United States Animal Health Association

2020 Resolution

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RESOLUTION NUMBER: **14** **APPROVED**

SOURCE: **COMMITTEE ON SWINE**

SUBJECT MATTER: **Sustainable Diagnostic Supply Chains and Lessons Learned from the COVID-19 Pandemic**

BACKGROUND INFORMATION:

African swine fever has spread throughout Europe, Russia, and Asia since 2007 despite ongoing efforts by numerous countries to control the disease. Greater than 50% of the global swine population is at risk for this high morbidity/high mortality disease. The implications for food and economic security in the pork sector are severe. Fortunately, the Western hemisphere has yet to be impacted, but preparation for the emergence of the virus in this hemisphere should occur.

The COVID-19 pandemic has highlighted diagnostic and health system limitations. Lack of adequate testing capabilities and a shortage of sampling supplies interfered with the early response to the pandemic, but the United States Food and Drug Administration's ability to evaluate and approve novel diagnostics for emergency use allowed for rapid resolution of that deficit. A similar program for animal health may be needed for rapid evaluation of suspect premises to properly assess risk.

Diagnostic efforts to detect SARS-CoV-2 appear to demonstrate that mass testing can overcome lower sensitivity thresholds associated with some diagnostic tests and diagnostic samples. Surveillance that uses repeat testing of easily available samples may be more accurate than surveillance that limits itself to single individual tests that are difficult to obtain.

Outbreak readiness must include secondary options and logistic supply plans, particularly for sampling and diagnostic purposes. United States (US) animal agriculture requires this to be a critical part of planning for catastrophic swine diseases as US commercial systems are highly integrated, have efficiency built on animal movement, and include millions of animals.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the Strategy and Policy and Diagnostics and Biologics units of the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), to work through the National Animal Health Laboratory Network (NAHLN) and its membership to support and advance the following efforts to ensure a sustainable supply of necessary diagnostics for use during an African swine fever (ASF) outbreak:

- Review the lessons learned to date from the appropriate United States (US) public health entities (Centers for Disease Control, Food and Drug Administration, Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, public health groups) to identify issues of concern and apply novel approaches that would be beneficial for emergency preparedness in the animal agricultural arena.
- Develop a publicly available list of approved commercial diagnostic tools for use in control of an animal disease outbreak and provide guidance on how and when they should be used.
- Develop emergency use authorization guidelines to rapidly assess new diagnostic assays for World Organization for Animal Health (OIE) reportable transboundary animal diseases foreign to US herds and flocks.

Evaluate the validity of realistic and sustainable surveillance scenarios using diagnostic assays on aggregate samples (oral fluids, processing fluids and other sample types) compared to individual animal sampling to ensure that on farm testing is implementable.

INTERIM RESOLUTION

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond.

APHIS set up internal working groups to address and work on these issues. Furthermore, APHIS is actively working with other interagency programs to address supply issues and develop mechanisms to improve overall USG responses. An interim progress report is below:

Lessons Learned: NAHLN currently participates in the One Health Federal Interagency Covid-19 Coordination Group and the Integrated Consortium of Laboratory Networks. Both groups are evaluating lessons learned from the COVID experience. NAHLN is working with the National Veterinary Services Laboratories' Foreign Animal Disease Diagnostic Laboratory (FADDL) to incorporate these lessons learned and identify improvements for emergency preparedness. Several areas we initially addressed include providing feedback through webinars from NAHLN laboratories with CLIA certification; and, coordinating communication between NAHLN laboratories and with vendors to address supply shortages. We also coordinate regular calls among NAHLN laboratories doing SARS-CoV-2 testing to discuss issues and concerns as they arise.

Diagnostic Tools: To ensure continuous access to diagnostic equipment, reagents, and test kits, NAHLN and FADDL developed a list of second vendors for equipment and reagents to provide options to currently approved protocols. FADDL approved two commercially available PCR test kits for use in the NAHLN laboratory, in case of an outbreak.

Approved NAHLN laboratories have Standard Operating Procedures (SOPs) describing the kits and how/when they should be used. These documents are controlled to ensure that only the most current version is being used. If laboratories outside of the NAHLN are asked to support testing during an outbreak, they will be provided with the most current version of the SOPs.

A list of commercially available diagnostic test kits is available on the Center for Veterinary Biologics' (CVB) website. Approved kits are listed in a document entitled the Product Code Book. They are broken out by agent tested for, and the different types of tests, i.e. antibody, antigen, etc. Directions for use can be found in the approved labeling insert for each approved diagnostic test kit. How best to clinically use a test kit will vary depending on disease prevalence, purpose, etc.

In a situation where there is an urgent need for a diagnostic test kit, CVB has the ability to reallocate resources and expedite the review and evaluation of a diagnostic and its supporting

data to make it available as quickly as possible to the market. Additionally, another option is to look at unapproved test kits that are evaluated internationally to determine their suitability to be permitted into the United States for use under a Research & Evaluation (R&E) Permit. R&E permits are generally evaluated on the data available, and the risk (if any) that importation would present to U.S. agriculture. There is no provision in the regulations for conditionally approved diagnostics, as some level of data to establish sensitivity and specificity is required to give the diagnostic some utility in use.

Emergency Use Authorization: FADDL, in collaboration with NAHLN, developed a working group to develop a streamlined approach for emergency evaluation and approvals of new diagnostic assays and sample types in the face of a U.S. outbreak. This is in addition to the NAHLN Emergency Validation Process SOP developed in 2020.

Diagnostic Assays for use on Aggregate Samples: The ASF Oral Fluids (OF) Fit for Purpose working group is addressing the validity of realistic and sustainable surveillance scenarios to support diagnostic testing with approved ASF assays using aggregate samples (OF). The working group drafted a document that outlines potential use cases for OF deployment, including the risks and potential mitigations. In the interim, NAHLN/FADDL initiated a pilot study in 2020 to add OF as an unapproved ancillary sample to swine fever (ASF/CSF) foreign animal disease investigations from farms. This will ensure both the field and laboratory are prepared to handle OF samples for a foreign animal disease investigation. Four states have been invited to participate based on negative cohort study (Iowa, Minnesota, North Carolina, South Dakota). Based on results, the pilot can be expanded to additional labs and potentially added to the surveillance plan.

In addition to aggregate samples, FADDL approved use of spleen swabs for ASF diagnostic testing and is currently evaluating blood swabs and dried blood spots (FTA cards), with approval anticipated in February 2021. These samples will mitigate concerns about availability of sample collection materials (blood tubes, etc.) and efficiency of field collection in the field. It will also facilitate more rapid sample processing in the laboratory, reducing turnaround time for results.

FINAL RESPONSE

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond.

APHIS set up internal working groups to address and work on these issues. Furthermore, APHIS is actively working with other interagency programs to address supply issues and develop mechanisms to improve overall US government responses. APHIS is represented on the U.S. government working group that evaluates the need to use the Defense Production Act for critical supplies. Actions to date include:

Lessons Learned: NAHLN currently participates in the One Health Federal Interagency Covid-19 Coordination Group and the Integrated Consortium of Laboratory Networks. Both groups are evaluating lessons learned from the COVID experience. NAHLN is working with the National Veterinary Services Laboratories (NVSL) to incorporate these lessons learned and identify improvements for emergency preparedness. We have addressed several areas including providing feedback through webinars from NAHLN laboratories with CLIA certification; and coordinating communication between NAHLN laboratories and with vendors to address supply shortages. We also coordinate regular calls among NAHLN laboratories conducting SARS-CoV-2 testing to discuss issues and concerns as they arise. These calls are now used to talk about response needs of the NAHLN to address the threat of African swine fever.

Diagnostic Tools: To ensure continuous access to diagnostic equipment, reagents, and test kits, NAHLN and NVSL continue to develop a list of alternative vendors for equipment and reagents to provide options to currently approved protocols. NVSL's Foreign Animal Disease Diagnostic Laboratory (FADDL) approved two commercially available PCR test kits for use in the NAHLN laboratory, in case of an outbreak. These kits are currently not licensed in the United States and, therefore, are not eligible for use in routine surveillance.

Approved NAHLN laboratories have Standard Operating Procedures (SOPs) describing the kits and reagents and how/when they should be used. These documents are controlled to ensure that only the most current version is being used. Analysts must successfully complete annual proficiency testing (PT) on these protocols. If laboratories outside of the NAHLN are asked to support testing during an outbreak, they would be provided with the most current version of the SOPs. Their analysts may be required to successfully complete a PT before testing results are accepted.

A list of commercially available diagnostic test kits is available on the Center for Veterinary Biologics' (CVB) website. Approved kits are listed in a document entitled the Product Code Book. They are broken out by agent, and the different types of tests, i.e. antibody, antigen, etc. Directions for use can be found in the approved labeling insert for each approved diagnostic test kit. How best to clinically use a test kit will vary depending on disease prevalence, purpose, etc.

In a situation where there is an urgent need for a diagnostic test kit, CVB has the ability to reallocate resources and expedite the review and evaluation of a diagnostic and its supporting data to make it available as quickly as possible to the market. Additionally, another option is to look at unapproved test kits that are evaluated internationally to determine their suitability to be permitted into the United States for use under a Research & Evaluation (R&E) Permit. R&E permits are generally evaluated on the data available, and the risk (if any) that importation would present to U.S. agriculture. There is no provision in the regulations for conditionally approved diagnostics, as some level of data to establish sensitivity and specificity is required to give the diagnostic some utility in use.

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In addition to evaluating aggregate samples, FADDL approved use of spleen swabs, blood swabs and blood cards for ASF testing following confirmation in the United States. These

samples will significantly increase testing through-put in the laboratories. In addition, these samples will mitigate concerns about the availability of sample collection materials (blood tubes, etc.) and efficiency of field collection.