United States Animal Health Association
2019 Resolution
123rd Annual Meeting
Oct. 24-30, 2019
Providence, RI

RESOLUTION: 24 APPROVED

SUBJECT MATTER: Chronic Wasting Disease Amplification Assay Approval

BACKGROUND INFORMATION

There are currently two official tests approved by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) for chronic wasting disease (CWD) diagnostics: immunohistochemistry (IHC) and enzyme-linked immunosorbent assay (ELISA).

Early detection of CWD is critical for wild, farmed, and captive cervid disease management. Tests that can detect prions earlier in the course of infection than those currently available would enhance intervention and could potentially lead to better outcomes. Additionally, tests that are more sensitive and could potentially be used with other tissues and biofluids, such as those from live or hunter-collected carcasses, would be extremely useful.

These tests, known as amplification assays, are used in human diagnostics at present. Several federal and university laboratories have been using real-time quaking induced conversion (RT-QuIC) and protein misfolding cyclic amplification (PMCA) for influential CWD research. These assays have advanced our knowledge of disease pathogenesis and prion shedding.

Despite their documented increased sensitivity, these assays have not been evaluated by the USDA, APHIS, VS, National Veterinary Services Laboratory or Agricultural Research Services for approval to be used by National Animal Health Laboratory Network and state veterinary diagnostic laboratories. A recent survey of diagnostic laboratories with current IHC or ELISA capabilities indicated an overwhelming willingness to use the RT-QuIC platform if it was approved by USDA.

RESOLUTION

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to evaluate the utility of real-time quaking induced conversion (RT-QuIC) as an official test for Chronic Wasting Disease (CWD). If this CWD test demonstrates acceptable

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sensitivity and specificity, we urge USDA to approve the assay to be used by the National Veterinary Services Laboratory and National Animal Health Laboratory Network approved veterinary diagnostic labs. We encourage USDA-APHIS to work with the United States Department of the Interior United States Geological Survey (USGS) to determine an appropriate source of recombinant prion protein for use in RT-QuIC assays that will be provided to approved NAHLN labs at a minimum cost.

INTERIM RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. Due to significant interest from stakeholders, VS is evaluating the appropriateness of using the RT-QuIC assay as an official ante and/or post mortem CWD diagnostic test that would be used by VS, or in partnership with National Animal Health Laboratory Network (NAHLN) laboratories.

To accomplish this, VS is collaborating with the Agricultural Research Service (ARS) and the USGS to generate the data necessary to evaluate the sensitivity and specificity of the RT-QuIC assay for detection of CWD in ante mortem rectal and tonsil biopsies, as well as post mortem medial retropharyngeal lymph nodes. Issues that need to be addressed include the following: lack of a commercially available testing substrate suitable for widespread use (currently this assay is limited to research use), lack of a standardized kit, and challenges associated with procuring the correct, clean sample tissues required for the assay under field conditions. We look forward to further discussion, should this CWD test demonstrate its utility as an official CWD diagnostic assay.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. Due to significant interest from stakeholders, VS is evaluating the appropriateness of using the RT-QuIC assay as an official ante and/or postmortem CWD diagnostic test that would be used by VS, or in partnership with NAHLN laboratories.

VS is collaborating with ARS, USGS, and the National Institutes of Health to generate a standardized RT-QuIC protocol and the data necessary to evaluate the sensitivity and specificity of the RT-QuIC assay for detection of CWD in ante mortem rectal and tonsil biopsies, as well as post mortem medial retropharyngeal lymph nodes. Issues that need to be addressed include the following: lack of a commercially available testing substrate suitable for widespread use (currently this assay is limited to research use), lack of a standardized kit, and challenges associated with procuring the correct, clean sample tissues required for the assay under field conditions. We look forward to further discussion, should this CWD test demonstrate its utility as an official CWD diagnostic assay.