**Anigen Rapid AIV Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of avian influenza type A viruses antigen (H1~H16) in avian cloaca, trachea, kidney swab and feces.

## **Background**

Influenza viruses that infect birds are called "Avian Influenza virus (AIV)" with only influenza type A viruses infecting birds. Influenza type A viruses are divided into subtypes based on two proteins, hemagglutinin (HA) and neuraminidase (NA), on the surface of the virus. AIV can infect chickens, turkeys, pheasants, quail, ducks, geese, and guinea fowl, as well as a wide variety of other birds. AIV is spread primarily through direct contact from infected birds to healthy birds, and through indirect contact with contaminated equipment and materials. The virus is excreted through infected birds' feces and secretions from their noses, mouths, and eyes.

# **Specifications**

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - Monoclonal anti-AIV(Capture) AIV Type A Monoclonal anti-AIV(Detector)
  - · Monoclonal antibody against Type A specific nucleoprotein of Avian influenza virus
- Purpose: Detection of Avian influenza type A virus(H1~H16)
- Specimen: Avian cloaca, trachea, kidney or feces swab
- Reading time: 5~10 minutes
- Sensitivity: 100% by farm (n=19), 77.3% by feces (n=150)
- Specificity: 100% vs. HA, PCR (n=1,402)
- No cross reaction against NDV, IBV, ILTV, Pneumovirus, Reovirus, IBDV, MDV, Mycoplasma and REV
- Detection limit: 10<sup>3.1</sup> EID<sub>50</sub>/ml
- Shelf life: 24 months
- Storage temperature: 2~30°C
- Packing size: 30 multi-devices/Kit, 10 and 25 individual devices/Kit
- The Pigeons have very low possibility of AIV infection and the specimens from pigeon feces may show unsual result in the kit. To test the pigeon feces, Choose Anigen pigeon feces preparation kit that is commercially available.

#### **Special Features**

- Optimal screening method of AIV in the farm or laboratory
- Detection of all avian influenza type A viruses (H1N1 ~ H16N9)
- High Sensitivity compared with PCR, virus isolation method, HA and other immunoassays
- High specificity: No cross-reaction with other avian viruses.
- Detection of AIV in Chickens, Ducks, Turkeys, and Geese
- World's first commercialized rapid test kit for detection of avian influenza virus since December 2003
- Easy assay procedure: No technical expertise required, and Saving Labor & Time
- No additional equipment is required.
- It is recommended to test 10 birds in every AIV suspected flock for the excellent result.

#### **Test Procedures**



- 1. Collect a cloaca feces swab, traceal swab, kidney swab or scattered wet feces swab.
- 2. Dilute the swabbed sample with assay diluent and drop 4 drops.
- 3. Wait for 5~10 minutes and read the test result.





## **Performance Data**

#### 1. Evaluation of Influenza virus type A Reactivity

21 Evaluation of 2 machina that type A	redecivity
A/RP/8/34 (H1N1)	Positive
A/Singapore/1/57 (H2N2)	Positive
A/Duck/Ukrine/1/63 (H3N8)	Positive
A/Duck/Czechoslovakia/56 (H4N6)	Positive
A/Duck/Vietnam/TG24-01/05 (H5N1)	Positive
A/Duck/Hong Kong/820/80 (H5N3)	Positive*
A/Shearwater/Australia/1/72 (H6N5)	Positive
A/Duck/Hong Kong/301/78 (H7N1)	Positive
A/chicken/Germany/R28/03 (H7N7)	Positive*
A/Turkey/Ontario/6118/68 (H8N4)	Positive
A/Turkey/Wisconsin/1/66 (H9N2)	Positive
A/Chick/Germany/N/49 (H10N7)	Positive
A/Duck/England/56 (H11N6)	Positive
A/Duck/Alberta/60/76 (H12N5)	Positive
A/Gull/Maryland/707/77 (H13N6)	Positive
A/Mallard/Gurjev/263/82 (H14N5)	Positive
A/Shearwater/West Austalia/2576/79 (H15N9)	Positive
A/BHG/Sweden/5/99 (H16N3)	Positive**

Evaluated at National Verinary Research & Qurantine service (NVRQS), Korea 'Evaluated at Friedrich Loeffler Institute (FLI), Germany (OIE AIV Ref. Lab.) ''Evaluated at CSIRO, Australian Animal Health Laboratory (OIE AIV Ref. Lab.)

#### 2. Detection Limit Study

Specimen	AIV A/ch/Germ/R28/03 (H7N7)					
	14/3/R 5*10 <sup>3.8</sup> EID <sub>60</sub> /ml	14/1/R 5*10 <sup>3.1</sup> EID <sub>50</sub> /ml	14/2/K 5*10 <sup>2.8</sup> EID <sub>50</sub> /ml			
Anigen AIV Ag	Strong positive	Strong positive	Negative			

Evaluated at Friedrich Loeffler Institute (FLI), Germany (OIE AIV Ref. Lab)

#### 3. Early Detection Study

Challenge method: SFP Chicken (H9N2, 10°EIDso/0.1ml) by nasal inoculation

	Detection Rate(%) by Day Post Inoculation						
	1 DPI	2 DPI	3 DPI	4 DPI	5 DPI	7 DPI	10 DPI
Anigen	1/8	3/8	8/8	8/8	8/8	8/8	0/8
AIV Ag	(12.5)	(37.5)	(100)	(100)	(100)	(37.5)	(0.0)
Virus	4/8	5/8	8/8	8/8	8/8	8/8	4/8
Isolation	(50.0)	(62.5)	(100)	(100)	(100)	(100)	(50.0)
RT-RCR	3/8	4/8	8/8	8/8	8/8	7/8	2/8
	(37.5)	(50.0)	(100)	(100)	(100)	(87.5)	(25.0)

Anigen AIV Ag kit shows 100% correlation from 3~5 days post infection comparing Virus Isolation and RT-PCR Evaluated at Rearch Unit of Green Cross Vetennary Products Co. Ltd., Korea

### 4. Comparsion Study with other companies

Strain	EID50	Dil. virus	Anigen ICT*	"B" Flu Ag ICT	"I" AIV Ag ELISA
Consult Scotters	10 <sup>8,5</sup> /ml	10-1	+	+	+
A/ty/It/		10-2	+	+	+
2962/03/ H7N3 LPAI		10-3	+	+	+
		10-4	343	21	343
A/ty/It/		10-1	+	+	+
214845/02/	10 <sup>7,5</sup> /ml	10-2	+	+	+
H7N3 LPAI	201	10-3	+/-	+	+
A/ty/It/ 90302/05/ H5N2 LPAI		10-4	5¥5	- 4	(*)
		10-1	+	+	+
	10 <sup>7,5</sup> /ml	10-2	+	+	+
		10-3	+	+/-	+
		10-4	3.61	*	
A/Chicken/Vietnam #8 (γ-irradiated) – A(H5N1)			+	NT**	NT
A/Duck/Vietnam #7A ( \gamma-irradiated) - A(H5N1)			+	NT	NT
A/?/Vietnam #Pooled ( ? -irradiated) - A(H5N1)			+	NT	NT

(\*ICT: Immunochromatographic test, \*\*: NT(Not Tested))

Matrix	Animal	Anigen ICT Kit	"B" Flu Ag ICT	"I"AIV Ag ELISA	Inoculation	Strain
Faeces	Duck	+	NT**	+/-	+	H11N9
Faeces	Duck	+	NT	+	+	H9N8
Tracheal	Turkey	+	+	+	+	H7N3
Tracheal	Turkey	+	+	+	+	H5N2
Tracheal	Turkey	+	+	+	+	H5N2
Faeces	Avian	+	NT	+	+	H5N3
Faeces	Turkey	171	NT	877		187
Tracheal	Avian		-		3	
Lung	Pig	(4)	NT	1940	4	(545)
Tracheal	Turkey	196		580	-	1500

<sup>\*\*:</sup> NT (Not Tested)

# 5. Comparison of Rapid Diagnostic Test with AIV field sample

	Sensitivity (%)	Specificity (%)	Cohen's kappa 0.71	
Anigen AIV Ag	76	97		
A Company	70	90	0.58	
B Company	63	97	0.57	

'Evaluated by Australian Animal Health Laboratory (AAHL), Australian Quarantine and inspection Service (AQIS), Disease Investigation Centre Region IV, Yogyakarta, Indonesia



<sup>&</sup>quot;B" Flu Ag ICT: Not for animal use