

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 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 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 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.