RESOLUTION NUMBER: 1 Combined with 13, 27 and 32 Approved

SOURCE: **COMMITTEE ON NATIONAL ANIMAL HEALTH LABORATORY NETWORK (NAHLN)**
COMMITTEE ON ANIMAL EMERGENCY MANAGEMENT
COMMITTEE ON CATTLE AND BISON
COMMITTEE ON FOREIGN AND EMERGING ANIMAL DISEASES

SUBJECT MATTER: **Foot-and-Mouth Disease Diagnostics – Serology Assay Deployment to National Animal Health Laboratory Network Laboratories**

BACKGROUND INFORMATION:

A group of stakeholders from the bovine germplasm industry, state and federal animal health officials and veterinary diagnostic laboratory representatives are collaborating to create guidance criteria to allow domestic movement of bovine germplasm and high genomic merit animals located in a regulatory control area during a foot-and-mouth disease (FMD) outbreak in the United States (US). The Bovine Germplasm Movement Plan is a guidance document being developed through funding provided by the United States Department of Agriculture (USDA) National Animal Disease Preparedness and Response Program (NADPRP). Maintaining safe domestic movement of germplasm and high genomic merit animals from their birth location into the genetic system is the focus of this guidance. This provides business continuity opportunities for the entire cattle industry and preservation of genetic material.

The bovine germplasm industry consists of semen production, oocyte harvest, and embryo production. Most of the new genetic stock in both dairy and beef industries is produced by artificial insemination (AI) and embryo transfer (ET). It is estimated that 70-75% of dairy cattle and 10% of beef cattle in the US are bred by artificial insemination (source: National Association of Animal Breeders (NAAB), Certified Semen Services (CSS)). Frozen semen and embryos are shipped to cattle operations in all 50 states (source: NAAB and the American Embryo Transfer Association).

Every year, millions of doses of bovine semen and nearly 0.5 million bovine embryos are transported in the US from their site of collection/creation to laboratories for quality control, further processing and then moved to livestock facilities for use in cattle. Movement from FMD control areas will require a movement permit and is based on risk. Serologic

surveillance of the donor bull or female on the day of semen, embryo or oocyte collection could provide a high degree of confidence that the animal was not infected 14 days previously. Test results, combined with active observational surveillance of the donor animals, can be useful for issuing movement permits for animal products that can be stored for 14 days (e.g., frozen semen and embryos).

Collecting and storing serum at the start of an FMD outbreak from bulls and donor females actively having semen/oocytes/embryos collected could be part of a business contingency plan for germplasm facilities. These banked serum samples would be available to test for permitting requirements, as needed. The cost of testing serum for business continuity will be the responsibility of the submitter (owner, business, etc.) not the state and federal agencies managing the response.

Some AI bull stations (studs) collect and retain serum samples for bulls with semen destined for international export. These serum samples are collected by or under the guidance of a USDA Category II Accredited Veterinarian approximately every 28 days when the bull semen is being collected. In some cases, the germplasm facilities archive or "bank" these serum samples for up to 3 years. Samples would be available in an outbreak for confirming the serology status of the bull and semen stored frozen and distributed beyond the point of origin. It is uncommon for serum samples to be retained for female donors.

Some veterinary diagnostic laboratories that test serum for semen export purposes archive/retain samples for a few weeks up to 6 months after submission. These serum samples could be an option for bulls that have had semen exported before the first diagnosis of FMD in the US and used to determine the status of that bull before domestic semen movement.

The USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Services Laboratory (NVSL), Foreign Animal Disease and Diagnostic Laboratory (FADDL) has a commercially available and validated antibody enzyme linked immunosorbent assay (ELISA) test for FMD that could be deployed to National Animal Health Laboratory Network (NAHLN) laboratories. Deployment of the assay will require an accompanying Standard Operating Procedure (SOP) and technicians at the NAHLN laboratories will need to pass a proficiency test (PT) before they are approved to perform the assay. Development of a PT panel and administration of the PT program will require time and resources from each NAHLN laboratory and USDA-APHIS-VS-NVSL-FADDL. In the face of an outbreak, this additional time burden could be a barrier to establishing this diagnostic assay.

There is a small cohort of NAHLN laboratories that conduct the majority of antibody ELISA testing on serum for domestic diseases as part of semen and embryo export protocols. Once exports cease due to an FMD outbreak, these high-volume serum testing NAHLN

labs should have the capacity to conduct outbreak serology testing. The majority of these labs have expressed interest in undergoing non-outbreak proficiency testing for FMD antibody testing using serum. As of October 2023, there is no FMD serologic testing approved for NAHLN laboratory use. A defined testing protocol and authorized laboratories (trained and passed proficiency testing) will allow swift deployment of the assay if an outbreak occurs. State animal health officials would need to support sample movement to one of the authorized laboratories at the beginning of the outbreak until more laboratories can be onboarded. Deployment of the assay and PT of personnel prior to disease emergence would allow NAHLN labs to incorporate this assay into their toolbox to support the industry and decision makers should an FMD outbreak occur. This assay would allow surveillance of bulls and female germplasm donors (semen, oocytes, embryos) in a control area for business continuity, contribute information to the animal health officials managing the response, and preserve genetic material.

This resolution does not include considerations for serologically testing vaccinated animals and the serum ELISA assay's ability to differentiate infected from vaccinated animals (DIVA). Emergency vaccination in an FMD outbreak with corresponding diagnostic testing is complex and outside the scope of this resolution.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Veterinary Services Laboratory, Foreign Animal Disease Diagnostic Laboratory to deploy foot-and-mouth disease antibody enzyme-linked immunosorbent assay (ELISA) tests to National Animal Health Laboratory Network (NAHLN) laboratories. This would require, at a minimum, development of a NAHLN Standard Operating Procedure, a training and proficiency testing program, and a procurement and distribution plan of a commercially available and validated ELISA test. The program should prioritize NAHLN laboratories that currently conduct high-volume serum testing. Policy describing test result interpretation and reporting protocols should be developed under the guidance of the National Preparedness and Incident Coordination Center. Testing frequency guidance should be developed with input from the Center for Epidemiology and Animal Health Surveillance Design and Analysis Group.

USAHA urges Congress to appropriate additional funding for NAHLN to support this work.

INTERIM RESPONSE:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

APHIS VS' National Veterinary Services Laboratories (NVSL) is finalizing the standard operating procedure for a commercial foot and mouth disease (FMD) ELISA kit licensed in the United States and discussing the potential NVSL development of a proficiency test. NVSL is also discussing assay-use parameters, including testing frequency, interpretation, and reporting.