

Avian Influenza Virus Antibody Test Kit, cELISA *Flu* DETECT® BE

Introduction

Avian Influenza Virus (AIV) is an infectious disease of domestic and wild birds that is characterized by a full range of symptoms, from mild respiratory signs to severe decreases in egg production and very high mortality. The rapid and often "hidden" spread of AIV makes early detection from avian and other species critical in its control.

Suggested Uses

Flu DETECT® BE is an in-vitro immunoassay designed to aid in the qualitative detection of antibody to AIV in serum of avian and other species. This blocking ELISA detects all 16 subtypes of Avian Influenza. Positive results should be submitted to a reference lab for confirmation and subtype determination. Negative results indicate that no detectable Influenza Type A antibody is present.

Kit Performance

The Flu DETECT® BE has a shelf-life of 18 months and it has been extensively tested with the following parameters:

A. Flu DETECT® BE Performance vs. AGID

1. Specificity

The data shown below demonstrate that the Flu DETECT® BE ELISA test kit has an excellent specificity for the detection of antibody to AIV in chicken and duck serum samples.

Table 1:

Reactivity pattern of NVSL* Specificity Panel

Fifteen sera raised against various pathogens of poultry were tested. All 15 sera were non-reactive to Flu DETECT® BE suggesting **100% Specificity.**

Sample	I.D.	O.D.	S/N Ratio	Flu DETECT® BE
CELO AS	BG 78-15	0.91	0.77	Negative
SB-1 AS	BG 88-8	0.94	0.80	Negative
MOCK CEF-C	BG 88-2	1.19	1.02	Negative
MOCK AAF	BG 88-2	1.00	0.85	Negative
LLB AS	BG 89-3	0.92	0.78	Negative
LT AS	BG 86-16	0.95	0.81	Negative
10 CK VAC DMB	BG 88-2	0.89	0.76	Negative
HVT AS	BG 81-19	0.87	0.74	Negative
MOCK CH EMB	88-2	1.48	1.26	Negative
REV AS	88-8	0.83	0.71	Negative
NEG serum	BG 88-8	0.84	0.72	Negative
LLA AS	BG 89-3	0.85	0.72	Negative
POX AS	87-7	0.83	0.71	Negative
NDV-C AS	88-9	0.83	0.71	Negative
NEG serum	88-8	0.73	0.62	Negative

* NVSL: National Veterinary Services Laboratory

Table 2:

The results shown below demonstrate the specificity of Flu DETECT® BE ELISA Test Kit as compared to the conventional AGID test in serum from ducks, chicken and quail.

Species	Number of Samples	Flu DETECT® BE	AGID
Chicken	460	0/460	0/460
Ducks	182	0/182	0/182
Quail	65	0/65	0/65

The Specificity of Flu DETECT® BE is 100% compared with AGID



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M-0109-0309

2. Sensitivity

The data shown below demonstrate that Flu DETECT[®] BE has an excellent sensitivity for the detection of antibody to AIV in serum samples from multiple species.

Table 3:
Flu DETECT[®] BE and AGID methods were compared for sensitivity and specificity using multiple species serum samples at the USDA Diagnostic Virology and OIE Reference Laboratory.

Species	# of Samples	Flu DETECT [®] BE		AGID	
		+	-	+	1
Turkey	38	35	3	36	2
Ducks	20	13	7	12	8
Flamingo	15	11	4	11	4
Ostrich	24	11	13	11	13
Pheasant	2	2	0	2	0
Quail	6	3	3	3	3
Wild birds	8	7	1	7	1
Equine	10	5	5	5	5
Swine	11	6	5	6	5
Loon-5 Crane-2 Lion-20 Pigeon-6	39	0	39	0	39
Normal Control Sera-6	6	0	6	0	6
H11N9 Chicken	1	Pos	Pos	Pos	Pos
H2N9 Chicken	1	Pos	Pos	Pos	Pos
H8N4 Chicken	1	Pos	Pos	Pos	Pos
H3N2 Swine	1	Pos	Pos	Pos	Pos

B. Flu DETECT[®] BE Performance versus HI and Conventional ELISA

Figure 1:
% positive comparison between Flu DETECT[®] BE and HI in temporal study.

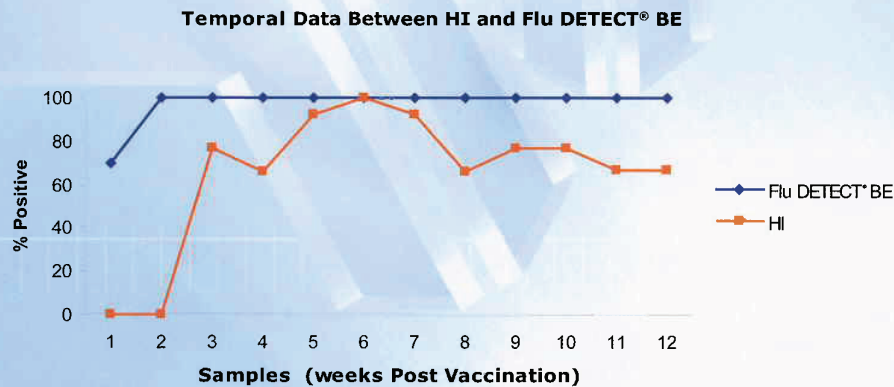
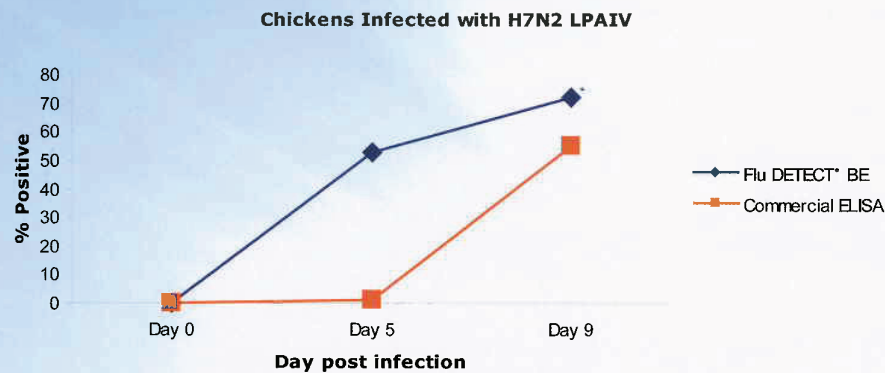


Figure 2:
Early detection:
AIV antibody can be detected as early five days post infection with H7N2 low path infection.



CONCLUSIONS

1. The sensitivity of Flu DETECT[®] BE is 99% compared to AGID (Table 3).
2. The data shown in Figure 1 suggest Flu DETECT[®] BE is MORE SENSITIVE and consistent compared to HI test.
3. Flu DETECT[®] BE detects antibody to AIV with HIGHER SENSITIVITY at 5 days post infection compared to a commercial indirect ELISA (Figure 2).