

# USAHA

## Committee on Animal Emergency Management



## NVSL – NAHLN Emergency Preparedness Update

Dr. Beth Lautner  
Director, NVSL  
U.S. Department of Agriculture  
Animal and Plant Health Inspection Service  
Veterinary Services  
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## ‘Partners in Preparedness’

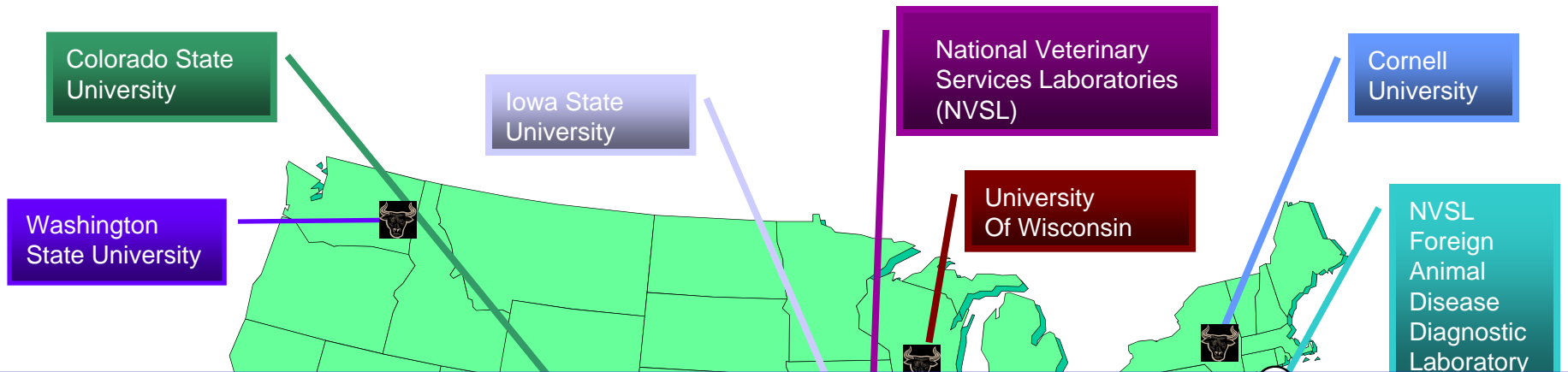
- Multiple projects and partners to improve our Nation’s preparedness for adverse animal health events
- Inter-related, building upon each other to contribute to mission of preparedness



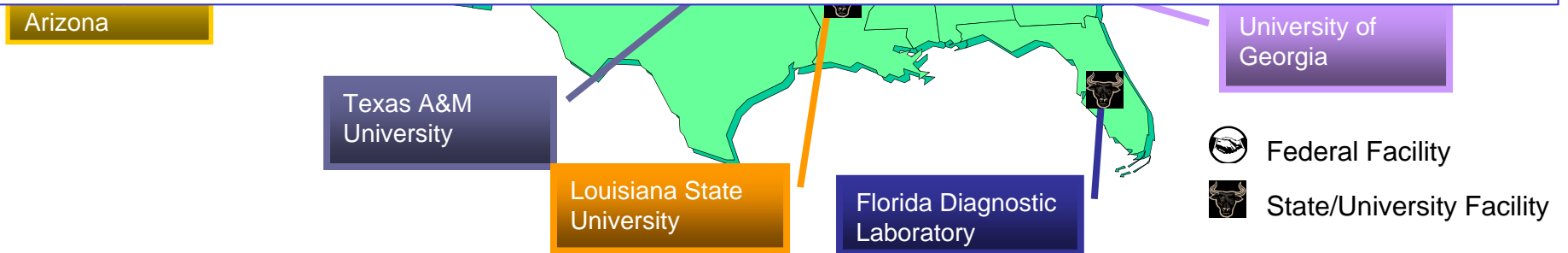
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# The original 12 NAHLN laboratories



## Happy 10<sup>th</sup> Anniversary NAHLN!



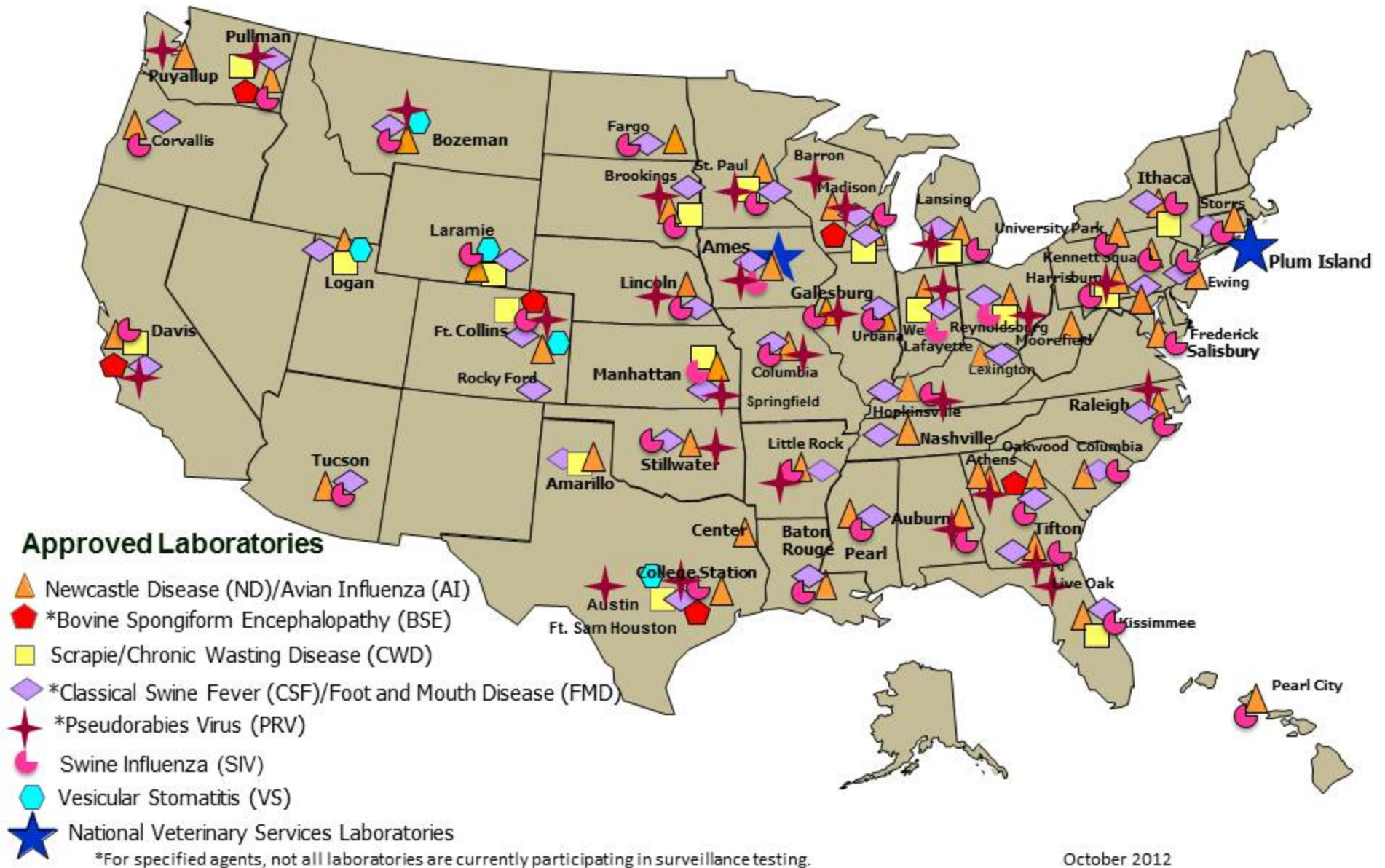
-  Federal Facility
-  State/University Facility



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# National Animal Health Laboratory Network (NAHLN)



# Trained Personnel and Modern Equipment

## *Train the Trainer Program*

- Established 2005 in response to need to increase number of people trained and proficiency tested to address animal health emergencies

Disease/Agent	Approved Laboratories		Approved Analysts	
	FY2004	FY2011	FY2004	FY2011
AI	15	52	28	220
CSF	12	38	24	167
END	15	49	28	212
FMD	12	38	24	167



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## Laboratory Capacity Estimation Model

- Collaboration between NAHLN/FAZD/AAVLD
- Software tool for evaluating/monitoring NAHLN capacity
  - Allows for labs to define their specific processes and identify their rate limiting steps
  - Allows for estimation of network capacity and sample allocation during an outbreak

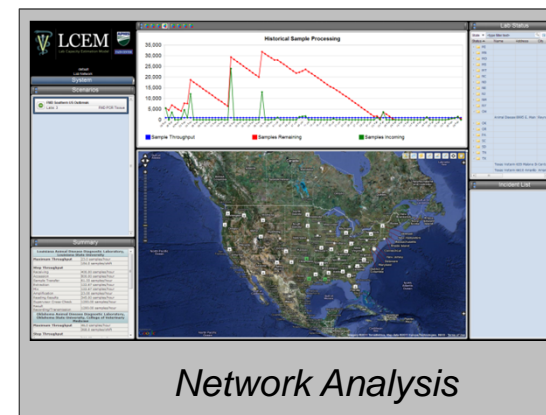
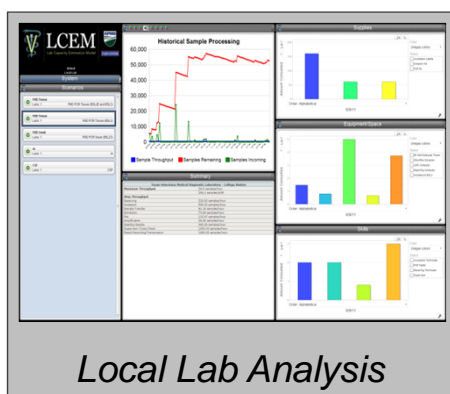


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# Laboratory Capacity Estimation Model Objectives

- Improve knowledge in individual lab and overall NAHLN diagnostic testing capacity
- Aid in the modification of the NAHLN activation plan
- Assist in the prioritization of additional resources needed
- Serve as critical tool for managing a large number of diagnostic tests simultaneously





- Scenarios allow for the analysis of lab capacity and determination of limiting factors
- Provides both graphical and textual displays of capacity details, and full report generation capabilities
- Supports both planning and operational analysis



## Laboratory Capacity Estimation Model

- Phase 2 activities include:
  - Integration with NAHLN Portal (ongoing)
  - Incorporate limited budget and accounting capabilities
  - Incorporate monitoring of consumable laboratory supplies and reagents
  - Utilize the national capacity estimates in ICLN exercises
  - On-going support and training
  - Expansion of use in laboratories through training and use in web-based exercises



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## Web-Based Exercises

- Program to leverage and integrate existing tools for enhancing preparedness by regularly practicing outbreak response
- Several pilot exercises have been conducted in 2012
  - Input from those informing next steps to best train prepare labs for exercises
  - Creating a pre-exercise checklist
  - Pre-exercise LCEM modules
- Plan to include additional labs in next exercises in late 2012 through 2013





## NAHLN Portal: secure mechanism for NAHLN laboratories to share information

- Active modules:
  - Laboratory Directory including funding mechanisms and USDA equipment inventory
  - Collaboration capability through workgroups and webinars
- Next modules for release:
  - SOPs
  - PT
  - Assay performance



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# Ag Screening Tools Workshops

FAZD/DHS sponsored

- AST I – November 2010
  - The goals were to define agricultural screening tools, evaluate their current status, and identify and discuss the gaps and needs defined by the agricultural community.
  - Stakeholder input on requirements was obtained.
- AST II – April 2011
  - Industry perspectives on diagnostic testing were discussed and input was obtained on diagnostic screening tools for transboundary, emerging, and zoonotic diseases.
  - Input was obtained on priorities for diagnostic method development.



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# Ag Screening Tools Workshops

- AST III – October 2011
  - Many NAHLN stakeholders participated in the AST III.
  - Gathered input on lab-related concept of operations-- specifically use of diagnostic assays during an outbreak, laboratory operations; and prioritization of samples and reagents.
- AST IV – May 2012
  - NAHLN Coordinating Council and other stakeholders reviewed laboratory related policies including use of PCR, milk, ELISA and penside assays, prioritization of samples, biosafety requirements, and validation of assays during an outbreak.



# NAHLN Sponsored Trainings

## Investigation and communication during a potential FAD or EDI investigation

- May 2012 – VS Memo 580.4 Training provided to NAHLN laboratory representatives as a review that included table top scenario-based exercises



## Quality Management System Trainings

- June 2012 – Training provided to an Iraqi scientist as part of a scientific exchange and international capacity building project
- July 2012 – Training provided to NAHLN laboratories and representatives from India, Iraq, Kazakhstan, Kenya, Russia, Tajikistan, Tanzania, Uganda, Ukraine and Pakistan
- September 2012 – AAVLD NAHLN QMS training



# NVSL Exercises – AI and FMD

Held in March 2011

- Define and practice coordination and communication between Ames and FADDL
- Explore roles and responsibilities of Ames and FADDL as primary and support laboratories
- Identify testing algorithms and decision making for samples to NVSL and/or NAHLN laboratories
- Examine testing capacity



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# NVSL Exercises – AI and FMD

- Areas to address:
  - Options for sample collection tubes
  - Sample storage at NAHLN laboratories
  - Virus characterization – how many samples to come to NVSL for tracking purposes?
  - NVSL reporting via LIMS and/or spreadsheets
  - Triage and prioritization of samples for resource sparing – avoiding duplication of testing
  - Continue other surveillance programs?
  - Requests for NVSL personnel at IC
  - Validation and deployment of new diagnostics during outbreak
  - Policy around use of pensides if deployed



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## NAHLN Diagnostic Development and Validation projects



- Collaborative projects with FADDL and NAHLN laboratories:
  - FMD Penside: Negative Cohort study – completed in January 2012
  - FMD Serology: Negative Cohort study – Fall 2012
  
- Collaborative projects between FADDL, NAHLN laboratories and FAZD include:
  - FMD PCR in Milk: Inter-laboratory Comparison study - completed in Spring 2012
  - FMD PCR in Milk: Negative Cohort study – Currently underway
  - FMD Penside Negative Cohort study – Winter 2012
  
- Developing processes and policy for deployment of CSF and FMD ELISAs to NAHLN labs for preparedness
  
- ASF PCR additional sample validation work



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# NAHLN Strategic Planning Concept Paper

- 2011 AAVLD/USAHA Meeting
  - Distributed NAHLN Concept Paper for comment
- May 2012 - Coordinating Council Meeting
  - Further discussion of the NAHLN concept paper
  - Subgroup from Coordinating Council volunteered to expand document
- September 2012
  - Edits collated
  - Met with WERC Staff
  - Developed work plan and memo
- October 2012
  - Submit completed documents to WERC
  - Provide update to stakeholders concerning comment period and next steps



## Overview of the NAHLN Concept Paper

- Defines NAHLN laboratory membership structure and requirements
- Recognizes NAHLN oversight by USDA
- Identifies the role of the NAHLN Coordinating Council
- Identifies NVSL as the reference labs for NAHLN
- Affirms the opportunity for each State to have a NAHLN lab when meet defined minimum criteria



# Proposed NAHLN Structure



- Structure based on increasing levels of responsibility
- Provides opportunity for each State to have a NAHLN lab if requirements are met
- Recognizes the need to maintain enhanced National capacity
  - ❖ Number and location of labs with enhanced responsibilities would be determined in a transparent manner based on criteria that include:
    - Commodity density, capacity needs, geographic location, existing infrastructure
  - ❖ Labs would be subject to an annual accountability review and Level I laboratories reassessed at least every 5 years
- Specialty labs may be designated
  - ❖ Allows private labs if there's a national need and address conflict of interest
  - ❖ Must meet all NAHLN standards and work with a designated NAHLN lab and the SAHO.
- Proposed structure allows for changes in responsibilities of numbers of labs based on national needs and evolving animal and public health situations



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## Next Steps

- Publish NAHLN Concept Paper in Federal Register
  - Collect and review comments
- Concurrent activity - write Program Standards including:
  - Laboratory approval and removal processes
  - NAHLN site visit policies and processes
- Transition to Regulation Analysis Division (RAD)
  - Proposed Rule Process
  - Final Rule Process



## Influenza at the Human-Animal Interface

- Joint PH-AH investigations prior to 2009 H1N1 pandemic
  - Local, State, and Federal levels
- Pandemic strengthened interactions
- Prior experience with fair investigations
  - Killian ML et. al. 2012. *Zoonoses and Public Health*
- NAHLN laboratories play key role



## NAHLN Functions for SIV Surveillance

- Screen compatible swine cases for influenza by PCR
- Positive cases evaluated for subtype by PCR
- Virus isolation and sequencing H, N, M genes
- Viruses sent to NVSL for inclusion in a National repository-dx updates, vx updates, research
- Test information and limited epi collected for National data base
- Surveillance is anonymous and doesn't measure prevalence



# Hoofbeats – Horses or Zebras?

## Schmallenberg Virus

- First detected in November 2011 in Germany from samples collected in summer/autumn 2011 from ill dairy cattle (fever, reduced milk yield)
- Similar clinical signs (including diarrhea) detected in dairy cows in the Netherlands with confirmation in December 2011
- Affects sheep, goats, cattle, possibly other ruminants.
- Clinical signs –
  - Fetal malformations in sheep, goats or cattle
  - Fever, anorexia, diarrhea, and decreased milk production seen in adult cattle



Lamb affected by arthrogryposis (persistent flexion of the joints) – arthrogryposis is one of the congenital abnormalities associated with SBV infection



# Schmallenberg Virus

## U.S. Response

- ✓ **Information** – USDA/APHIS/VS
  - ✓ *Schmallenberg Virus Case Definition and Guidance*
  - ✓ *Schmallenberg Virus Guidance for U.S. Veterinary Diagnostic Laboratories*
  - ✓ Shared information with Diagnostic Laboratories and SAHOs
- ✓ **Laboratory testing** acquired protocols and reference materials from FLI, Germany
  - ✓ Surveillance of suspect cases (FADs)
- ✓ **Vaccines** - CVB monitoring information on vaccine development in EU



## Schmallenberg Virus Testing

- NVSL has obtained SBV agent, protocols and reagents for PCR testing from Germany.
- Have ability to conduct diagnostic tests (PCR, VI and VN) for Schmallenberg virus at NVSL (Ames and Plum Island).
- NVSL can accept samples to test for Schmallenberg; work with AVIC and SAHO.
- SBV sheep antiserum produced at NVSL, Ames.



# Conclusion

- Emergency Preparedness and Response requires the input, collaboration, and cooperation of multiple partners.

