FAZD CENTER

National Center for Foreign Animal and Zoonotic Disease Defense

fazd.tamu.edu

Protecting Agricultural Infrastructure:

Defining the Needs and Requirements for Agricultural Screening Tools

Report from the
Agricultural Screening Tools Workshop

Status, Gaps, and Requirements

November 1-2, 2010 | Washington, DC

Published by the National Center for Foreign Animal and Zoonotic Disease Defense, Texas A&M University, College Station, Texas 77843-2129, 979.845,2855, trbeckham@ag.tamu.edu

Protecting Agricultural Infrastructure: Defining the Needs and Requirements for Agricultural Screening Tools

The DHS National Center for Foreign Animal and Zoonotic Disease Defense convened an agricultural screening tools workshop on November 1-2, 2010 in Washington, DC. This workshop was attended by some of the nation's leading foreign animal and emerging disease diagnostic experts. The workshop was designed to reach a consensus on the definition of the term "agricultural screening tool," evaluate the current status of agricultural screening tools and identify and prioritize gaps and requirements for protecting the US agriculture and public health sectors.

Subject matter experts (SMEs) were first asked to formulate a consensus definition for the term "agricultural screening tools." The group of experts defined an agricultural screening tool as:

A tool used to detect a potential disease or condition in an animal, group of animals, or animal product. The tool may be used in any phase of an outbreak response, and is not required to be confirmatory (diagnostic) in nature, but rather is intended for rapid initial detection.

Once a consensus was reached on the definition, the SMEs were asked to evaluate the current status of agricultural screening tools, as well as identify and prioritize gaps and requirements for future research. To focus conversation, discussion was limited to screening tools for foot-and-mouth disease virus (FMDV), with the assumption that the outcomes of the meeting would serve as a model for guiding future gap analysis and discussion for additional high-priority agricultural agents. In identifying gaps, as well as current and potential future technologies, the workshop attendees were asked to place emphasis on those tools and/or

technologies that could be integrated with minimal disruption into daily business practices, and give highest priority (both immediate and long term) to those which would enhance national security, facilitate industry resiliency, and ensure animal agriculture and associated business continuity.

The workshop participants included experts from diverse fields and disciplines, including: molecular diagnosticians, veterinary epidemiologists, veterinary medicine, veterinary emergency management, state animal health officials, and representatives from the agricultural industry. A summary of the conference discussions and the key findings of the Agricultural Screening Tools Workshop follow in this report.

1. Background and the Need for Agricultural Screening Tools/Surveillance

The possible impacts of a foreign animal disease on the US economy and infrastructure are immense. As has been shown in the past, the length of time between detection and response is directly proportional to the overall economic impact and agricultural losses.[1-3] Therefore, rapid, accurate screening tools are essential to our nation's agricultural defense. Availability of these tools helps to enhance our national security, protect agricultural infrastructure, enhance resiliency, and ensure business continuity. Agricultural screening tools (tools that can be used to detect a potential disease or condition in an animal, group of animals, or animal product that requires confirmation) can have value at all three stages of an outbreak: early detection, response, and recovery. Because of this, it is important to note that the type of tool, as well as and how and when it will be used and by whom, will vary with each stage. Also, it is important to note that the screening tool design and performance characteristics can

vary between animal species and biological agent. The US currently has several tools at its disposal, but not all have been fully developed or validated for use. This workshop was convened to define when and how an agricultural screening tool would be used, discuss tools that are currently in use and those still in development, and prioritize gaps in current diagnostic capabilities. This information will subsequently be utilized to aid in future agricultural screening tool funding decisions.

2. Diagnostic Updates/Needs

Prior to opening the floor for discussion and to help frame the workshop, an overview of the meeting and the meeting objectives were presented followed by a short series of informational presentations. In order for the participants to become familiar with stakeholder programs, practices and requirements, representatives from DHS Customs and Border Protection, USDA APHIS, and the DHS Science and Technology Directorate (S&T) were asked to present their programs, including updates on diagnostic activities relevant to the conference topic.

- Ms. Barbara Martin (Coordinator, NAHLN) provided updates on the "Joint DHS/USDA 2005 Diagnostic Roadmap" and outcomes from the recent NAHLN FMD table top exercises (held in 15 states during 2010).

- Ms. Petrina Evans (DHS Customs and Border Protection) presented an overview of the CBP agriculture activities as well as their needs/requirements to aid in fulfilling their mission.

- Dr. David Brake (SAIC, Plum Island Animal Disease Center) presented an overview of the outcomes from an FMD outbreak response exercise held in conjunction with the 2010 FMD Summit in Australia. This

presentation highlighted the diagnostic challenges and decisions that were encountered during this exercise.

- Dr. Luther Lindler (DHS S&T, Chem/Bio Division) presented an overview of the DHS S&T new start program “Agricultural Screening Tools.” Dr. Lindler discussed the origin of the new program and summarized the process that identified the availability and deployment of agricultural screening tools as a critical national gap. The larger “agricultural screening tool” program originated from a “composite gap” composed of four submitted and approved gaps.

- Dr. Rocco Casagrande (Gryphon Scientific) presented results from an initial capabilities study contracted by DHS and performed by Gryphon Scientific, designed to evaluate the current status of agricultural screening tools in the US.

3. Discussion Topics

The Ag Screening Tools workshop attendees were asked to focus their discussion on 5 major thematic areas (listed below). This discussion was designed to identify and prioritize gaps and requirements for researching, developing, validating, and deploying existing and next generation agricultural screening tools. The emphasis of this initial workshop was identification of gaps in research and development, including a process for providing standardized requirements needed for development of these tools.

The meeting focused on each of the following topics:

1. Definition of an “Agricultural Screening Tool.”

2. Agricultural Screening tools—current status and availability

    a. Currently available and deployed to a defined end-user:
        i. Validated, with standard operating procedures and policy in place.
    b. Under validation, deployment to end-user possible within 9 months from conference date.
        i. Needs minimal additional validation, standard operating procedures under development, policy for deployment being developed.

3. Identification of gaps, future needs and requirements
    a. Additional technologies identified and requirements defined.
    b. Additional specimen matrices identified and requirements defined.
    c. New technologies.

4. Requirements for validating, deploying and maintaining testing capacities
    a. Policy, end-user, con-ops, resources for validation and deployment.

5. Prioritization of gaps and defined requirements

3-1. Definition of an “Agricultural Screening Tool”

To date, the term “agricultural screening tool” has not been utilized widely among the agricultural community. Thus, the first challenge presented to the SMEs was to generate a consensus definition of an agricultural screening tool. Formulation of this definition required careful consideration and discussion that centered on the fitness for purpose and utilization of such a tool, (i.e., performance requirements, end-user, con-

ops, and policy) in addition to the requirements for validating a screening test prior to deployment.

For the purpose of this meeting, as well as for future discussions and development, the task force defined an agricultural screening tool as:

A tool used to detect a potential disease or condition in an animal, group of animals, or animal product. The tool may be used in any phase of an outbreak response, and is not required to be confirmatory (diagnostic) in nature, but rather is intended for rapid initial detection.

Dependent on the specific testing needs and tool design, result obtained from agricultural screening tools may trigger subsequent confirmatory testing or regulatory action. Because the performance characteristics most desirable for a screening tool vary with the intended use, it is unlikely that a single technology will effectively fit all intended applications. However, all screening tools should share the common denominators of being deployable, validated, and used by trained operators.

Based on the proposed use of agricultural screening tools in each of the three defined phases of an outbreak, critical performance elements were established. Performance elements for each of the three phases are defined below.

- ***Early/Initial detection (pre-disease)*:** Agent, antigen or antibody detection. Used for early detection of the initial case and for surveillance activities.
    - Technologies capable of routine targeted population screening.

- Compatible with convenience sampling (e.g., samples collected as part of routine animal management or with minimal disruption to producer business practices.)
- Requirement for extremely low false negative detection rate.
- Multiplex approaches that allow endemic disease/animal production tests to be produced for profit by commercial suppliers and supplemented within the same test with FAD/high consequence detection capability.
    - Dual use tests that embed endemic disease(s) or differential diagnostic testing with FMDV or other high consequence disease detection.

- ***Outbreak/Response (post-disease detection)*:** Agent or antigen detection. Used for identification of new cases, to support business continuity, for determining the extent of disease incursion and monitoring spread.
    - Technologies capable of monitoring populations and preferably that allow for pooling of samples (e.g., saliva, milk, environment),
    - High-throughput applications and portable technologies (on-site testing).
    - Testing that facilitates business continuity.
        - Sample/specimen matrices critical and when possible should be in alignment with normal business practices

- ***Recovery*:** Agent, antigen, and antibody detection. Used for identification of new cases, screening for vaccinates vs. infected animals/herds; release from regional, national, international control measures.
    - Technologies capable of monitoring populations (e.g. saliva, milk, environment).
        - Sample/specimen matrices critical and when possible should be in alignment with normal business processes.
    - High-throughput applications and portable technologies (on-site testing).
    - Tests that can Differentiate Infected from Vaccinated Animals (DIVA) that are paired with ongoing next-generation DIVA vaccine development.

- Technologies should include ability to detect current and past infections

3-2. Agricultural Screening Tools – current status and availability

Since 2001, the US has significantly expanded and enhanced its high consequence disease surveillance and response capabilities. The USDA, APHIS Veterinary Services, USDA NIFA and state and university laboratories have partnered to build and expand a robust animal health laboratory network infrastructure: the National Animal Health Laboratory Network (NAHLN). The NAHLN has expanded in number to include 60 laboratories spread throughout 43 states, with the majority accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD), each practicing and adhering to strict quality standards for testing.[4] The network laboratories utilize National Veterinary Services Laboratories' (NVSL) approved standard operating procedures (SOPs) and work as an integrated, cohesive animal health laboratory network, protecting the nation's agriculture and veterinary public health sectors. At present, the NAHLN laboratories serve as the nation's frontline for agricultural surveillance and screening against high consequence agricultural and zoonotic diseases. Assays developed and validated for use within the NAHLN are reviewed by the NAHLN Methods Technical Working Group and approved and managed by NVSL. NAHLN assays are deployed only after an extensive process that involves development of SOPs, development of concepts of operation and response plans, deployment of training, proficiency testing, and certification of NAHLN personnel.

- **Screening tools currently available in the NAHLN:**
  Over the last several years, many assays have been developed, validated and deployed to the NAHLN.[5-8] Assays for foot-and-

mouth disease (FMD), exotic Newcastle disease (END), bovine spongiform encephalopathy (BSE), avian influenza (AI), classical swine fever (CSF) and vesicular stomatitis are all in use in the NAHLN. Others (rRT-PCR for African swine fever and rinderpest) are currently under validation or early evaluation.[9,10] The following section describes a list of those assays, their intended use and current status.

- **Screening Tools That Rely on Agent, Antigen and/or Nucleic Acid Detection:**
  Real-time RT-PCR (rRT-PCR) assays for FMD, CSF, END and AI have been deployed to the NAHLN laboratories. These assays were validated and intended for use in early detection and response (providing national surge capacity). More specifically, they were validated for defined specimen matrices (rRT-PCR for FMD [epithelium and oral and nasal swabs] and rRT-PCR for CSF [nasal swabs and tonsil scrapings]) and intended to be used as a screening tool within the NAHLN laboratories for identification of suspect cases of FMD, CSF, END and/or AI. Standard operating procedures, operational and response plans and policy for use have been established for each of these assays. The real time PCR assays for rinderpest (RP) and African swine fever (ASF) are currently undergoing the final stages of validation by NVSL, in collaboration with the NAHLN, and expected to be deployed within the next year. Like their FMD, CSF and AI counterparts, the ASF and RP assays' intended use will be for early detection and response.

- **Serological Screening Tools:**
  Assays for use during recovery (serological assays which can help prove freedom from disease and are vital for re-gaining trade

status) are not currently approved for use in the NAHLN laboratories. NVSL is in the final stages of validating a serological assay (Prionics FMD 3-ABC test) for use during the recovery phase of an FMD outbreak.[11] This assay has herd-level DIVA capabilities. However, it is time consuming (requires overnight incubation), is not adapted to high throughput/robotic platforms, and lacks the required specificity (currently produces an unacceptable number of false positive results). NVSL has also begun pilot testing of a commercially available CSF serological assay (Ceditest ®, ID-Lelystad) in two of the NAHLN laboratories. Serological assays for other high priority FADs have not yet been developed, validated or deployed to the NAHLN. Currently, none of the serology tests produced by foreign manufacturers are approved for importation, sale and distribution by USDA CVB.

Additional screening tools under development, evaluation and/or validation:

- **On-site "Penside" Screening Tools:**
  At present, the US does not have validated pen-side and/or on farm/premise technologies available for screening individual animals, herds and/or animal products for any of the high-priority diseases.[12,13] A commercialized lateral flow antigen detection device is available that is capable of rapid-penside detection of FMD and has sensitivity equivalent to that of the vesicular antigen ELISA.[14] Initial studies by USDA APHIS at Plum Island have shown that this device is adequate for use with epithelial samples from experimentally challenged cattle. Initial recommendations for use of this assay include: 1) triage tool for prioritizing samples arriving at the regional or reference laboratory and 2) "ruling-in" (not ruling-out) FMD when clinical signs are present in a herd.

- **Other technologies:**
  Infrared thermography (IRT) has been assessed as a means of identification of animals for further testing to confirm FMD infection. Initial work performed at Plum Island using this technology in a highly controlled experimental setting indicated that infrared thermography is a promising screening technology for quickly detecting potentially infected animals prior to onset of clinical lesions for subsequent confirmatory diagnostic testing during FMD outbreaks.[15] Further evaluation of this technology is needed to develop a practical prototype for further evaluation under field conditions, and to determine the value and feasibility of IRT in screening for FMDV-infected animals with mild clinical signs or sub-clinical disease.

3-3. Identification of gaps, future needs and requirements

Although validation and deployment of several real time RT-PCR assays to the NAHLN greatly boosted the nation's preparedness status, a significant amount of additional work remains. Specifically, business continuity planning for the different agricultural sectors calls for the capability to move animals and animal products from within disease a buffer zone (BZ) and control area (CA) during a high consequence disease event. The *Fast Egg* and *Secure Milk* Supply (draft in progress) plans are two examples of business continuity documents under development by the federal, state and industry stakeholders to help alleviate unnecessary destruction of animals and products during an FAD outbreak response. The overall goals of these plans are to allow safe movement of agricultural products from, into, or within a control zone without endangering flocks and/or herds; support a continuous supply of food for the US public; and facilitate business continuity and resiliency for the industries and their retail and food service customers.[16] Meeting these

objectives will require: 1) additional sample/specimen matrix validation and 2) evaluation and validation of pooled samples with the currently deployed rRT-PCR assays.

Once a high consequence disease has been introduced into the US, focus will quickly be shifted to controlling, eradicating, and subsequently proving freedom from disease in the impacted region and/or entire country. The earlier these actions occur, the lower the biological and economic tolls. As stated previously, if FMD or other high consequence diseases were introduced in the US, there will be severe economic and societal ramifications. The country could lose many of its key trading partners, as shown during the 2009 nH1N1 human influenza virus pandemic. After the initial identification of nH1N1 human influenza cases in people in the US, over 22 countries placed a full or partial ban on US pork imports.[17] Some countries, such as China and Russia, did not lift the ban for months after initial human cases were detected.[18] With an outbreak of FMD or other FAD, extensive testing would have to be done among susceptible animals to prove freedom of disease and re-establish trade. Requirements for testing during the recovery phase of an outbreak are projected to significantly escalate as regions and individual states work to regain freedom status. During the response and recovery phases, high-throughput molecular and serological-based assays will be critically needed. At present, the US has not deployed within the NAHLN a serological assay for FMD or for other high consequence diseases. Serological tests are currently required for demonstrating freedom of disease under the internationally-recognized OIE standards.[19] Serological assays that allow differentiation of vaccinated from infected animals (DIVA) are the optimal choice for use in critical disease eradication programs while recognized in the international community, have not been validated or deployed in the US.

The availability and performance characteristics of current “penside” or on-site assays and projected future technologies were discussed at length. Currently available platforms (e.g., lateral flow antigen detection devices) at present have limited use for business continuity testing due to sensitivity issues, as well as regulatory and policy concerns. Newer, more sensitive and specific portable technologies for use pen-side and/or within other animal or animal product concentration points are considered critical to supporting business continuity plans for each of the country’s agricultural sectors. Additional research into this area and subsequent development of newer more sensitive technologies is critically needed. These portable screening tools would ideally: 1) be self-contained and technically easy to use, 2) rapid (within 20-30 minutes), and 3) have high detection sensitivity. Future investment in promising technologies such as loop-mediated isothermal amplification (LAMP) and the use of fluorophores was also discussed.[20-23]

While targeting attention on the significant gaps in current status and existing gaps in assay availability, validation, and field-based performance data, the attendees identified several additional areas and topics that are critically needed for efficient screening and reporting of test results. More practical methods for sample collection, preservation, and transport are critically needed. In the event of an outbreak, accredited veterinarians affiliated with large production facilities or private clients will likely be called upon to collect samples for testing, requiring sample collection technologies that allow for enhanced preservation, decreased likelihood of cross-contamination, and ease of transport.[24-26] Workshop attendees suggested that additional research and resources be utilized to enhance this process.

Information management, including field data collection, sample identification, data transmission, results reporting, and analysis was

identified as a serious deficiency in the current system for detecting and responding to animal agriculture threats. The methods currently available for communicating and distributing test results for disease response and regulatory purposes are insufficient for the rapid, secure transmission of large amounts of data as needed during disease outbreak and recovery phases. In order to ensure rapid screening and decision making for business continuity and/or quarantine processes, the nation must have an effective method for rapid collection of data, reporting results, and electronic communication to and between regulatory officials and laboratories in real-time. Additional resources are critically needed to enhance this system for delivery and utilization of screening tools.

Finally, it was recognized that there are new technologies that could be utilized to enhance the speed, reliability, and cost-effectiveness of disease detection. The workshop attendees stressed the practical need for development of multiplexed assays and approaches that would support dual-purposes (e.g., exotic disease assays embedded into routine diagnostic testing). This type of technology would significantly enhance national preparedness and disease surveillance effectiveness, as deemed appropriate and warranted for early detection purposes.

3-4. Additional requirements for development, evaluation, validation and deployment of an agricultural screening tool.

The general consensus of the workshop discussion was that the development and validation of any screening tool for high consequence agricultural pathogens should follow a standardized process with pre-identified performance metrics based upon the intended use of the assay. It was further discussed that the process should equally inform funding proposal and grant review, support initial design and development efforts, validation, and deployment efforts. The NAHLN Methods Technical

Working Group (NMTWG), established in 2006, utilizes a standardized approach for the technical review of assays and equipment platforms prior to deployment to the NAHLN. The process includes review of development and validation dossiers. The NMTWG review specifically utilizes NAHLN laboratory experts and focuses on the laboratory technical aspects of the assays and equipment during their review process. The workshop attendees agreed that the standardized NMTWG process could serve as an effective model in developing an integrated and comprehensive process for development, evaluation, validation, and deployment of agricultural screening tools from the point of design through deployment. It was envisioned that the FAZD Center could assist in developing and communicating a documented process that would facilitate involvement of experts representing animal agriculture and allied industries, regulatory officials, technical experts from both commercial and public-service enterprises, communication and information technology experts, and others, as appropriate to each stage of the development and validation design and review process. The immediate need for a published and accessible, standardized process including documented requirements associated with design, validation, and deployment of agricultural screening tools beginning at the time the tool is conceptualized through deployment to the end-user was emphasized by the meeting attendees. The process of defining “fitness for purpose,” end-user, operational procedures for utilization of an assay, and documentation of standard was felt to be critical in establishing appropriate funding prioritization and development timelines.

FINDINGS:

Findings are presented in order of priority as determined by the group of subject matter experts.

1 In order to facilitate the goals set forth in sector-specific business continuity plans (*Fast Egg and Secure Milk Supply* plans (in progress)), the rRT-PCR assays currently in use in the NAHLN (FMD and CSF) must be validated for use with additional specimen matrices. Additional sample types should include those that are currently in use or can be collected as part of the animal management routine with minimal disruption to daily business practices. Specifically, the assays should be evaluated for, and where practical validated for use with:

- Bovine bulk milk tank samples
- Swine oral fluids
- Bovine oral fluids (possibly drinking trough)
- Blood

As part of normal business operations, the milk hauler routinely collects samples from each bulk tank. These samples are tested for a variety of components, to include antibiotic residues, milk protein, lactose, and total solids. "In a highly contagious FAD outbreak, this same process could be used for disease testing and positive farm identification."[27] In commercial swine operations, the sample of choice for routine surveillance is oral fluids. Other sample types collected in various operations include blood, nasal and epithelial swabs. Having the ability to utilize these sample matrices with the deployed rRT-PCR assay will greatly enhance resiliency in the agricultural community.

2 Evaluate and where possible validate a procedure for pooling of samples with multiple specimen types (matrices).

- Pooling should be evaluated for multiple matrices, where appropriate. Pooling of samples will allow for greater surge testing capability and thus, enhance resiliency and business continuity.

3 Complete validation and deployment of available serological assays for use in proving freedom from disease.

a. Prionics FMD-NS test (Ceditest ® 3ABC) ELISA for FMD
b. IDEXX, Inc. CSF ELISA Assay
c. SVANOVIR® FMDV 3ABC-Ab ELISA

Serological assays capable of establishing freedom of disease are available commercially. Advancing the speed at which these assays are validated and subsequently deployed will ensure that the nation is better prepared to recover from a high consequence disease. While it was clearly recognized that improved serological assays are needed (companion DIVA tests to vaccines under development), general agreement among the group was that validation on the currently available assays should be completed as rapidly as possible and hence deployed for use.

4 Support development of more rapid, accurate FMD DIVA ELISA assay (e.g., joint FAZD/USDA/TVMDL –USDA ARS/APHIS Project- "Differentiation of FMDV in infected and vaccinated animals using a competitive ELISA base on an Immunodominant B-cell epitope of the 3B protein," FADDL/DHS Project "Diagnostic Technologies for FMD (3D ELISA)")

FMD serological assays, currently available for use and undergoing validation, are time consuming (require an overnight incubation), and lack sensitivity. A new more rapid FMD DIVA ELISA assay is required to demonstrate freedom from disease at the level of the individual animal.

5 On-site (penside) tests

- Continue to evaluate and if warranted, validate commercialized lateral-flow antigen detection device(s) for FMD (e.g., **SVANODIP® FMDV-AG**).
- Invest in more rapid, detection-sensitive technologies for use at penside/premise and/or processing points of animal or product concentration
    - Develop policy and concept of operations for on-site testing tools.

The general consensus of the group was that penside assays currently available for FMD antigen detection lack sensitivity required to be utilized as a screening tool, but instead were appropriate for use to 1) triage laboratory samples and 2) “rule-in” FMD on a premise with animals demonstrating clinical signs. Additional, more sensitive assays/technologies are needed for pen-side testing.

Additional Findings (not prioritized)

- Invest in development of additional DIVA serological assays for other high priority diseases.
- Invest in further evaluation (both field and laboratory) of the potential of infrared thermography as a screening tool.
- Develop new more efficient methods for sample collection, preservation and transport.
- Enhance current methodologies for data capture, transmission, results reporting and data analysis.
- Convene task force for additional workshop(s) to identify and evaluate novel and emerging technologies appropriate for screening tools. Address current and future screening tools for other high priority agents.

References:

1. Gibbens JC, Sharpe CE, Wilesmith JW, Mansley LM, Michalopolou E, Ryan JBM, Hudson M. Descriptive epidemiology of the 2001 foot-and-mouth disease epidemic in Britain: the first five months. *Vet Rec*, 2001. 149: 729-43.

2. Early warning as the weakest link in disease surveillance systems. EMPRES Transboundary Animal Diseases Bulletin, 2002. 20:2-11. http://www.fao.org/docrep/004/Y3649E/Y3649E01.htm

3. Tomassen FHM, de Koeijer A, Mourits MCM, Dekker A, Bouma A, Huirne RBM. A decision-tree to optimize control measures during the early stage of a foot-and-mouth disease epidemic. *Prev Vet Med,* 2002. 54(4): 301-24.

4. AAVLD accreditation requirements: http://data.memberclicks.com/site/aavld/Requirements%20v5%200%2009-16-10.pdf

5. Callahan JD, Brown F, Osorio FA, Sur JH, Kramer E, Long GW, Lubroth J, Ellis SJ, Shoulars KS, Gaffney KL, Rock DL, Nelson WM. Use of a portable real-time reverse transcriptase-polymerase chain reaction assay for rapid detection of foot-and-mouth disease virus. *J Am Vet Med Assoc,* 2002 Jun 1. 220(11):1636-42.

6. King DP, Ferris NP, Shaw AE, Reid SM, Hutchings GH, Giuffre AC, Robida JM, Callahan JD, Nelson WM, Beckham TR. Detection of foot-and-mouth disease virus: comparative diagnostic sensitivity of two independent real-time reverse transcription-polymerase chain reaction assays. *J Vet Diagn Invest*, 2006 Jan. 18(1):93-7.

7. King DP, Ferris NP, Shaw AE, Reid SM, Hutchings GH, Giuffre AC, Robida JM, Callahan JD, Nelson WM, Beckham TR. Specific detection of Rinderpest virus by real-time reverse transcription-PCR in preclinical and clinical samples from experimentally infected cattle. King DP, Ferris NP, Shaw AE, Reid SM, Hutchings GH, Giuffre AC, Robida JM, Callahan JD, Nelson WM, Beckham TR. *J Clin Microbiol*, 2010 Nov. 48(11):4094-101.

8. Risatti GR, Callahan JD, Nelson WM, Borca MV. Rapid detection of classical swine fever virus by a portable real-time reverse transcriptase PCR assay. *J Clin Microbiol*, 2003 Jan. 41(1):500-5.

9. Preclinical diagnosis of African swine fever in contact-exposed swine by a real-time PCR assay. Zsak L, Borca MV, Risatti GR, Zsak A, French RA, Lu Z, Kutish GF, Neilan JG, Callahan JD, Nelson WM, Rock DL. *J Clin Microbiol,* 2005 Jan. 43(1):112-9.

10. Eberling AJ, Bieker-Stefanelli J, Reising MM, Siev D, Martin BM, McIntosh MT, Beckham TR. Development, Optimization, and Validation of a Classical Swine Fever Virus Real-Time RT-PCR Assay. *J Vet Diagn Invest*. Submitted, 2010

11. Personal communication, Dr. Michael McIntosh, Head Proficiency and Validation Services Section, USDA APHIS, Plum Island.

12. Schmitt B, Henderson L. Diagnostic tools for animal diseases. *Rev sci tech Off int Epiz,* 2005. 24(1): 243-50.

13. Ferris NP, et al. Development and laboratory validation of a lateral flow device for the detection of foot-and-mouth disease virus in clinical samples. *J Virol Meth*ods, 2009. 155: 10-7.

14. Mulhern E, Fabian A, O'Hearn E, Mohamed F, Das A, McIntosh M, Metwally S. Laboratory validation of a lateral flow device for the detection of Foot-and-Mouth disease virus in clinical samples. American Association of Veterinary Laboratory Diagnosticians (AAVLD), Virology Scientific Session, 2010.

15. Rainwater-Lovett K, Pacheco JM, Packer C, Rodriguez L. Detection of foot-and-mouth disease virus infected cattle using infrared thermography. *Vet J*, 2009.180(3):317-24.

16. Secure Egg Plan. http://secureeggsupply.com/

17. CRS Report 7-5700- Potential Farm Sector Effects of 2009 H1N1 "Swine Flu": Questions and Answers. Renee Johnson. Congressional Research Service, 2009.

18. Statement by Michael Scuse before the Subcommittee on Livestock, Dairy, and Poultry, Committee on Agriculture, October 2009.

19. 2010 OIE Terrestrial Code- Volume 2. http://www.oie.int/eng/normes/mcode/en_sommaire.htm.

20. Dukes JP, King DP, Alexandersen S. Novel reverse transcription loop-mediated isothermal amplification for rapid detection of foot-and-mouth disease virus. *Archives Virol*, 2006. 151(6): 1093-106.

21. Parida M, Sannarangaiah S, Dash PD, Rao RVL, Morita K. Loop mediated thermal amplification (LAMP): a new generation of innovative gene amplification technique; perspectives in clinical diagnosis of infectious diseases. *Rev Med Virol*, 2008. 18(6): 407-21.

22. Hoffmann B, et al. A review of RT-PCR technologies used in veterinary virology and disease control: Sensitive and specific diagnosis of five livestock diseases notifiable to the World Organisation for Animal Health. *Vet Microbiol*, 2009. 139 (1-2): 1-23.

23. Belák S. Molecular diagnosis of viral diseases, present trends and future aspects: A view from the OIE Collaborating Centre for the Application of Polymerase Chain Reaction Methods for Diagnosis of Viral Diseases in Veterinary Medicine. *Vaccine,* 2007. 25(30): 5444-52.

24. Beard CW, Brugh M Jr. Nobuto strips. *Avian Dis*, 1977. 21(4):630-6

25. OIE Report of the Meeting of the OIE Biological Standards Commission. 74th General Session- International Committee. 2006.

26. Lederman ER, et al. Prevalence of Antibodies against Orthopoxviruses among Residents of Likouala Region, Republic of Congo: Evidence for Monkeypox Virus Exposure. *Am J Trop Med Hyg*, 2007. 77(6): 1150-6.

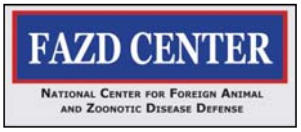
27. Foreign Animal Disease Preparedness and Response Plan (FAD PReP)- Dairy Manual. USDA APHIS Veterinary Services and Iowa State Center for Food Security and Public Health, 2010.

Alphabetical List of Participants

Agricultural Screening Tools Workshop | Nov. 1-2, 2010 | Washington, DC

April, Michele	USDA APHIS Veterinary Services (VS), Centers for Epidemiology and Animal Health, (CEAH) National Surveillance Unit
Barnaby, Neel	FBI
Beckham, Tammy	FAZD Center and Texas Veterinary Medical Diagnostic Laboratory (TVMDL)
Brake, David	SAIC, Plum Island Animal Disease Center (PIADC)
Breitmeyer, Richard	UC Davis, Center for Animal Health and Food Safety
Casagrande, Rocco	Gryphon Scientific
Cawley, Rusty	FAZD Center
Clavijo, Alfonso	TVMDL and FAZD Center
Coats, Matthew	DHS S&T, Office of University Programs
Colby, Michelle	DHS S&T, Chem/Bio Division, Food and Agricultural Defense
Elsken, Larry	USDA APHIS VS, Center for Veterinary Biologics
Evans, Petrina	DHS CBP, Office of Field Operations, Agricultural Safeguarding
Gay, Cyril	USDA ARS, Animal Health and Safety
Goldsmith, Stephen	FBI
Harper, Bruce	DHS S&T, PIADC
Hefferin, Melissa	DHS S&T, Office of University Programs
Hesse, Richard	Kansas State University, Center of Excellence in Emerging and Animal Diseases, Detection and Diagnostics
Hietala, Sharon	UC Davis, School of Veterinary Medicine
Hullinger, Pam	UC Davis, School of Veterinary Medicine
Kamicker, Barb	SAIC, PIADC
Korslund, John	USDA APHIS VS, CEAH, National Surveillance Unit
Kramer, Liz	Gryphon Scientific
Lautner, Elizabeth	USDA APHIS VS, National Veterinary Services Laboratories
Levings, Randall	USDA APHIS Veterinary Services

Lindler, Luther	DHS S&T, Chem/Bio Division
Martin, Barbara	USDA APHIS VS, National Animal Health Laboratory Network
McElwain, Terry	Washington State University, School for Global Animal Health
McIntosh, Mike	USDA APHIS, PIADC, Foreign Animal Disease Diagnostic Laboratory (FADDL)
Olivarez, Lori	FAZD Center
Orr, Robert	Booz Allen Hamilton, DHS S&T
Rinderknecht, Jennifer	FAZD Center
Rooney, Jane	USDA APHIS, Emergency Management
Snelson, Harry	American Association of Swine Veterinarians
Stokes, Marty	DHS S&T, Chem/Bio Division
Torres, Fernando	USDA APHIS, PIADC, FADDL
Webb, Patrick	National Pork Board, Swine Health Programs
White, William	USDA APHIS, PIADC, FADDL
Zack, Jon	USDA APHIS, Emergency Management
Zaudtke, Anne Marie	Booz Allen Hamilton, DHS S&T



Agenda
Protecting Agricultural Infrastructure: Defining the needs and requirements for Agricultural Screening Tools

Nov. 1-2, 2010
Holiday Inn Capitol
550 C Street, SW
Washington DC 20024

Goals

Definition for Agricultural Screening tools

Evaluate current status (nationally and internationally)

Identify and Discuss the Gaps and Needs defined by Agricultural community

Consensus on Requirements for Agricultural Screening Tools

Outcomes

White paper report to DHS and for publication

Monday November 1, 2010 – Room – Discovery I

7:15-8:15	Breakfast
8:15-8:45	Welcome and Overview of Meeting Goals and Objectives – Tammy Beckham
8:45-9:00	Where did AST come from? – Luther Lindler
9:00-9:15	Ag Screening Tools: Overview – Tammy Beckham
9:15-9:30	Outcomes from FMD NAHLN Exercises: 2010 – Barbara Martin
9:30-9:45	Overview of DHS/USDA Diagnostic Roadmap – Barbara Martin
9:45-10:00	Customs and Borders Protection: Ag Screening Tool Needs – Petrina Evans
10:00-10:15	Ag Screening Tools: Needs Identified at FMD Workshop during 2010 FMD International Symposium - David Brake
10:15-10:30	Overview of Ag Screening Tools – Tammy Beckham
10:30-10:45	Break

10:45-11:00	Gryphon study findings on FAD Diagnostics - Rocco Casagrande
11:00-12:00	Defining the Need: Definition of Ag Screening Tools – Group Discussion
12:00-1:00	Lunch (On-site)
1:00-2:30	Current Status/Availability of tools (National and International) – Group Discussion
2:30-3:00	Regulatory acceptance of available tools/Impact on Trade – Group Discussion
3:00-3:20	Afternoon Break
3:20-5:00	Defining the Gaps and needs – Group Discussion
6:00-8:00	Dinner (Discovery II)

Tuesday November 2, 2010 – Room – Discovery I

7:30-8:00	Breakfast
8:00-10:00	Resume: Defining the Gaps and needs
10:00-10:15	Break
10:15-12:00	Defining the operational requirements
12:00-1:00	Lunch
1:00-3:00	Defining the operational requirements
3:00-3:30	Policy and the use of Ag Screening Tools
3:30-5:00	Summary/Discussion/Wrap Up