

UNITED STATES ANIMAL HEALTH ASSOCIATION

2016 Resolution 120th Annual Meeting October 13-19, 2016 ~ Greensboro, NC

RESOLUTION NUMBER: 33 APPROVED

SOURCE: COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY

AND OTHER AVIAN SPECIES

SUBJECT MATTER: Approval of Real Time Reverse Transcriptase Polymerase

Chain Reaction Matrix Assay for Avian Influenza Surveillance in National Poultry Improvement Plan Authorized Laboratories

BACKGROUND INFORMATION:

National Poultry Improvement Plan (NPIP) authorized labs have successfully conducted avian influenza (AI) screening of flocks using agar gel immunodiffusion (AGID) and enzyme linked immunosorbent assay (ELISA) tests with approval of their Official State Agency (OSA), and state animal health officials for 18 years. The real time reverse transcriptase polymerase chain reaction (RRT-PCR) matrix assay for influenza A provides highly sensitive detection that is critical to ensure that birds are negative prior to translocation to other facilities. Authorized laboratories have successfully utilized molecular diagnostics for Salmonella and Mycoplasma and these assays have proven invaluable in NPIP program testing and compliance. An NPIP authorized primary breeder company laboratory not affiliated with the National Animal Health Laboratory Network (NAHLN) that uses a United States Department of Agriculture approved influenza A matrix assay RRT-PCR, achieves ISO 17025 quality certification, satisfactorily passes an National Veterinary Services Laboratory (NVSL) avian influenza matrix RRT-PCR proficiency test, and has an agreed memorandum of understanding (MOU) with their state animal health officials and official state agency (OSA) should be allowed to use the assay as a screening test within the NPIP's US Avian Influenza Clean program. Any non-negative detection at NPIP authorized laboratory would immediately be forwarded to the NVSL for confirmation and notification of state animal health officials and the OSA will occur as outlined in NPIP provisions and State animal health emergency protocols.

The following proposal was approved at the 2016 NPIP Biennial Conference:

§ 145.14 Testing

(d) For avian influenza.

- (2) Agent detection tests. Agent detection tests may be used to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Samples for agent detection testing should be collected from naturally occurring flock mortality or clinically ill birds.
- (i) The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.
- (A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary

Services Laboratories (NVSL) official protocol for RRT-PCR or a test kit licensed by the Department and approved by the OSA and the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test.

- (a) For non-National Animal Health Laboratory Network (NAHLN) Authorized Laboratories:
- (i) RRT-PCR testing can only be used by primary breeder company Authorized Laboratories,
- (ii) RRT-PCR testing can only be performed on their own breeding flocks and only used for routine surveillance,
- (iii) the Authorized Laboratory has a quality system that is accredited as ISO/IEC 17025 or equivalent to perform the avian influenza RRT-PCR assay,
- (iv) the Authorized Laboratory Memorandum of Understanding (MOU) included approval of use between the Authorized Laboratory, the Official State Agency (OSA), and the State Animal Health Official(s) of both the location of the Authorized Laboratory and the location where the breeder flocks reside,
- (v) split samples for testing must occur between the Authorized Laboratory and a NAHLN laboratory at a frequency designated in the MOU.
- (B) Positive results from the RRT-PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

§ 146.13 Testing

(b) Avian influenza.

- (2) Agent detection tests. Agent detection tests may be used to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Samples for this testing should be collected from naturally occurring flock mortality or clinically ill birds.
- (i) The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.
- (A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services (NVSL) official protocol for RRT-PCR or a test kit licensed by the Department and approved by the OSA and the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test.
- (a) For non-National Animal Health Laboratory Network (NAHLN) Authorized Laboratories:
- (i) RRT-PCR testing can only be used by primary breeder company Authorized Laboratories,
- (ii) RRT-PCR testing can only be performed on their own breeding flocks and only used for routine surveillance,
- (iii) the Authorized Laboratory has a quality system that is accredited as ISO/IEC 17025 or equivalent to perform the avian influenza RRT-PCR assay,
- (iv) the Authorized Laboratory Memorandum of Understanding (MOU) included approval of use between the Authorized Laboratory, the Official State Agency (OSA), and the State Animal Health Official(s) of both the location of the Authorized Laboratory and the location where the breeder flocks reside,
- (v) split samples for testing must occur between the Authorized Laboratory and a NAHLN laboratory at a frequency designated in the MOU.
- (B) Positive results from the RRT-PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services to approve the use of a USDA approved real time reverse transcriptase polymerase chain reaction matrix assay for influenza A in National Poultry Improvement Plan (NPIP) authorized primary breeder company laboratories as outlined in the NPIP proposed and passed change to the 9 Code of Federal Regulations 145.14 and 146.13 (Testing).