§ 146.13 Testing.

(a) Samples. Either egg or blood samples may be used for testing. Samples must be collected in accordance with the following requirements:

(1) Egg samples. Egg samples must be collected and prepared in accordance with the requirements in §147.8 of this subchapter.

(2) Blood samples. Blood samples obtained in the slaughter plant should be collected after the kill cut with birds remaining on the kill line. Hold an open 1.5 mL snap cap micro-centrifuge tube under the neck of the bird directly after the kill cut and collect drips of blood until the tube is half full. Keep the blood tubes at room temperature for the clot to form, which should require a minimum of 4 hours and a maximum of 12 hours. Refrigerate the tube after the clot has formed. Put tubes in a container and label it with plant name, date, shift (A.M. or Day, P.M. or Night), and flock number. After the clot is formed, the clot should be removed by the Authorized Agent in order to ensure good-quality sera. Prepare a laboratory submission form and ship samples with submission forms to the laboratory in a polystyrene foam cooler with frozen ice packs. Submission forms and the manner of submission must be approved by the Official State Agency and the authorized laboratory to ensure that there is sufficient information to identify the samples and that the samples are received in an acceptable condition for further tests to be reliably performed. Blood samples should be shipped routinely to the laboratory. Special arrangements should be developed for samples held over the weekend to ensure that the samples can be reliably tested. Blood samples for official tests shall be drawn by an Authorized Agent or State Inspector.

(b) Avian influenza. The official tests for avian influenza are described in paragraphs (b)(1) and (b)(2) of this section:

(1) Antibody detection tests—(i) Enzyme-linked immunosorbent assay (ELISA). ELISA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(ii) The agar gel immunodiffusion (AGID) test. (A) The AGID test must be conducted on all ELISA-positive samples.

(B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(C) Standard test procedures for the AGID test for avian influenza are set forth in §147.9 of this subchapter. The test can be conducted on egg yolk or blood samples.

(D) Positive tests for the AGID 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.

(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 Laboratories (NVSL) official protocol for RRT–PCR (AVPR01510) and must be conducted by personnel who have passed an NVSL proficiency test.

(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.

(ii) USDA-licensed type A influenza antigen capture immunoassay (ACIA). (A) The USDA-licensed type A influenza
ACIA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(B) Positive results from the ACIA 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.

(3) The official determination of a flock as positive for the H5 or H7 subtypes avian influenza may be made only by NVSL.

(Approved by the Office of Management and Budget under control number 0579–0007)


§ 146.23 Terminology and classification; flocks and products.

Participating flocks which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §146.9 of this part:

(a) U.S. H5/H7 Avian Influenza Monitored. This program is intended to be the basis from which the table-egg layer industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in table-egg layers and table-egg layer pullets through routine surveillance of each participating commercial table-egg layer and table-egg layer pullet flock.