USDA United States Department of Agriculture

HPAI Outbreak 2014-2015

Use of the Antigen Capture Immunoassay

September 10, 2015

Please note: This policy may be revised as the situation develops.

BACKGROUND

Antigen capture immunoassays (ACIA) can be effective flock-based screening tools that have lower sensitivity than molecular assays but are highly specific for avian influenza when used for testing of clinically ill or dead birds. As screening tests, additional confirmatory testing is routine. Currently, there are commercially available licensed ACIA kits available. Testing at the National Veterinary Services Laboratories using 2014-2015 outbreak samples indicates a positive ACIA result in the presence of clinical signs consistent with HPAI is highly suggestive of infection and its use offers the potential of rapid detection at the farm level. However, due to the low sensitivity of these assays, molecular confirmation of negative results as well as positive results is required when used during outbreak situations.

GENERAL GUIDANCE

- 1. Collect duplicate tracheal/oropharyngeal and/or cloacal swab samples¹ from clinically ill or dead birds.
- 2. Perform ACIA test according to package insert on one set of samples.
- 3. Regardless of ACIA test results, ship the second set of samples immediately to the National Animal Health Laboratory Network Laboratory (NAHLN) laboratory for additional testing, as false negatives are possible with the use of this test. Results of ACIA testing should be included on the sample submission form.
- 4. If the ACIA test results are either positive or weak positive, the flock meets the criteria for a suspect case (according to the H5/H7 AI Case Definition, August 31 2015) and the poultry veterinarian should immediately contact the State Veterinarian or VS Assistant Director in the State where the birds are located. The following information should be provided:

Owner and premises name Premises address Type and number of birds

- 5. When the flock meets the criteria for a presumptive positive HPAI case (according to the H5/H7 AI Case Definition, August 31 2015), the APHIS Administrator or Veterinary Services Deputy Administrator (Chief Veterinary Officer of the United States) or their designee will authorize APHIS personnel—in collaboration with State, Tribal, and Incident Command personnel—to initiate depopulation, cleaning, and disinfection of the index case. Depopulation of poultry meeting the suspect case definition (e.g., a positive or weak positive ACIA result on clinically ill or dead birds) may also be warranted depending on the epidemiological information; this action will be authorized by APHIS and State Animal Health Officials/Tribal officials.
- 6. If the situation arises where the ACIA results are positive/weak positive and the PCR is negative, a second set of samples, including tissues, should be collected and submitted directly to the National Veterinary Services Laboratories for further testing.

¹ Refer to WI-AV-0020 http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/WIAV0020.pdf