Response to the Use of Non-Validated, Commercially-Available Tests for Chronic Wasting Disease (CWD)

Prepared by: MAFWA Fish and Wildlife Health Technical Working Committee (October 2023)

As CWD continues to spread in North American wild cervid populations, we recognize the importance of research efforts to develop and improve diagnostic tools that enhance early disease detection and efficiency of surveillance programs. We fully support expansion of diagnostics to include broad sample types, both biological and environmental, as well as test that return CWD test results to hunters as quickly as possible; however, new test methods must adhere to the integrity of the scientifically rigorous validation process. With commercially-available CWD tests on the market, state and provincial natural resource agencies should establish consistent and actionable responses to CWD-positive test results from these non-validated tests. Further, we suggest state and provincial wildlife health professionals proactively advise agency leadership and stakeholders on the potential for non-validated CWD-positive detections in their states.

The MAFWA Fish and Wildlife Health Committee currently recommends:

- Continued promotion of validated, no-cost and fee-based, CWD testing opportunities available to hunters in many states and provinces with tissues (e.g., lymph nodes or brain stem) required for validated testing.
- Several commercial companies are currently marketing their non-validated CWD tests to hunters and farmers. Positive results from these tests should not be recognized as valid without confirmation from validated tests using acceptable tissue; therefore, it is recommended that agencies cautiously evaluate how such results may affect CWD response and management plans.
- Hunters or farmers who receive a CWD-positive test result from a non-validated test should be encouraged to submit tissues validated for CWD testing, retropharyngeal lymph nodes or brain stem, from the same animal for additional testing by validated methods. To validate these initial results, tissue samples must be available and viable.
- If a non-validated test identifies a CWD positive cervid it will be important to gather information from the hunter, including hunting location. This information may be advantageous to increase surveillance efforts using validated tests in some areas; however, these efforts will undoubtedly vary by jurisdiction and may be dependent on the agency's CWD response plan and available resources. The Midwest Fish and Wildlife Health Technical Working Committee suggests proactively determining if increasing CWD surveillance will be actionable by the state or province.

What is the difference between a validated and non-validated test method?

- A validated test method has been rigorously tested and proven to be highly accurate and consistently generates a result that fits within a defined sensitivity and specificity for its intended use. Typically, standard operating procedures (SOPs) are generated through the validation process to ensure test results are free of errors, defects, abnormalities, or deviations from the expected outcome. Further, validated diagnostic tests have accreditation requirements set for by USDA-

APHIS to ensure the laboratory meets standards for specific tests. To be a part of the National Animal Health Laboratory Network for CWD, testing labs must demonstrate proficiency and undergo regular auditing of testing procedures and results. Using a validated test method assures the user that results will be reliable and reproducible, regardless of who performs the test.

- A non-validated test method have not gone through standardization to ensure parameters that reduce errors in test results or limit contamination of the sample in the testing process are well established or repeatable. Also, they often use tissue or material that has not been validated using accepted methods, e.g. muscle, urine, and soil. Results from non-validated tests may not have consistently applied standards and provide less confidence to the end user in accuracy of findings and are not offered through accredited diagnostic laboratories.

What are the validated and non-validated tests for Chronic Wasting Disease?

- There are two testing methods validated for detecting the presence of CWD prions. These tests have different authorized uses in reference to free-ranging or farmed/captive deer programs. These tests are the enzyme-linked immunosorbent assay (ELISA) and the immunohistochemistry (IHC) CWD test. These tests are primarily performed on either brainstem or retropharyngeal lymph nodes.
- Real-time quaking-induced conversion (RT-QuIC) is a non-validated testing method commercially marketed as able to detect CWD prions. In research settings, this diagnostic test is promising and has been used on a variety of biological tissues including plants and environmental samples (e.g., soil, surfaces). However, until standard operating procedures are defined for these tests, they are validated, and laboratory accreditation is provided, it is recommended that they not be used to define wildlife management policies since labs using these tests have not completed the testing requirements through USDA and results from these tests cannot at this time be considered definitive or actionable at this time.

Why do state, federal, and provincial governments use only validated laboratory methods for CWD testing?

- Detections of CWD in free-ranging or captive animals often requires a regulatory response that impacts movement of animals or their parts, agency priorities, hunting seasons, and testing requirements. These responses have enormous financial costs and often disrupt traditional hunting seasons. This has the negative effect of draining agency budgets, redirecting staff to the response, and diminishing trust among stakeholders.
- Using validated CWD testing methods and accredited laboratories creates a common, consistent, and reliable language among jurisdictions charged with managing wild or farmed cervid populations.
- A recent report from the National Deer Association stated that all states or provinces testing for CWD used either the ELISA, IHC, or both in their testing program. No states or provinces reported using the non-validated, RT-QuIC test or PMCA as part of their CWD management efforts.

For more information on CWD, including research on diagnostics:

Non-validated commercially-available tests include:

Deer Urine: https://www.cwdevolution.com/rt-quic-urine-testing
Deer Feces: https://www.cwdevolution.com/fecal-testing
Deer Muscle and Environmental Samples: https://www.priogen.store/

Literature Cited and Web Resources

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CDC. Chronic Wasting Disease, https://www.cdc.gov/prions/cwd/index.html

Chronic Wasting Disease Alliance, https://cwd-info.org/

Cornell Wildlife Health Lab, https://cwhl.vet.cornell.edu/disease/chronic-wasting-disease

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National Deer Association.2021. Deer Report 2021, https://deerassociation.com/wp-content/uploads/2021/03/Final-DR2021.pdf