

National Veterinary Services Laboratories and National Animal Health Laboratory Network Overview



April 7, 2008

Veterinary Biologics Public Meeting

Beth Lautner, D.V.M., M.S.

Director, National Veterinary Services Laboratories

NVSL Mission

- To safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate laboratory support* is provided by a nationwide animal health diagnostic system.

* Includes both domestic and foreign animal diseases

NVSL Activities

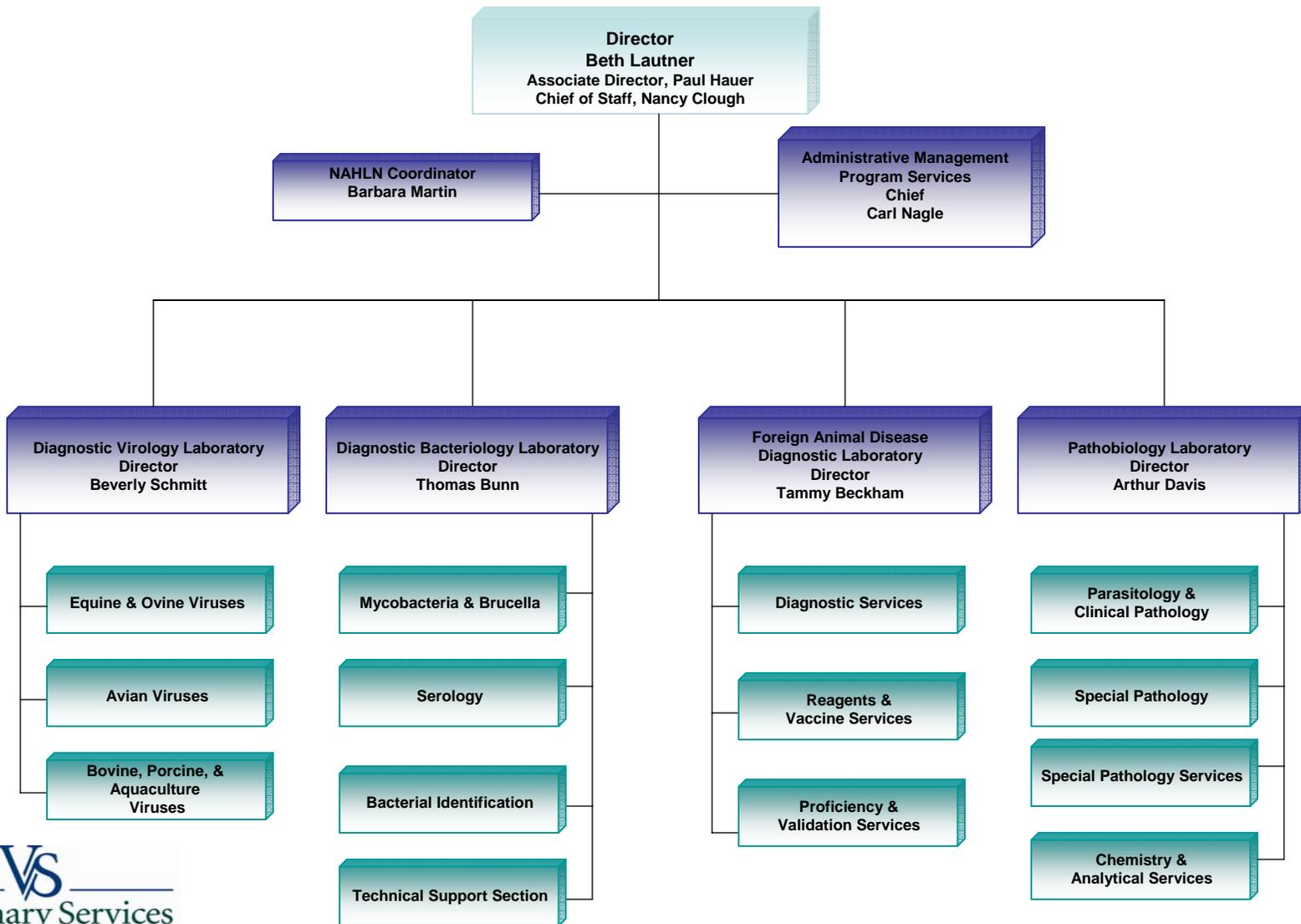
- Conduct diagnostic testing
- Supply reference reagents to other laboratories
 - Exchange diagnostic reagents with other laboratories to standardize and harmonize testing
- Provide training in diagnostic techniques
 - State, university, private and foreign government laboratory personnel
 - APHIS or other agency personnel
- Conduct proficiency testing of other laboratories
- Consult on agents/techniques
- Conduct developmental projects to improve diagnostic techniques for diseases of significance
- Participate in World Organization for Animal Health (OIE) Collaborating Centre for the Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas – CVB, ISU
- Serve as OIE reference laboratory
 - high pathogenicity avian influenza, anthrax, pseudorabies, bluetongue, contagious equine metritis, equine encephalomyelitis, equine infectious anemia, leptospirosis, Newcastle disease, vesicular stomatitis and West Nile encephalitis
- ISO 17025 accredited laboratory

ISO Accreditation



- Accreditation to ISO 17025 received December 2006
- View complete scope on NVSL website www.aphis.usda.gov/animal_health/lab_info_services/quality_assurance.shtml

National Veterinary Services Laboratories (NVSL)



Diagnostic Bacteriology Laboratory

Dr. Tom Bunn, Director

- Serology Section – Dr. David Kinker
- Bacterial Identification Section – Dr. Matthew Erdman
- Mycobacteria & Brucella Section – Dr. Beth Harris
- Technical Support Section – Terri Klein



Diagnostic Bacteriology Laboratory

- Brucellosis
- Tuberculosis
- Johne's disease
- Anthrax
- Salmonella
- Leptospirosis
- Contagious equine metritis
- Anaplasmosis
- Piroplasmosis



Diagnostic Virology Laboratory

Dr. Beverly Schmitt, Director

- Avian Viruses Section - Dr. Brundaban Panigrahy
- Bovine/Porcine Viruses Section – Dr. Sabrina Swenson
- Equine/Ovine Viruses Section – Dr. Eileen Ostlund



DVL
Section

Diagnostic Virology Laboratory

- Avian influenza
- Newcastle disease
- Pseudorabies
- Equine encephalitis, Eastern, Western, Venezuelan, West Nile
- Bluetongue
- Infectious salmon anemia
- Spring viremia of carp
- Equine infectious anemia



Capacity to diagnose more than 90 diseases

Pathobiology Laboratory

Dr. Arthur Davis, Director

- Special Pathology Section – Dr. Mark Hall
- Special Pathology Services Section – Ms. Cindy Chard-Bergstrom
- Chemistry and Analytical Services Section – Vacant
- Parasitology/Clinical Pathology Team – Dr. Jack Schlater



Pathobiology Laboratory

Diagnostics

- Bovine Spongiform Encephalopathy
- Scrapie
- Chronic Wasting Disease
- Bovine Tuberculosis
- Screwworm myiasis



Foreign Animal Disease Diagnostic Laboratory

Dr. Tammy Beckham, Director

- Diagnostic Services Section (DSS) – Dr. Samia Metwally
- Reagents and Vaccine Services Section (RVSS) – Vacant
- Proficiency and Validation Services Section (PVSS) – Dr. Mike McIntosh



Foreign Animal Disease Diagnostic Laboratory

- Detection of an introduction of an FAD
- Testing imported animals and animal products to prevent introduction of FADs
- Training of Veterinarians in the recognition and diagnosis of FADs
- North American FMD Vaccine Bank
- VS' experts for many FADs



Administrative Management and Program Services

Carl Nagle, Administrative Officer

Biological Materials Processing Section

- Central receiving
- Diagnostic sample processing and distribution
 - 49,111 accession numbers assigned in FY 2007
- Biologics repository
 - 13,401 biological serials processed
- Shipping
 - 48,556 packages per year
- Warehouse
 - Local laboratory and office supplies
 - Maintain approximately 1,300 different items

Training

Provides management/assistance with:

- 3,438 Training events in FY 2007
- 474 Visitors in FY 2007
- In-house training
- Commercial training
- Formal diagnostic courses held in Ames

Procurement

- Over 15,000 purchase requests processed in FY 2007
- Initiated procurement action on more than \$26,000,000 in FY 2007



- AMPS has 46 staff years
- Shared support for NVSL and CVB

International Capacity Building - 2007

NVSL scientists provided training and expertise on:

- **Foot-and-Mouth Disease**
 - Kazakhstan
 - Afghanistan
- **Avian Influenza**
 - Mexico
 - Brazil
 - Tanzania
 - U.S. training courses offered to participants from 27 countries
- **African Swine Fever**
 - Republic of Georgia
- **Brucellosis**
 - Kazakhstan
 - Republic of Georgia

AI Diagnostics International Training

- **Two one-week courses in 2007**
- **Joint effort**
 - Iowa State University (IICAB)
 - USDA's Agricultural Research Service (ARS)
 - USDA's Animal and Plant Health Inspection Service (APHIS) - NVSL
 - Foreign Agricultural Service (FAS)
- **Commitment to international partners**
 - AI preparedness
 - Response efforts
- **Objectives**
 - Overview of diseases (avian influenza and Newcastle disease)
 - Focus on diagnostic tests
 - Virus isolation
 - Molecular diagnostics (real time RT-PCR)
 - Serologic tests (HI, AGID, ELISA)
 - Sample collection/preservation
 - Shipping

AI Diagnostics International Training



47 Scientists (27 countries)

- Benin
- Bolivia
- Botswana
- Brazil
- Burundi
- Chile
- Colombia
- Ecuador
- Egypt
- Ethiopia
- India
- Mali
- México
- Morocco
- Pakistan
- Peru
- Russia
- Rwanda
- Saudi Arabia
- South Africa
- Thailand
- Togo
- Tunisa
- Turkey
- USA
- Venezuela
- Yemen

Security and Prosperity Partnership (SPP)

- March 2005 – A commitment by Canada, Mexico and U.S. to work together to build a safer and economically more dynamic North America
 - Includes North American Animal Health Network
 - Harmonization of diagnostics launched Feb 2007
 - Vesicular Diseases Working Group
 - Avian Influenza Working Group
 - Tuberculosis Working Group
- “Ensuring an equivalency of diagnostic test results between the laboratories, regardless of protocols practiced by each country.”

The National Animal Health Laboratory Network (NAHLN)

Barbara Martin, Coordinator
Bonnie Coyle, Associate Coordinator



NAHLN- A State and Federal Partnership to Safeguard Animal Health

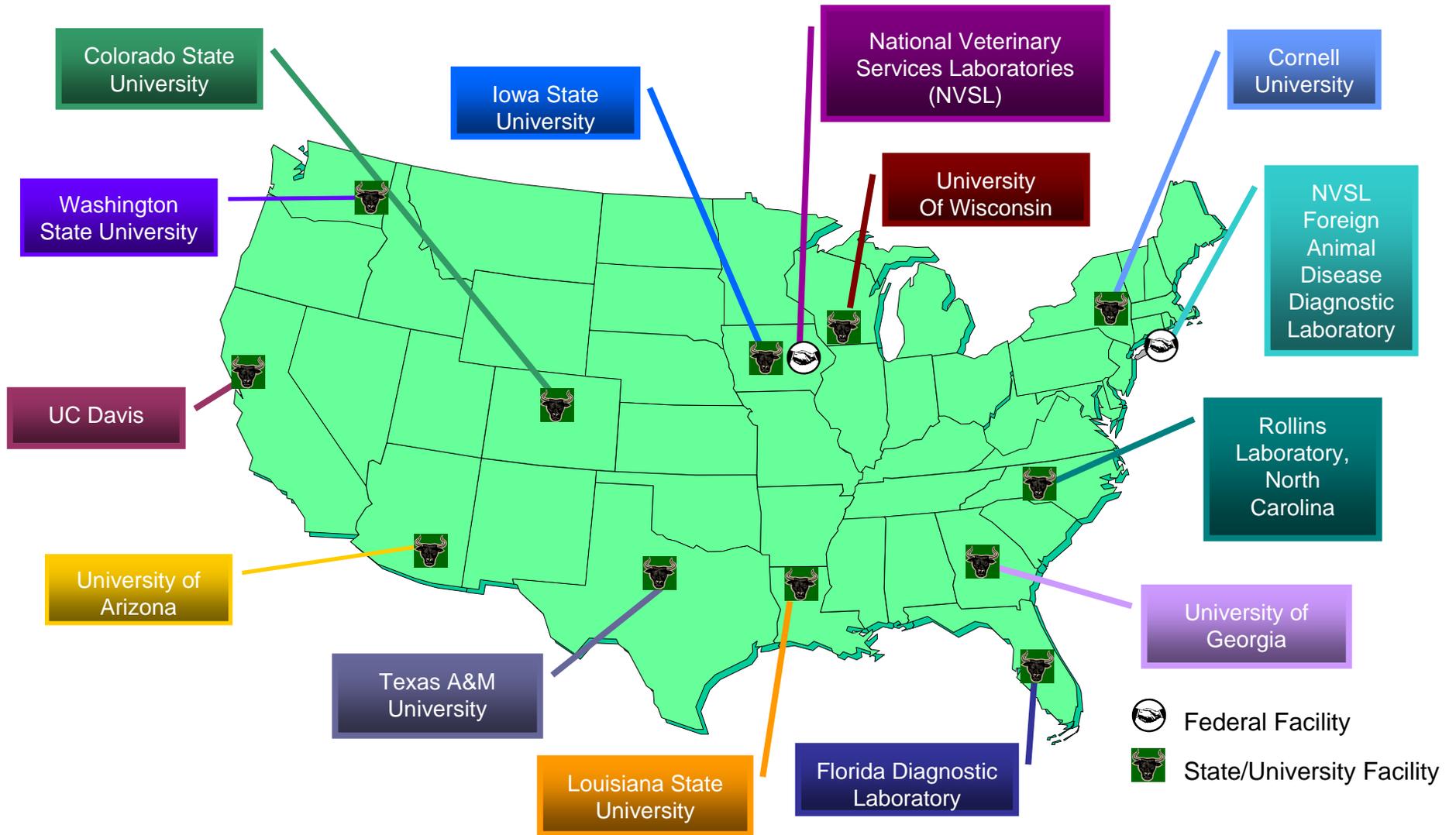
National Animal Health Laboratory Network

- Partnership
 - USDA
 - Animal and Plant Health Inspection Service
 - Cooperative State Research Education and Extension Service
 - American Association of Veterinary Laboratory Diagnosticians
- Purpose
 - Early detection
 - Targeted surveillance based on population density & risk
 - Rapid response
 - Surge capacity to test outbreak samples
 - Appropriate recovery
 - Large numbers of samples tested to show freedom



NAHLN- A State and Federal Partnership to Safeguard Animal Health

National Animal Health Laboratory Network-2002



Founding Principles and Features of NAHLN

- Standardized, rapid diagnostic techniques
- Trained personnel, modern equipment
- Quality standards, proficiency testing
- Secure communication, alert, reporting system
- Adequate facility biosafety/biosecurity levels
- Scenario testing



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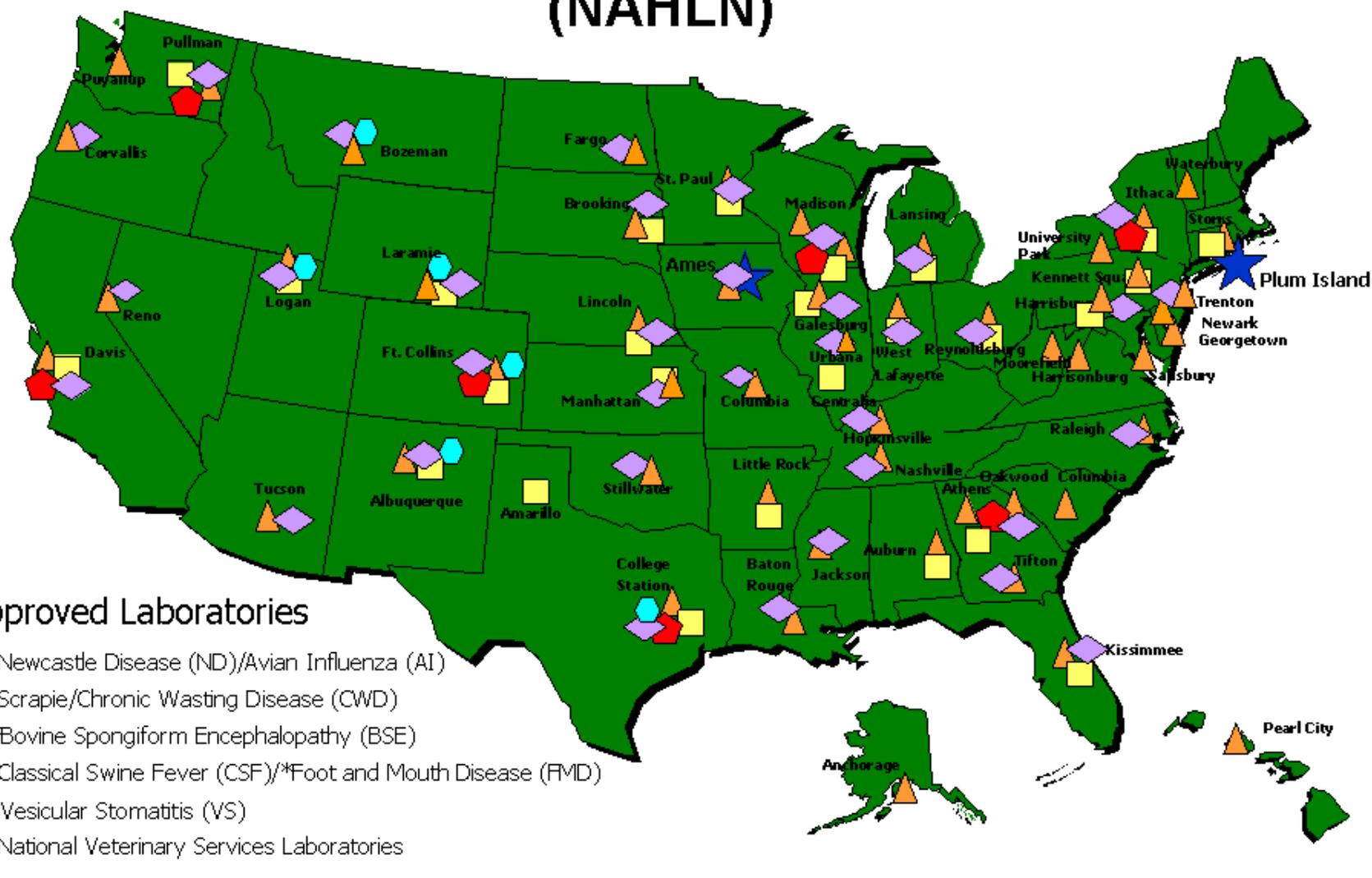
Laboratory Designation

- **Core Member laboratory** – labs that are receiving significant infrastructure support and are conducting fee-for-service testing from USDA. This group currently includes the original 12 laboratories.
- **Member laboratory** – labs that are receiving limited annual support from USDA for specific purposes and also perform fee-for-service testing. Currently there are 16 laboratories in this group.
- **Contract Member laboratory** – labs that are performing fee-for-service testing for control of specific animal diseases **ONLY**.
- **Adjunct Member laboratory** – labs that wish to be members of the NAHLN but whose primary mission is not domestic animal disease diagnostic work within the United States.



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National Animal Health Laboratory Network (NAHLN)



*For specified agents, not all laboratories are currently participating in surveillance testing.

April 1, 2008

Standardized, Rapid Diagnostic Techniques

- Established NAHLN Methods Technical Working Group
 - Provide input on methods validation and approval
 - Review of available methods and associated gaps
 - Identify potential new technologies
 - Determine equivalency of modified methods or platforms
 - Monitor performance of assays
 - Development of performance characteristic summary documents
- Implemented dossier review and assay approval processes



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Assay Development, Validation, and Deployment

Assay Validation

- Bench Development (Assay developers)
 - State intended purpose of assay
 - Feasibility study
 - Reagents
 - Antigen, primers/probes, controls & expiration dates
 - Initial development and optimization
 - Develop protocol
 - Inter-laboratory studies
 - Determine
 - Ruggedness
 - Adequacy of protocol
 - Determine
 - Analytical sensitivity
 - Define detection limits
 - Document for all sample types
 - Analytical specificity
 - Determine cause of false positive reactions
 - Review and determine how to proceed (PVSS, NAHLN, assay developers)
 - Address any gaps
 - Determine if validation processes should continue
- Field Validation (Assay developers, APHIS)
 - Collect and test positive samples
 - Collect and test negative samples
 - Determine
 - Diagnostic sensitivity
 - Diagnostic specificity
 - Precision and Accuracy
- Dossier preparation (Assay developers)
- Dossier review (NAHLN Methods Technical Working Group)
 - Fitness for purpose
- Licensing (VS, CVB)
- Monitor assay performance and add data to improve confidence

Concurrent Activities

- Training and proficiency testing (NVSL)
 - Develop
 - Reference panels and materials for PT and assay controls
 - Training materials
- Develop and review surveillance plan (CEAH, NSU)
 - NCAHP, disease experts, stakeholders, other agencies
- Develop response plan (EM&D)
 - CEAH, NCAHP, Regions, NVSL other agencies, stakeholders
- Develop communication plan (EM&D)
 - CEAH, NCAHP, Regions, NVSL, other agencies, stakeholders
- Determine funding needs for implementation (NCAHP and NVSL)
 - CEAH, NCAHP, Regions, NVSL, other agencies, stakeholders
 - Identify necessary equipment, reagents, supplies, testing cost
 - Identify funding source
- Develop agreements (NCAHP and NVSL)
 - Regions, other agencies, stakeholders
 - Sample collection
 - Testing
- Develop and implement data reporting mechanism (CEAH, CADIA)
 - NAHLN IT system – messaging
 - CEAH, NCAHP, NVSL, NAHLN
- Implement surveillance plan (NCAHP)
 - CEAH, NVSL, Regions, NAHLN, stakeholders

Train the Trainer



- Need to increase the number of people able to respond to an animal health emergency
- 2005 Activities
 - Implemented with CSF & FMD
 - Increased the number of trained labs from 12 to 28 and personnel from 24 to ≈100
- 2006 Activities
 - Incorporated AI & END
 - Cross training for PCR accepted across diseases
 - Interlaboratory Training
- 2007 Activities
 - Increase personnel trained and PT'd to ≈200
- 2008 Activities
 - High Throughput System Training



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CSF Surveillance

- Plan developed by National Surveillance Unit with stakeholder input
 - Target clinical signs, feral swine, slaughter condemned
 - All high risk states involved
- Implemented – January 2006
 - >10,000 samples tested first year
 - 36 laboratories participating
- Data submission
 - Web based and electronic messaging



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AI Wildbird Surveillance

- 45 laboratories participating
- Conducting surveillance for Wildlife Services
 - Real time PCR
 - 2006 - 80,000 pooled samples
 - 2007 – 50,000 samples from individual birds
- Inter and intra-agency coordination, communication and training



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Wild Bird Surveillance for HPAI H5N1 – FY 07

- **DOI-U.S. Geological Survey (WI)**
 - Cloacal swabs – live, hunter-killed water fowl
 - PCR, VI
- **USDA-Wildlife Services (CO)**
 - Hunter-killed water fowl, environment
 - NAHLN labs – PCR
 - NWRC – feces – PCR
- **USDA-APHIS-NVSL**
 - Confirmation testing of H5 & H7 positives (all sources)
 - Die-offs of >500 birds



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Wild Bird Surveillance for HPAI H5N1 – FY 07

>1,500 presumptive H5 rRT-PCR specimens received for confirmation testing

- **No HPAI H5N1 detected**
- LPAI H5N1 (North American lineage) detected in 5 states (DE, IL NJ, MD, and MI)
- LPAI H5N2 – Predominate subtype (46 isolations from 23 states)
- Other subtypes detected
 - H1, H2, H3, H4, H6, H7, H10 and H11



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AI Implementation Plan - High Throughput Testing

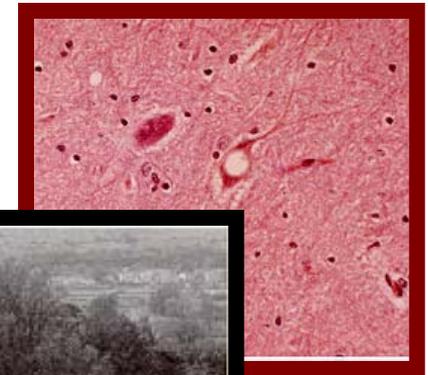
Goal: Double testing capacity in NAHLN

- Semi-automated high throughput equipment
 - 31 Systems distributed to laboratories
 - Equivalency performed for CSF/FMD
- Training
 - KSU cooperative agreement
 - Manual developed
 - Pilot – September 24-25, 2007
 - Training NAHLN labs - 2008



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- Personnel from 7 laboratories trained and PT'd
- Enhanced surveillance
 - >800,000 samples tested since June 2004
- Maintenance surveillance
 - September 2006
 - 40,000 samples/year



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CWD and Scrapie IHC



- Personnel from 26 laboratories trained and PT'd
- >250,000 samples tested/year



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Technology Development FMD real time PCR



- Assay validated
 - Dossier review in 2007
- Personnel from 36 laboratories trained and PT'd
- Development of vesicular disease surveillance plan
- Use of assay in an outbreak situation



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- 2005 - AAVLD/USAHA
 - NAHLN and QA
- 2006 - AAVLD/USAHA
 - Laboratory Emergency Management
- 2007 – AAVLD/USAHA
 - Validation of Diagnostic Assays
- 2008 – AAVLD/USAHA
 - Emergency Response
- 2009 – WAVLD
 - Implementation of Veterinary Diagnostic Networks



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NAHLN Exercises and Response



- NAHLN Exercises and Drills Working Group
 - Formed September 2007
- Facilitated Tabletops
 - Focusing on laboratory issues with field input
 - Training and reusable tabletop exercise will be provided to each NAHLN lab
 - Beta testing to be initiated in February 2008
 - Iowa and Ohio
 - Regional presentations - 2008
 - NAHLN labs
 - State Vets and State animal health officials
 - VS Field Staff and AVICS
 - Other interested groups



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Modeling to Determine Diagnostic Capacity



- Data used
 - Current laboratory information
 - Location
 - BSL-2 and BSL-3 space
 - Trained personnel
 - Equipment
 - Animal populations
 - Risk
- Other uses for model
 - Prioritization need for new/remodeled laboratory space
 - Assistance in development of policy concerning where samples will be tested



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Activation of the NAHLN

- Multiple concepts of “activation”
 - Single lab responding to local outbreak
 - Trained personnel from additional NAHLN labs traveling to initial responding lab to assist
 - Multiple NAHLN laboratories receiving samples from single outbreak zone
 - Multiple NAHLN laboratories receiving samples from multiple outbreak zones
- Actual response will be situation dependent
 - Will incorporate State and individual laboratory Emergency Response Plans



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Successes of the NAHLN

- Strategically combines the infrastructure and expertise in the state veterinary diagnostic laboratories and the National Veterinary Services Laboratories.
- Established the animal health laboratory backbone of the United States emergency response and recovery program.
- Implemented national, standardized surveillance for high priority diseases.



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Updated NVSL Web Site



USDA United States Department of Agriculture
Animal and Plant Health Inspection Service

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- ▶ Wildlife Damage

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Animal Health

Laboratory Information and Services

National Veterinary Services Laboratories
APHIS laboratory services are provided by the National Veterinary Services Laboratories (NVSL) in Ames, Iowa and Orient Point (Plum Island), New York. The NVSL provides a wide variety of information and services, centered around diagnosis of domestic and foreign animal diseases, support of disease control and eradication programs, reagents for diagnostic testing, training, and laboratory certification.

Laboratory-Related Forms and Publications
Click here to see lists of laboratory-related forms and publications.

Diagnostic Testing
Authorized individuals may submit specimens to the NVSL facilities for diagnostic testing. This section describes the types of tests performed at the NVSL and provides instructions for submitting samples.

Reagents

Related Topics

- Overview
- Animal Diseases
- Animal Diseases by Species
- Animal Health Report
- Emergency Management
- Laboratory Information & Services
 - Diagnostic Testing
 - Approved Labs
 - Reagents
 - Diagnostic Training
 - NAHLN
- Veterinary Biologics
- Veterinary Accreditation
- Monitoring & Surveillance
- Professional Development Training

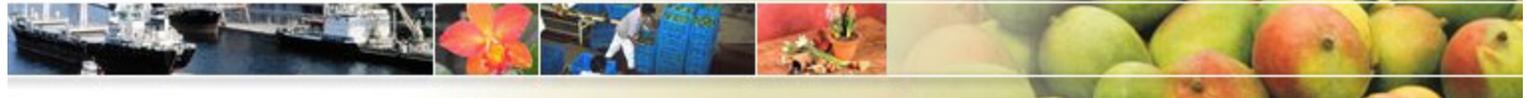


URL:
www.aphis.usda.gov/animal_health/lab_info_services

Updated NAHLN Web Site



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Animal Health

National Animal Health Laboratory Network

A State and Federal Partnership to Safeguard Animal Health

When a large-scale animal-disease outbreak occurs, tracking its progress and performing diagnostic tests on thousands of diagnostic samples is a big challenge. To get the job done, it is very important that all the parties involved--Federal agencies and laboratories managed by State governments and universities--communicate and collaborate effectively. The National Animal Health Laboratory Network (NAHLN) now forms part of a nationwide strategy to coordinate the work of all organizations providing animal disease surveillance and testing services.

[About NAHLN](#)

Click here to learn more about the organization, mission, and vision of the NAHLN.

[NAHLN Laboratories](#)

Click here to view lists of approved NAHLN laboratories, as well as requirements for membership in the NAHLN.

Related Topics

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- [Animal Diseases](#)
- [Animal Diseases by Species](#)
- [Animal Health Report](#)
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Veterinary Services

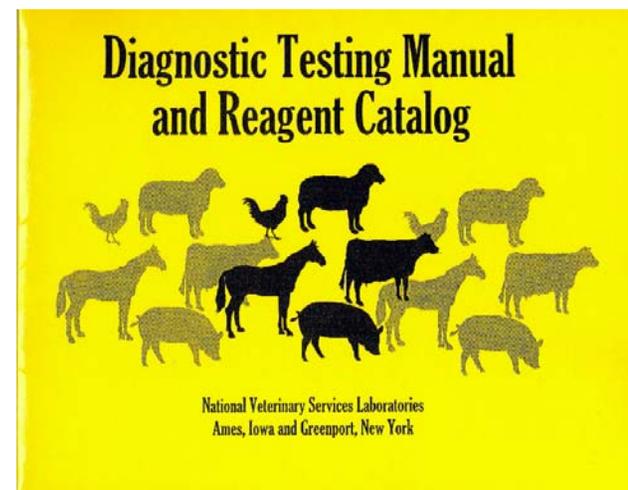


APHIS • USDA
National Veterinary Services Laboratories

URL: www.aphis.usda.gov/animal_health/nahln

Testing & Reagents Catalog Online

- New website includes all information currently in Diagnostic Testing Manual and Reagent Catalog, including searchable, up-to-date, printable listings of services and products



NVSL User Fees

- NVSL's new user fee rates became effective January 18, 2008
- The new rates are available on our web page at:
http://www.aphis.usda.gov/animal_health/lab_info_services/diagnos_tests.shtml

Proficiency Test Working Group

- Working group formed at request of AAVLD
 - Phase 1: Increase transparency of PTs provided by NVSL.
Open a dialogue to improve process using customer feedback.
 - Phase 2: Determine if demand for other PTs and prioritize.
- Developed standardized summaries to describe PT panels offered by NVSL
- Summaries are posted on NVSL website under diagnostic reagents section



Safeguarding Animal Health