

RESOLUTION NUMBER: 8 APPROVED AS AMENDED

SOURCE: COMMITTEE ON EQUINE

SUBJECT MATTER: Point of Care Testing

BACKGROUND INFORMATION:

With the increase in equine herpesvirus (EHV-1) outbreaks over the last few years, the United States Animal Health Association recognizes that early identification and isolation of horses are critical steps in disease response. Even with the availability of polymerase chain reaction testing at veterinary diagnostic laboratories, diagnosis of the index case can take several days. Pending diagnostic results, there is discussion on whether or not to isolate the tested horse. Typically, there are limited isolation options available, thus causing hesitation to move a horse of unknown status. Waiting for confirmation of the diagnosis to move the horse into isolation places cohort horses at risk.

Point of care testing to detect EHV-1 would be extremely beneficial while awaiting confirmatory diagnostic laboratory test results. Currently, several entities are conducting pilot field studies of point of care tests while pursuing United States Department of Agriculture licensure for their products. The licensure and approval of point of care tests supports equine health and advances equine diagnostics. However, the distribution and sale of these point of care tests should be restricted to veterinarians who are performing clinical evaluation of the horse and herd. Additionally, simultaneous confirmatory testing of samples at a veterinary diagnostic laboratory should be required for validation of the screening result. Therefore, the licensure for these point of care test(s) should be under specified conditions and include an immediate reporting requirement for positive test results and the authority to remove test kits/testing equipment for failure to immediately report.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) Center for Veterinary Biologics to require that sale or use of point of care tests/testing for an equine disease listed on the USDA National List of Reportable Animal Diseases be restricted to licensed and accredited veterinarians.

FINAL 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.

License restrictions are applied based on Title 9, Code of Federal Regulations, Part 102.5(d) (9 CFR 102.5(d)) to protect domestic animals, public health interests, and/or safety. APHIS has already put such restrictions on diagnostic products used for program diseases. Equine Infectious Anemia diagnostic products have a restriction that states "Sale and use in the United States restricted to laboratories approved by State and Federal (USDA) animal health officials." This aligns with APHIS requirements per 9 CFR 71.22, 75.4, and VS Guidance 15201.1. APHIS will consider adding the proposed restrictions on future licenses on a case-by-case basis.