each State's laboratory involvement is that of the SAHO and/or Governor's office.
- While the Network is partially activated, an individual laboratory may have the capacity and choose to continue to run routine testing of samples and/or shift samples to another laboratory in their system or another State. NAHLN Program staff can help to coordinate the redirection of such testing; however, pre-established agreements with other States/laboratories for such a contingency are recommended.
- If personnel from other NAHLN laboratories are deployed to another NAHLN laboratory, the NAHLN Program staff will coordinate the reimbursement of overtime and travel expenses with the home laboratory.
- Additional equipment needs in activated laboratories will be addressed on a case-by-case basis.
- The use of mobile laboratories (such as those resources available to States through Civil Support Teams or other emergency response agencies) to support outbreak testing may be considered. The NAHLN Program staff and NVSL staff have developed standards and guidelines for standing up mobile laboratories to be used as temporary NAHLN laboratories. The decision to use a mobile laboratory will be made in concert with the Incident Commander, NAHLN Laboratory Director, SAHO, NVSL Director and NAHLN Coordinator.

Full Activation of the Network

Full activation of the network occurs when all NAHLN laboratories operate with their surge procedures to meet the national demand for trace investigation, surveillance, and proof of disease freedom samples generated from the outbreak. The final/official decision for Full activation of the NAHLN will be decided by the VS Deputy Administrator in consultation with the Incident Commander, VS Executive Team, NVSL Director, and NAHLN Coordinator. Sample distribution for testing will be coordinated by the Incident Commander and NAHLN Program in consultation with SAHOs and NAHLN laboratory directors.