

Non-Confidential Description - PSU No. 2628
“Dot-ELISA for the Detection of Avian Influenza Virus”

Keywords:

Veterinary science, poultry, avian influenza virus, viral testing

Links:

[U.S. Patent 7,083,912](#)

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Background

Isolation of avian influenza virus (AIV) using embryonating chicken eggs (ECE) has been the gold standard to date although it is a labor intensive and time consuming procedure, which requires at least a minimum of two to three (2-3) days to determine a test result. During the past decade, new methodologies of monoclonal antibody (Mab)-based assays and molecular techniques have been studied and/or developed for the direct demonstration of antigens of AIV from clinical and field specimens. Although these advanced methods are not yet applicable for routine diagnostic or surveillance purpose, they have been each used in certain circumstances for virus identification along with virus isolation (VI) in embryonating chicken eggs (ECE).

Invention Description

A novel rapid diagnostic test of Dot-ELISA has been developed that specifically detected AIV. The Dot-ELISA is highly sensitive and specific for AIV and detects live virus as well as inactivated antigens of AIV directly from clinical and field specimens. Furthermore, the Dot-ELISA was specific for AIV as no cross-reactions were obtained with other avian viruses. The novel Dot-ELISA costs less than \$0.50 per test. Its sensitivity and specificity in the detection of AIV are comparable to a commercial *Directigen*® kit, which costs over \$18 per test. The novel Dot-ELISA is a very economical test that can be applied in mass testing during an avian influenza outbreak or routine surveillance. One individual can test over 100 samples in one run using this invention.

Invention Status

The subject invention detected virus antigens directly from clinical and field specimens. No significant difference was seen between the subject invention and the *Directigen*® test for their sensitivity and specificity. Sensitivity (Se) is a test that detects the proportion of animals that are truly infected or the proportion of specimens that are truly positive. Specificity (Sp) is a test that detects the proportion of animals that are truly not infected or the proportion of specimens that are truly negative. Data obtained from experimentally AIV infected SPF chickens and a recent outbreak of H7N2 positive flock indicated that the sensitivity (Se) of the Dot-ELISA ranged from 45% to 68% and the specificity (Sp) ranged from 85% to 90% in comparison with VI using embryonating chicken eggs (ECE). On routine AIV surveillance samples, this Dot-ELISA invention achieved 92-100% Sp based on testing

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over 1500 AIV surveillance samples which were all negative for VI. The Dot-ELISA invention detected AIV in allantoic fluids that contained a concentration as low as 0.4 hemagglutinating units. Furthermore, the Dot-ELISA was specific for AIV as no cross-reactions were obtained with other avian viruses.

Advantages/Applications

To be utilized for diagnostic services and surveillance program for the detection of avian influenza virus. This same-day test can be conducted on site to screen up to 100 clinical samples in one run within two hours.

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