

FLU DETECT™ Antigen Capture Test Strip

from Synbiotics

The **Synbiotics FLU DETECT™ Antigen Capture Test Strip** is an in-vitro, rapid immunochromatographic assay designed to aid in the qualitative detection of Influenza type A virus in tracheal and cloacal swabs from symptomatic birds or flocks. The FLU DETECT™ Test Strip is designed to detect all 15 subtypes of Influenza type A virus. The kit contains swabs, test tubes, test strips and reagents necessary to test 20 samples. Simply insert a test strip into an extracted sample and read the results in 15 minutes!

Avian Influenza, also known as Fowl Plague, is a viral disease of domestic and wild birds that is characterized by a full range of responses from almost no signs of the disease to very high mortality. Influenza type A viruses can infect avian, porcine, equine and other species including humans. Fifteen serologically distinct hemagglutinin and nine neuraminidase subtypes of Influenza type A virus have been isolated from avian species. Subtypes H5 and H7 are associated with significant to catastrophic losses. Disease signs in poultry range from only a slight decrease in egg production to a highly fatal fulminating infection. Signs of infection may include respiratory problems, edema of the head and face or diarrhea.

Specificity

The results in Figure 1 below demonstrate that the Synbiotics FLU DETECT™ Test Strip shows excellent specificity to Influenza type A virus. The Synbiotics FLU DETECT™ kit, like all Synbiotics ELISA kits, is highly specific to provide valid, reproducible test results.

Figure 1: Subtype Reactivity

Influenza A Subtype Reactivity

A/New Caledonia/20/99 (H1N1)	Positive
A/Swine/TN/25/77 (H1N1)	Positive
A/Mallard/Alberta/11(9/98) (H1N1)	Positive
VR-897, A/New Jersey/8/76 (H1N1)	Positive
VR-97, A/FM/1/47 (H1N1)	Positive
VR-98, A/Malaya/302/54 (H1N1)	Positive
VR-95, A/PR/8/34 (H1N1)	Positive
A/New Caledonia/20/99 (H1N1)	Positive
A/Taiwan/1/86 (H1N1)	Positive
A/Beijing/262/95 (H1N1)	Positive
A/Mallard/NY/6750/78 (H2N2)	Positive
A/Mild/Potsdm/178-4/83 (H2N2)	Positive
VR-100, A2/Japan/305/57 (H2N2)	Positive
A/Mallard/Alberta/33/01 (H2N4)	Positive
A/Ruddy Turnstone/DE/142/99 (H3N2)	Positive
A/HongKong/1/68 (H3N2)	Positive
A/Duck/HK/3/75 (H3N2)	Positive
A/HK/1/68/Luman (H3N2)	Positive
VR-810, A/Port Chalmers/73 (H3N2)	Positive
VR-544, A/Hong Kong/8/68 (H3N2)	Positive
VR-547, A/Aichi,2/68 (H3N2)	Positive
VR-822, A/Victoria/3/75 (H3N2)	Positive
A/Panama/2007/99 (H3N2)	Positive
A/Kiev/301/94 (H3N2)	Positive
A/Shangdong/9/93 (H3N2)	Positive
A/Texas/1/77 (H3N2)	Positive
A/Mallard/Alberta/31/01 (H3N9)	Positive
CK/AI/75/A (H4N8)	Positive
Duck Meat/AVL/China-1/01 (H5N1)	Positive
AI/Chicken/86 (H5N2)	Positive
A/Teal/HongKong/w312/97 (H6N1)	Positive
A/Mallard/Alberta/20 (6/96) (H6N8)	Positive

A/CK/DE/04/297267(Hobo Farm) (H7N2)	Positive
A/Mild/Alberta/24/01 (H7N3)	Positive
A/Mallard/Alberta/19 (4/92) (H8N4)	Positive
A/Qa/AR/29209-1 (H9N2)	Positive
A/Ck/HK/WF2/99 (H9N2)	Positive
A/Ck/HK/SF3/99 (H9N2)	Positive
A/Ck/HK/G9/97 (H9N2)	Positive
A/Duck/HK/Y280/97 (H9N2)	Positive
RG A/Qa/HK/A28945/88(H9N2) 10/16/03A/RG (H9N2)	Positive
A/Shorebird/DE (9/96) (H9N6)	Positive
A/Pintail/Alberta/202/00 (H10N7)	Positive

Influenza B and non-Influenza Reactivity

VR-790, Russia/69	Negative
VR-295, B/Taiwan/2/62	Negative
VR-102, B/Allen/45	Negative
B/Tokio/53/99	Negative
VR-101, B/Lee/40	Negative
B/Victoria/504/00	Negative
B/Quingdao/102/91	Negative
VR-823, B/Hong Kong/5/72	Negative
CAP Flu B VR1-04 2004, B/Maryland/1/59	Negative
RSV VR-1341, Caprine, Lot 1W	Negative
RSV VR-1401, B, Wash/18537	Negative
RSV Strain A-2, Lot 263504	Negative
RSV VR-1400, B-1, Wild Type	Negative
RSV VR-26	Negative
Adenovirus 8, 9/23/94	Negative
Adenovirus 40, VR-931, Lot 6W	Negative
Adenovirus 11, TH408	Negative
Adenovirus 2, TJ2184	Negative

For more information about this and other Synbiotics products please contact us

Synbiotics Corporation
11011 Via Frontera
San Diego, CA USA
858.451.3771
www.synbiotics.com

Synbiotics Europe
2, rue Alexander Fleming - 69367 LYON
Cedex 07 – France
Tel: +33 4 72 76 11 11
www.synbiotics.fr

SYNBIOTICS
CORPORATION

Specificity

The data in Figure 2 below exhibits the specificity of the FLU DETECT™ Test Strip as compared to a competitor's rapid test. In this study various non-AIV antigen preparations were tested along with a positive control containing H4N8, CK/AI/75/A (10^{7.9}/0.1ml).

Figure 2: Specificity

	SBIO H4N8	Kit A H4N8	
A	Negative	Negative	A = NDV CEK Primary Cells, first passage (tissue pool of trachea, eyelid)
B	Negative	Negative	B = NDV 3rd passage in eggs (tissue pool of trachea, lungs)
C	Negative	Negative	C = ILT 1st passage in eggs (tissue pool of trachea, eyelid)
D	Negative	Negative	D = ILT 1st passage in eggs (tissue pool of trachea, eyelid)
E	Negative	Negative	E = NDV CEK Primary Cells, second passage (tissue pool of trachea)
F	Negative	Negative	F = ILT CEK Primary Cells, first passage (tissue pool of trachea, eyelid)
G	Negative	Negative	G = REO CEK Primary Cells, 3rd passage (spleen)
H	Negative	Negative	H = NDV 3rd passage in eggs (tissue pool of trachea, lungs)
I	Negative	Positive	I = Feces spiked with B
J	Negative	Positive	J = Feces spiked with G
K	Negative	Positive	K = Feces spiked with F
L	Positive	Positive	L = Feces spiked with positive control (H4N8, CK/AI/75/A)

Sensitivity

The data in Figure 3 demonstrate the sensitivity of the Synbiotics FLU DETECT™ Test Strip at detecting Type A AIV. In this study, quail were infected with H9N2 virus, tracheal swabs were collected, and results were compared to Virus Isolation as shown below.

Figure 3: Sensitivity comparison with Virus Isolation

Day	SBIO	Virus Isolation
0	0/10	0/10
1	7/10	not tested
3	9/10	10/10
5	10/10	10/10
7	4/10	10/10
9	0/10	6/10
11	0/10	0/10

Based upon these data, the correlation with the VI is 90 - 100% during the first 3 to 5 days post-infection.

These data indicate that the FLU DETECT™ Test Strip is efficacious for the surveillance of early Avian Influenza infection.

Figure 4 below provides data comparing the sensitivity of the Synbiotics FLU DETECT™ Test Strip to competitors' rapid tests.

Figure 4: Sensitivity comparison with Competitors

dilution	H4N8 CK/AI/75/A (10 ^{8.9} /ml)		H7N2 A/CK/DE/04/297267 (8x10 ⁹ EID ₅₀ /ml)			H5N2 AI/Chicken/86		H2N2 A/Mallard/NY/6750/78 (5x10 ⁷ EID ₅₀ /ml)		
	SBIO	Kit A	SBIO	Kit A	Kit B	SBIO	Kit B	SBIO	Kit A	Kit B
10 ⁻¹	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
10 ⁻²	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
10 ⁻³	Positive	Positive	Positive	Positive	Positive	Positive	Negative	Positive	Positive	Negative
10 ⁻⁴	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Positive	Negative	Negative
10 ⁻⁵	Positive	Negative	Positive	Negative	Negative	Positive	Negative	Negative	Negative	Negative
10 ⁻⁶	Positive	Negative	Positive	Negative	Negative	Negative	Negative	Negative	Negative	Negative
10 ⁻⁷	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	N/A
10 ⁻⁸	Negative	Negative	Negative	Negative	Negative	N/A	N/A	N/A	N/A	N/A
10 ⁻⁹	Negative	Negative	Negative	Negative	Negative					
10 ⁻¹⁰	Negative	Negative	N/A	N/A	N/A					
10 ⁻¹¹	Negative	Negative								
10 ⁻¹²	Negative	Negative								

Based upon these results and other testing, the minimum detectability of the FLU DETECT™ Test Strip is determined to be 10³ - 10⁴EID₅₀/ml