United States Department of Agriculture

United States Department of Agriculture

Marketing and Regulatory Programs

Washington, DC 20250

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Jerry Torrison, DVM, PhD, DACVPM
Director, Veterinary Diagnostic Laboratory
University of Minnesota
E220 VetDL
1333 Gortner Avenue
St. Paul, MN 55108

Dear Dr. Torrison:

Thank you for the opportunity to provide the Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) position on implementing and performing an unvalidated/unapproved assay (RT-QuIC) at the University of Minnesota Veterinary Diagnostic Laboratory which is approved to perform official testing for chronic wasting disease (CWD). Previous guidance has stated, "that testing for [National Animal Health Laboratory Network] NAHLN scope diseases should only occur on validated and approved samples using validated assays."

This guidance remains in effect. VS strongly discourages NAHLN laboratories from providing unofficial testing using unvalidated assays or protocols (kits not yet licensed in the U.S., RT-QuIC, etc.) or using any test on unapproved/unvalidated samples (feed components, meat products, environmental testing, etc.) for NAHLN scope diseases (see list below). If a NAHLN Laboratory chooses to participate in this testing, action will be taken based on the Laboratory Performance Policy document (NVSL-Policy-0036.02) to address what is considered outside the standard expectations of the NAHLN.

Rationale: Testing for program and other high consequence diseases in the U.S. such as those under NAHLN scope carries a high level of responsibility. Results of this testing have far-reaching effects for the states involved and the cervid industry. Specific to test results from NAHLN, stakeholders must have confidence in a negative test result and what that means; we need to know that a negative result indicates absence of disease or agent. A false negative test result could allow disease to spread before the laboratory accurately identifies it. We also must know what a positive test result is identifying. A false positive could affect producers' livelihoods, interstate commerce, and international trade. False positive results can also affect our ability to implement RT-QuIC as an official test once the assay is validated due to a loss in confidence in the test. Understanding the limitations of an assay is key in providing context for interpreting the test results. For the RT-QuIC assay, the approved validation has not been completed, no specific sample types evaluated for approval, or a standardized protocol accepted for official testing.

The National Veterinary Services Laboratories (NVSL) has validated the NVSL-NAHLN approved assays for specific sample types for use in the U.S. herds/flocks.

The assays have known performance characteristics on these sample types both in the laboratory and in the field. Both NVSL and the NAHLN laboratories have analysts with proven proficiency in running these assays, ensuring that test results are provided with confidence, and non-negative results for high consequence diseases received at the NAHLN laboratory can be confirmed by NVSL's reference laboratories. Thus, on the rare occurrence where discrepancies in test results occur between the NVSL and a NAHLN laboratory, we can evaluate these differences because of the reference laboratories clear understanding of the performance characteristics of the screening tests VS has deployed to the laboratories. Any troubleshooting can efficiently cover well-defined aspects of the screening tests and laboratories can report results with confidence in a timely manner. When laboratories use assays with unknown performance characteristics to test sample types for which NVSL has not validated the assay, the confidence in the test drops significantly. We cannot easily interpret test results, and this puts us at a significant disadvantage as we cannot make decisions in a timely manner or with confidence. The testing laboratory, whether it is a NAHLN laboratory or NVSL, must understand what a positive or negative result means.

As the U.S. confirmatory laboratories for high consequence animal diseases, NVSL may not be able to confirm these results. In the meantime, laboratories may spend an abundant amount of time and resources in attempting to troubleshoot the test. Moreover, State and Federal animal health officials must make decisions and take actions that have repercussions in response to a test result that may have questionable meaning and integrity. Our stakeholders would expect the U.S. to answer questions pertaining to testing conducted outside of APHIS' oversight, and the outcome could cause them to lose confidence in our country's disease status and control programs.

NAHLN Scope Diseases (animal sample testing)

- African swine fever
- Avian influenza
- Bovine spongiform encephalopathy
- Chronic wasting disease
- Classical swine fever
- Foot and mouth disease
- Infectious salmon anemia
- Newcastle disease
- Pseudorabies
- Scrapie
- Spring viremia of carp
- Swine influenza
- Viral hemorrhagic septicemia
- Vesicular stomatitis virus

Finally, APHIS VS is actively evaluating and funding research on the utility of using RT-QuIC in the CWD program and is optimistic about the potential of the assay. It is vital that a process of evaluation and validation is done across

laboratories to ensure the consistent performance of the assay. If you or others have questions, please direct them to Dr. Christina Loiacono, NAHLN Coordinator, at Christina.M.Loiacono@aphis.usda.gov.

Sincerely,

ROSEMARY SIFFORD

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Deputy Administrator
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CC: Dr. Beth Thompson, Executive Director, State Veterinarian, Minnesota Board of Animal Health
Dr. Stephan Schaefbauer, Minnesota Area Veterinarian in Charge, Veterinary Services