

upon which a *Mycoplasma* classification is based.

(c) *For M. meleagridis.* The official blood tests for *M. meleagridis* are specified in § 145.43(d)(2).

(d) *For avian influenza.* The official blood tests for avian influenza are the agar gel immunodiffusion (AGID) test and the enzyme-linked immunosorbent assay (ELISA).

(1) The AGID test must be conducted on all ELISA-positive samples. Positive tests by AGID or ELISA must be further tested by Federal Reference Laboratories. Final judgment may be based upon further sampling or culture results.

(2) The tests must be conducted using antigens or test kits approved by the Department and the Official State Agency and must be performed in accordance with the recommendations of the producer or manufacturer.

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

[36 FR 23112, Dec. 3, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 145.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 145.15 Approved tests.

(a) The procedures for the bacteriological examination of poultry and poultry environments described in part 147 of this subchapter are approved tests for use in the NPIP. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in part 147 of this subchapter are approved for use in the NPIP.

(b) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(1) The sensitivity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in part 147 of this subchapter. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the

magnitude and significance of the effect(s) can be evaluated.

(2) The specificity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by the official NPIP procedures found in part 147 of this subchapter. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP technical committee, and the technical committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the technical committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47 of this subchapter.

[72 FR 1418, Jan. 12, 2007]