ISO 9001 certified

# BIONOTE

## Product Catalog ver3.0

CIA 03-03

Anigen™

# Diagnostic Test Kits for Industrial Animals

### Rapid

**[Avian]**
AIV Ag
H5 AIV Ag
AIV/H5 AIV Ag
AIV Ab
NDV Ag
IBDV Ag
**[Bovine]**
B.brucella Ab
Bovine TB Ab
FMD NSP Ab
Rota Ag
**[Swine]**
PED Ag
TGE Ag
TGE/PED Ag

### ELISA

**[Avian]**
AIV Ab
H5 AIV Ab
NDV velo Ab
**[Bovine]**
B.brucella Ab
BTB Ab
FMD NSP Ab
**[Swine]**
CSFV Ab
PRRS Ab

### PCR

**[Avian]**
• General PCR Kit
AIV Detection Kit
NDV, IBDV Detection Kit
• Real-Time PCR Kit
AIV Detection Kit
Other poultry disease virus Detection Kit
**[Swine]**
• Real-Time PCR kit
PRRS, CSFV, PCV, Detection Kit
SIV Detection Kit

BIONOTE

BIONOTE

**Global expertise in In Vitro Diagnostics**

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# BIONOTE Product Catalog(Ver.3.0)

BIONOTE was established at the beginning of 2003, and is considered a expert of In –Vitro Diagnostics for veterinary in needs. We deliver inspirations, innovation and quality solutions for our customers and consumers to improve animal health care. BIONOTE has own automated facility to manufacture a wide range of high value products developed by high Qualified R&D center. BIONOTE manufactures diagnostic products to accordance with ISO9001:ISO13485 certification, and has expanded overseas sales network over 90 countries and is still continuing to grow.

## Company History

| | |
|---|---|
| **2009-2011** | **Expanding business** |
| 2011.01 | BIONOTE was mergered into with Allere. |
| 2009.03 | Moved to current facility at 2-9,Seogu-dong, Hwaseong-si, Gyeonggi-do, Korea 445-170 |
| 2009.02 | Company name was changed from Animal Genetics, Inc. to BioNote, Inc. |
| **2007-2008** | **Take – off stage** |
| 2007.12 | Won a prize at the 2007 self-audit evaluation(NVRQS) |
| 2007.07 | Certificated as a promising small & medium business of Gyeonggi province |
| **2005-2006** | **Installing Base profit** |
| 2006.06 | Certificated as the venture company |
| 2006.01 | Acquired new manufacturing facility area in Hwaseong-si(City) |
| 2005.08 | Moved to new manufacturing facility |
| **2003-2004** | **Improving Business Environment** |
| 2004.07 | Acquired technical innovation subject of small& medium business |
| 2003.12 | Acquired certificate of manufacture for animal health product [NVRQS] |
| 2003.11 | Acquired certificate of import for animal product [NVRQS] |
| 2003.03 | Establish "Animal Genetics, Inc." |

# Contents

# Avian
# AIV Ag

**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.

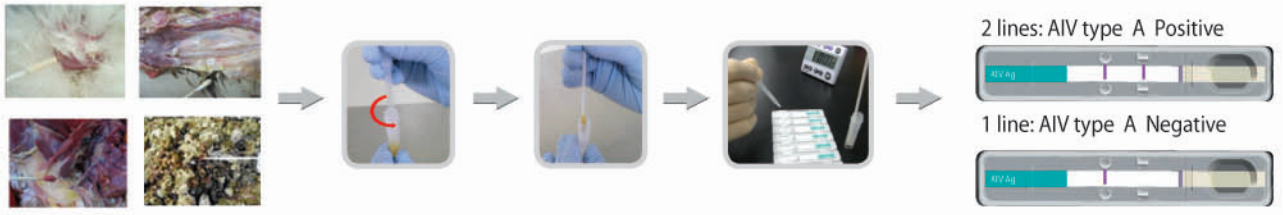
## Specifications

- 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: $10^{3.1}$ $EID_{50}$/ml
- Shelf life: 24 months
- Storage temperature: 2~30℃
- 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 preperation 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.

RAPID


CAT.No.: RG15-01

# Performance Data

## 1. Evaluation of Influenza virus type A Reactivity

| | |
|---|---|
| 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*103.8EID60/ml | 14/1/R 5*103.1EID50/ml | 14/2/K 5*102.8EID50/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 : SPF Chicken (H9N2, 106EID50/0.1ml) by nasal inoculation

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

Anigen AIV Ag Test 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 |
|---|---|---|---|---|---|
| A/ty/It/ 2962/03/ H7N3 LPAI | 108,5/ml | $10^{-1}$ | + | + | + |
| | | $10^{-2}$ | + | + | + |
| | | $10^{-3}$ | + | + | + |
| | | $10^{-4}$ | - | - | - |
| A/ty/It/ 214845/02/ H7N3 LPAI | 107,5/ml | $10^{-1}$ | + | + | + |
| | | $10^{-2}$ | + | + | + |
| | | $10^{-3}$ | +/- | + | + |
| A/ty/It/ 90302/05/ H5N2 LPAI | 107,5/ml | $10^{-4}$ | - | - | - |
| | | $10^{-1}$ | + | + | + |
| | | $10^{-2}$ | + | + | + |
| | | $10^{-3}$ | + | +/- | + |
| | | $10^{-4}$ | - | - | - |
| A/Chicken/Vietnam #8 (Y-irradiated) - A(H5N1) | | | + | NT** | NT |
| A/Duck/Vietnam #7A (Y-irradiated) - A(H5N1) | | | + | NT | NT |
| A/?/Vietnam #Pooled (Y-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 | - | NT | - | - | - |
| Tracheal | Avian | - | - | - | - | - |
| Lung | Pig | - | NT | - | - | - |
| Tracheal | Turkey | - | - | - | - | - |

**: NT (Not Tested)
"B" Flu Ag ICT: Not for animal use

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

| | Sensitivity (%) | Specificity (%) | Cohen's kappa |
|---|---|---|---|
| Anigen AIV Ag | 76 | 97 | 0.71 |
| 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

# Avian
# H5 AIV Ag

**Anigen Rapid H5 AIV Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of avian influenza type A subtype H5 virus antigen (High pathogenic avian influenza virus: HPAI) in avian cloaca swab, trachea swab, kidney swab and feces.


CAT.No.: RG15-05

## Background

Avian influenza A viruses can be classified into low and high pathogenic forms based on the severity of the illness they cause. Avian influenza A subtype H5 and subtype H7 viruses can be distinguished as "high pathogenic" form on the basis of genetic features of the virus and the severity of the illness. Avian influenza A subtype H5 potentially has nine different subtypes (H5N1 ~ H5N9) and these subtypes can be highly pathogenic (HPAI) or low pathogenic (LPAI). The Influenza type A subtype H5 infection has been reported among humans and sometimes causing severe illness and death.

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-AIV H5 (Capture) - AIV H5 - Monoclonal anti-AIV H5 (Detector)
  - •Monoclonal antibody against subtype H5 specific protein of avian influenza virus
- Purpose: Detection of Avian influenza type A subtype H5 virus (H5N1 ~ H5N9)
- Specimen: Avian cloca, trachea, kidney swab and feces
- Reading time: 5~10 minutes
- Sensitivity: 100% by farm (n=13), 76.6% by feces (n=115) vs. Virus isolation
- Specificity: 100% vs. Virus isolation, PCR (n=1,402)
- No cross reaction against NDV, IBV, ILTV, Pneumovirus, Reovirus, IBDV, MDV, and REV
- Detection limit: 104.9 EID50/ml or 0.125 HAU
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 25 Tests/Kit
- The Pigeons have very low possibility of AIV infection and the specimens from pigeon feces may show unsual result in the kit.

## Independent Comparison Study

| Virus | Anigen H5 ICT | "BN" Flu A ICT |
|---|---|---|
| A/Chicken/Vietnam #8 (γ-irradiated) – A(H5N1) | Positive | Positive |
| A/Duck/Vietnam #7A (γ-irradiated) – A(H5N1) | Positive | Positive |
| A/?/Vietnam #Pooled (γ-irradiated) – A(H5N1) | Positive | Positive |
| A/Human/New Caledonia6/2002 – A(H3N2) | Negative | Positive |
| A/Human/Ulan Ude/1/2001- A(H3N2) | Negative | Positive |

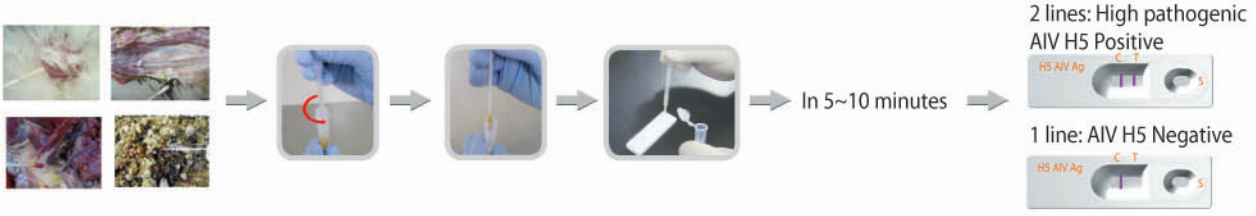
(*ICT: Immunocharomatographic test)

| Name of the farm infected with HPAI | Species | No. of random specimen | Anigen H5 ICT |
|---|---|---|---|
| | | | No. of Positive result |
| 1.LKB | Egg Layers | 3 | 2 |
| 2.KJT | Egg Layers | 3 | 2 |
| 3.SKU | Egg Layers | 3 | 1 |
| 4.SWS | Egg Layers | 3 | 2 |
| 5.CMK | Egg Layers | 5 | 5 |
| 6.STB | Egg Layers | 6 | 6 |
| 7.KBK | Egg Layers | 7 | 5 |
| Total | Positive rate by Farms 7/7(100%)<br>Positive rate by Specimens: 23/28(82.1%) | | |

## Special Features

- Optimal screening method of High pathogenic AIV subtype H5 in the farm or laboratory
- Detection of all avian influenza subtype H5 viruses (H5N1 ~ H5N9)
- High sensitivity compared with the virus isolation method
- High specificity: No cross-reaction with other avian viruses
- Detection of AIV H5 in Chickens, Ducks, Turkeys, and Geese
- World's first commercialized rapid test kit for detection of avian influenza virus subtype H5 since December 2003
- Easy test procedure: No technical expertise required, and Saving Labor & Time
- No additional equipment is required.
- Anigen AIV Ag test can be performed for initial screening, and Anigen H5 AIV Ag test for second line screening, HPAI subtype H5.

## Test Procedures




**1. Collect a cloaca feces swab, traceal swab, kidney swab or scattered wet feces swab.**
**2. Dilute the swab sample with assay diluent and drop 4 drops.**
**3. Interpret the test result.**

RAPID

Avian

# AIV / H5 AIV Ag

**Anigen Rapid AIV/H5 AIV Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of avian influenza type A viruses antigen and avian influenza subtype H5 virus antigen (High pathogenic avian influenza virus: HPAI) in avian cloaca swab, trachea swab, kidney swab or feces.

CAT.No.: RG15-06

## 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. Avian influenza A viruses can be classified into low pathogenic and high pathogenic forms based on the severity of the illness they cause. The subtype H5 and subtype H7 viruses of Avian influenza A viruses can be distinguished as "high pathogenic" forms on the basis of genetic features of the virus and the severity of the illness. The AIV subtype H5 is potentially nine different subtypes (H5N1 ~ H5N9) and these subtypes can be highly pathogenic(HPAI) or low pathogenic (LPAI). The AIV subtype H5 infections have been reported among humans, sometimes causing severe illness and death.

## Specification of AIV type A detection

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-AIV(Capture) - AIV Type A - Monoclonal anti-AIV
  - •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
- Sensitivity: 99.9% vs. HA, ELISA, 77.3% by feces vs. virus isolation
- Specificity: 99.9% vs. HA, PCR
- No cross reaction against NDV, IBV, ILTV, Pneumovirus, Reovirus, IBDV, MDV, REV
- Detection limit: 103.1 EID50/ml
- Reading time : 5~10 minutes

## Specification of AIV subtype H5 detection

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-AIV H5(Capture) - AIV H5 - Monoclonal anti-AIV H5
  - •Monoclonal antibody against subtype H5 specific protein of avian influenza virus
- Purpose: Detection of Avian influenza type A subtype H5 virus(H5N1~H5N9)
- Specimen: Avian cloaca, trachea, kidney or feces swab
- Sensitivity: 100% by farm (n=13), 76.6% by feces vs. Virus isolation
- Specificity: 100% vs. Virus isolation, PCR
- No cross reaction against NDV, IBV, ILTV, Pneumovirus, Reovirus, IBDV, MDV, REV
- Detection limit: 104.5 EID50/ml or 0.06 HAU
- Reading time : 5~10 minutes

## Special Features

- Optimal screening method of AIV Type A and High pathogenic subtype H5 in the field, laboratory
- High Sensitivity comparing with the virus isolation method
- High specificity: No cross-reaction with other avian viruses.
- Detection of AIV A and H5 in Chicken, Duck, Turkey, Goose
- World first commercialized rapid test kit for detection of avian influenza virus A and H5
- Easy test procedure: No technical expertise required and Labor & Time saving. No additional equipment is required.
- Fast Result : Result comes out within 5~10 minutes.
- Simultaneously AIV screening and HP AI subtype H5
- Shelf life : 24 months, -Storage temperature : 2~30℃
- Catalogue No.: RG 15-06

## Test Procedures


## Interpretation of the test result

1) Negative Result

2) AIV Type A Positive Result

3) AIV H5 Positive Result

4) Invalid Result

# Avian
# AIV Ab

**Anigen Rapid AIV Ab Test kit** is a solid phase chromatographic immunoassay for the qualitative detection of antibody against Avian Influenza A in serum or egg yolk.


CAT.No.: RB25-01

## Background

Wild birds and some poultry infected by HPAI show no clinical signs, and their virus excretion is too be detected by an antigen capture immunoassay. To detect these latent AIV carriers, BIONOTE has developed the Anigen AIV Ab Rapid Test Kit as another for detecting AIV antibodies in these bird populations.

## Specifications

- Principle: Competitive chromatographic immunoassay
- Purpose: Detection of AIV type A antibodies
- Species: Chicken, duck, turkey or wild birds
- Specimen: Serum or egg yolk.
- Reading time: 30 minutes
- Sensitivity: In case of HI 28, 96% (24/25)
- Specificity: In case of HI 20, 96.5% (55/57)
- No cross reaction against NDV, IBV, IBDV or MDV positive sera
- Shelf life: 24 monthes
- Storage temperature: 2~30℃
- Packing size: 10 Tests/kit

## Special Features

- Optimal screening method of High pathogenic AIV in carrier birds
- No special equipment or training required
- Suitable test method at the lab. or farm.
- Applicable to various species
- The world's first antibody for AIV Rapid test Kit
- High sensitivity and specificity compared with the HI test

## Sensitivity and Specificity

| HI titer | | Sensitivity | | Specificity | |
|---|---|---|---|---|---|
| | | ELISA Kit | Rapid Kit | ELISA Kit | Rapid Kit |
| Negative | $2^0$ | | | 95.1% (77/81) | 96.5% (55/57) |
| | $2^1$ | | | 100% (5/5) | 100% ( 2/2) |
| | $2^2$ | | | 38.5% ( 5/13) | 87.5% (7/8) |
| Positive | $2^3$ | 96.6% (28/29) | 60.7% (17/28) | | |
| | $2^4$ | 98.6% (68/69) | 88.0% ( 59/67) | | |
| | $2^5$ | 98% ( 96/98) | 91.3% (84/92) | | |
| | $2^6$ | 100% (65/65) | 95.2% (60/63) | | |
| | $2^7$ | 97.9% (46/47) | 100% (43/43) | | |
| | $2^8$ | 100% ( 28/28) | 96% (24/25) | | |

## Test Procedures

1) Take a sample of poultry serum with a disposable dropper.
2) Slowly add one drop of serum to the sample hole and wait for 10 minutes, and then add 3 drops of assay diluent.
3) Test results will appear as purple band(s) in the result window of the test device.
4) Interpret test results at 20 minutes after assay diluent dropping.


**As this is a competitve assay, 2 lines in the test result window are a negative result and 1 line is a positive result.**

* For egg yolk samples, 2ml of egg yolk should be mixed with 2ml of PBS (pH7.2) using a vortex agitator. And then the mixed egg yolk should be centrifuged at 3,000 rpm for 30 minutes. The supernatant is then used as the sample.

RAPID

# Avian
# NDV Ag

**Anigen Rapid NDV Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of Newcastle Disease virus antigen in avian cloaca or trachea swab.


CAT.No.: RG15-03

## Background

Newcastle Disease (ND) is characterized by sneezing, coughing, and nervous behavior. Affected birds may show tremors, circling, falling, twisting of the head and neck, or complete paralysis. Mortality reaches 90% in very young birds but adult mortality is very low. Among affected laying hens, egg quantity and quality drop sharply at first but usually return to former levels within four to eight weeks. ND can cause death even in vaccinated poultry and is characterised by it's sudden appearance and rapid spread to nearby flocks. Diagnosis is usually made by virus isolation, serology and clinical signs. The hemagglutination inhibition (HI) test is used widely in ND virus serology, with cross-reactions in HI tests between ND virus and some of the other paramyxoviruses being reported. The newly developed Anigen Rapid NDV Ag test kit is highly specific to NDV.

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  •Monoclonal anti-NDV (Capture) – NDV – Monoclonal anti-NDV (Detector)
- Purpose: All new NDV strains(Lasota, B1, VG/GA)
- Specimens: Avian cloaca or trachea swab
- Reading time: 5-10 minutes
- Sensitivity: 94.7% vs. RT-PCR
- Specificity: 96.4% vs. RT-PCR
- No cross reaction against AIV, IBV(infectious bronchitis), IBDV, Mycoplasma
- Detection limit: 0.125 HAU(Hemaglutination Unit)
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 10 Tests/Kit

## Sensitivity & Specificity Study

Table 1) Sensitivity study compared with a commercial NDV RT-PCR Kit

| | No. of Specimen | Anigen Rapid NDV Ag | RT-PCR |
|---|---|---|---|
| Positive result | 18 | + | + |
| | 1 | - | + |
| Sensitivity | 19 | 18/19(94.7%) | 19/19 |

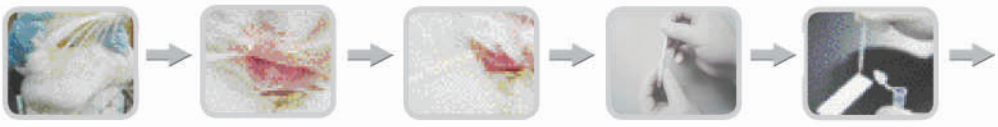
Table 2) Specificity study compared with a commercial NDV RT-PCR Kit

| | No. of Specimen | Anigen Rapid NDV | RT-PCR |
|---|---|---|---|
| Negative result | 81 | - | - |
| | 3 | + | - |
| Specificity | 84 | 81/84(96.4%) | 84/84 |

## Special Features

- NDV control is aided by fast and accurate diagnosis.
- Detection of all strains of NDV.
- World first commercialized rapid test kit for detection of NDV.
- Sample swabs are included for convenient test specimen sampling.
- Rapid test result: 10 minutes.
- Easy test procedure: No technical expertise required, Labor & Time saving.
- No additional equipment is required.

## Test Procedures




**1.Collect a cloaca or trachea swab**
**2. Dilute the swab sample with assay diluent and drop 4 drops**
**3. Wait for 10 minutes and read the test result**

**NDV Ag Positive**

**NDV Ag Negative**

# Avian
# IBDV Ag

**Anigen Rapid IBDV Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of Infectious Bursal Disease (Gumboro) virus antigen in avian Bursa of Fabricious or feces.


CAT.No.: RG15-04

## Background

Infectious Bursal Disease (IBD), or Gumboro Disease, is a viral disease usually affecting young chickens 3 to 6 weeks old, and is spread through contaminated feed and water. The target organ of the virus is the Bursa of Fabricious, an important organ in the young chickens developing immune system. IBDV serotype 1 causes clinical disease in chickens younger than 10 weeks, with older chickens usually showing no clinical signs. IBDV serotype 2 is very widespread in turkeys and is sometimes found in chickens and ducks. In practice, a diagnosis can be indicated by the sudden onset of mortality in chickens between 2 and 8 weeks of age, and the presence of distinctive lesions in the Bursa of Fabricious and accompanying blood spots in the musculature of the breast and thigh of affected chickens

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  •Monoclonal anti-IBDV (Capture) – IBDV – Monoclonal anti-IBDV (Detector)
- Purpose: Detection of Infectious Bursal Disease virus antigen
- Specimen: Avian Bursa of Fabricious or cloaca swab
- Reading time: 5-10 minutes
- Sensitivity: 99.9% vs. RT-PCR
- Specificity: 96.6% vs. RT-PCR
- No cross reaction with AIV, IBV (Iinfectious bronchitis), NDV, Mycoplasma
- Detection limit: 104.0 EID50/ml
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 10 Tests/Kit

## Special Features

- IBDV control is aided by fast and accurate diagnosis
- Good correlation with RT-PCR results
- Detection of all IBDV
- World first commercialized rapid test kit for detection of IBDV
- Convenient sampling of test specimens with a swab
- Rapid test result: 10 minutes.
- Easy test procedure: No technical expertise required, Saving time and labor
- No additional equipment is required

## Sensitivity and Specificity Study

(1) Sensitivity study in 20 feces originated from IBDV positive chickens

| Result | Anigen Rapid IBDV | RT-PCR |
|---|---|---|
| Positive | 17 | 20 |
| Negative | 3 | 0 |
| Sensitivity | 17/20(85%) | 20/20 |

(2) Sensitivity study in 12 Bursa of Fabricious originated from IBDV positive chickens

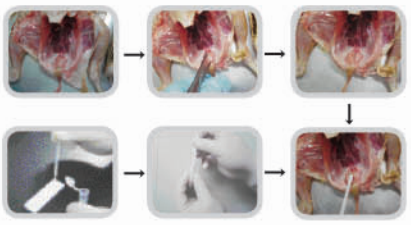
| Result | Anigen Rapid IBDV | RT-PCR |
|---|---|---|
| Positive | 12 | 12 |
| Negative | 0 | 0 |
| Sensitivity | 12/12(100%) | 12/12 |

(3) Specificity study in negative feces from healthy chickens

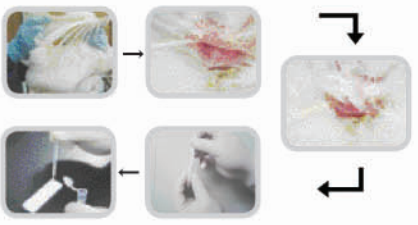
| Result | Anigen Rapid IBDV | RT-PCR |
|---|---|---|
| Positive | 15 | 150 |
| Negative | 145 | 150 |
| Specificity | 145/150(96.6%) | 150/150 |

## Test Procedures

1) Swab method of Bursa of Fabricious



2) Cloacal Swab Method



**3) Result Interpretation**

IBDV Ag Positive

IBDV Ag Negative

RAPID

Bovine

# B.brucella Ab

**Anigen Rapid B. Brucella Ab Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of *Brucella abortus* antibody in whole blood, plasma, serum or milk.


CAT.No.: RB23-01

## Background

Bovine brucellosis is commonly caused by Brucella abortus and less frequently by B. melitensis, and rarely by B. suis. Infection is widespread globally. Humans may be infected by contact with animals or animal products contaminated with these bacteria. Available serological tests include the Rose Bengal, ELISA, complement fixation test and tube agglutination test. However, these tests do not provide rapid diagnosis and each requires specialised laboratories and equipment. The new Anigen immunochromatographic rapid assay was developed to provide accurate, rapid and easy testing of B. brucellosis.

## Specifications

- Principle: Immunochromatographic assay
  - •(LPS capture)-(Antibody in blood, milk)-(Protein G detector)
  - •LPS (Lipopolysaccharide) antigen originated from B. abortus
- Purpose: Detection of Brucella abortus, melintensis or suis antibodies
- Specimen: Bovine whole blood, serum, plasma and raw milk
- Reading time: 20 minutes
- Sensitivity: 97.9% vs. a commercial ELISA, 96.2% vs. Milk Ring Test.
- Specificity: 96.8% vs. a commercial ELISA, 89.7% vs. Milk Ring Test
- No cross reaction against Brucella canis, Yersinia Enterocolitica
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 30 multi-devices/Kit, 10 tests/Kit

## Special Features

- Optimal screening method for Bovine brucellosis in the farm or laboratory
- Detection of antibodies against Brucella abortus, melintensis, suis
- High sensitivity versus a current confirmatory ELISA kit in blood, milk specimens
- Detection of B. brucellosis in goats, cows an oxen
- World's first commercialized rapid test kit for detection of B. brucellosis
- Easy test procedure: No technical expertise required
- Labor & Time saving with results in 20 minutes
- All components are included in the test kit. No additional equipment is required.
- Fast diagnosis helps to minimise losses to farmers and their cattles

## Independent Comparison Study

1) Sensitivity and Specificity in serum

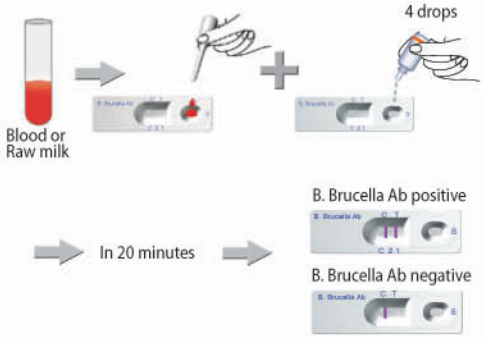
| No. of Specimen | | VLA B. Brucella ELISA, UK | |
|---|---|---|---|
| | | Positive result | Negative result |
| Anigen Rapid B. Brucella Ab Test | Positive result | 30 | 4 |
| | Negative result | 2 | 224 |
| | Total | 32 | 228 |
| Sensitivity | | 30/32=93.8% | |
| Specificity | | 224/228=98.2% | |

2) Sensitivity and Specificity in raw milk

| Raw milk | | "S" ELISA for B.Brucella Ab | |
|---|---|---|---|
| | | Positive result | Negative result |
| Anigen Rapid B. Brucella Ab Test | Positive result | 30 | 0 |
| | Negative result | 1 | 35 |
| | Total | 31 | 35 |
| Sensitivity | | 30/31=96.7% | |
| Specificity | | 35/35=100% | |

| Raw milk | | Milk Ring Test | |
|---|---|---|---|
| | | Positive result | Negative result |
| Anigen Rapid B. Brucella Ab Test | Positive result | 26 | 4 |
| | Negative result | 1 | 35 |
| | Total | 27 | 39 |
| Sensitivity | | 26/27=96.2% | |
| Specificity | | 35/39=89.7% | |

## Test Procedures




| | Rose Bengal & Milk Ring Test | Anigen Rapid Test | Anigen's benefit |
|---|---|---|---|
| Specimen | **-Rose Bengal:** Serum<br>**-Milk Ring Test:** Milk | **Whole blood, Serum, Plasma, Raw milk available** | All specimens are available |
| Testing Method | **- Rose Bengal**<br>1)Preparation of serum<br>2)1 drop of reagent of Rose Bengal + 1drop of serum : Mixing<br>3)Interpret the result within 4 min.<br>**- Milk Ring Test (MRT)**<br>1)Adding of 1ml of milk into a tube<br>2)Adding of 30ul of MRT reagent<br>3)Waiting for 1 hour at 37˚C<br>4)Reading the result | **1) Adding 1 drop of specimen**<br>**2) Adding one drop of assay diluent**<br>**3) Reading the test result at 20 min.** | Easy test procedure |
| Reading Method | -Rose Bengal : Agglutination<br>-MRT : Changing of blue color of Milk | **Positive : 2 lines**<br>**Negative : 1 line** | Simple |
| Testing time | one day | **20 Min.** | Rapid Testing |

Bovine

# Bovine TB Ab

**Anigen Rapid Bovine TB Ab Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of *Mycobacterium bovis* antibody in serum or plasma


CAT.No.: RB23-02

## Background

Bovine tuberculosis is a chronic infectious disease caused by Mycobacterium bovis. Bovine tuberculosis infection in cattle is usually diagnosed in the live animal on the basis of delayed hypersensitivity reactions. Infection is often sub clinical. When present, clinical signs are not specifically distinctive of this disease. Generally the purified protein derivative (PPD) test has been known 65.6% sensitivity (Wood et al., Vet. Microbiol, 40:125-135. 1994) as non M. bovis, including M. avium and other acid-fast bacteria infect the cattle in nature. A more sensitive and accurate diagnostic tool has been required. Recently, the MPB 70 protein was revealed to be a highly species specific protein secreted by Mycobaterium bovis, Resulting in the development of the Anigen Rapid Bovine TB Ab test kit. The new diagnostic blood test using the MPB 70 protein is now available.

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •(Rec. MPB70 Ag capture)-(Antibody in blood)-(Rec. MPB70 Ag detector)
  - •Capture and detector material: Recombinant MPB70 antigen
- Purpose: Detection of antibodies (IgM, IgG) against Mycobacterium bovis
- Specimen: Bovine serum, plasma
- Reading time: 20 minutes
- Sensitivity: •90% vs. BTB positive confirmed by bacterial isolation
  - •85.1% vs. PPD test
- Specificity: 98.6% vs. PPD test
- No cross reaction against Mycobacterium avium, Mycobacterium tuberculosis
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 30 multi-devices/Kit, 10 individual devices/Kit

## Special Features

- Optimal screening method of BTB in the farm or laboratory
- Higher sensitivity than the conventional PPD Test
- High specificity as it reacts only with the antibody against M. bovis
- No additional equipment is required
- Easy to use, saving time and labor

## Clinical Evaluation Study

| | Serum from naturally M. bovis infected cow (n=49) | Serum from artificially M. bovis inoculated cow n=20) | Serum from M. bovis infected cow (n=69) |
|---|---|---|---|
| Positive rate of Anigen B.TB Ab | 41/49 (83.7%) | 18/20 (90%) | 59/69 (85.5%) |

## What is the MPB70?

(1) MPB70 was identified as a major antigen from culture filtrate protein of M. bovis.
(2) MPB 70 is present predominantly in M.bovis and to a very limited degree in M. tuberculosis and other mycobacterial species (M.avium etc.).
(3) For that reason, Anigen BTB Ab test kit doesn't have cross-reaction with other species.

**[Comparison Table of Anigen BTB Ab Rapid Test vs. PPD Test ]**

| Virus | PPD Test | Anigen B. TB Ab Rapid Test | Anigen's Advantage |
|---|---|---|---|
| Principle | Delayed hypersensitivity with a purified protein derivatives | Chromatographic Immunoassay: Humoral immunity | |
| Specimen | Intradermal direct injection | Serum, plasma | |
| Method | 1) Intradermal injection of bovine tuberculin PPD<br>2)The subsequent detection of swelling at the site of injection 3 days later | 1) Adding 3 drop of specimen<br>2) Reading result at 20 min. | Easy Test procedure |
| Reading Method | By Observation of increases in skin-fold thickness<br>- No more than 2 mm : Negative<br>- 2 ~ 4mm : Inconclusive =>Another test after an interval of 42 days<br>- More than 4mm : Positive | By Observation of line appearance<br>2 line => Positive<br>1 line => Negative | Simple |
| Testing time | Minimum 3 days | 20 Min | Rapid Testing |
| Sensitivity | 65% vs. Culture of M. bovis => High false positive rate due to the cross reaction with M. avium and others | 90% vs. Culture of M. bovis | High Accurate |
| Early infection stage | False negative responses may occur | Less false negative responses may occur : By detection of IgM | Early detection |
| Late infection stage | False negative responses may occur | Less false negative responses may occur : By detection of IgG | |

## Test Procedures


Serum/Plasma

Features of Test Result

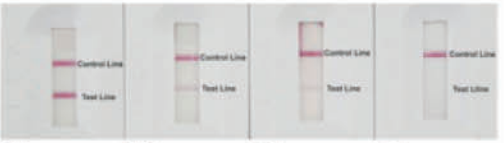



Fig. 1 Strong positive | Fig. 2 Weak positive | Fig. 3 Negative | Fig. 4 Negative

RAPID

Bovine

# FMD NSP Ab

**Anigen Rapid FMD NSP Ab Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of Foot and Mouth Disease virus antibody in whole blood serum or plasma


CAT.No.: RB23-03

## Background

Foot-and-Mouth (FMD) disease is a severe, highly contagious viral disease of cattle and swine.It also affects sheep, goats, deer, and other cloven-hooved ruminants. Signs of illness can appear after an incubation period of 1 to 8 days, but often develop within 3 days. There are FMD serotypes: O, A, C, SAT-1, SAT-2, SAT-3, and Asia-1. These subtypes show some regionality, and the O serotype is most common. The disease is characterized by fever and blister-like lesions followed by erosions on the tongue and lips in the mouth, on the teats, and between the hooves. It causes severe losses in the production of meat and milk.

## Explanation of the test

The Anigen Rapid FMD NSP Ab Test Kit is an immunochromatographic assay for the qualitative detection of FMDV antibody in whole blood, plasma and serum from bovine, ovine and porcine animals. It can be used for identification of FMD field infection in cattle, pig, goat and sheep. The specially selected recombinant nonstructural protein (NSP) antigens are used as capture material in the test

## Specifications

- Principle: Immunochromatographic assay
- Coated Antigen: Recombinant NSP antigen
- Specimens: Blood, Plasma, Serum
- Species: Cattle, Sheep, Goat, Pig
- Total Testing Time: 20~30 minutes
- Shelf life: 24 months
- Packing size: 10Tests/Kit
- Storage: 2~30℃

## Advantages

- Mass screening in the farm or laboratory
- Confirmation of FMDV infection in non-vaccination herds
- Differential test of FMD infected of vaccinated ones
- Excellent surveillance tool of FMDV
- Saving Labor & Time
- No additional equipment or technical expertise required

## Sensitivity and Specificity study

**1. Bovine**

1) Specimen collected in outbreak region(Sensitivity)

| | | AniGen ELISA | Commercial ELISA |
|---|---|---|---|
| Anigen | + | 217 | 270 |
| Rapid | - | 8 | 13 |
| | | 225 | 283 |

2) Specimen collected in FMD free region(Specificity)

| | | |
|---|---|---|
| Anigen | + | 507 |
| Rapid | - | 5 |
| | | 512 |

3) Result

| | Anigen Rapid FMD NSP | |
|---|---|---|
| | Sensitivity | Specificity |
| AniGen ELISA | 94.4% (217/225) | 99.0% |
| CommercialELISA | 95.4% (270/283) | |

**2. Swine**

1) Specimen collected in outbreak region(Sensitivity)

| | | AniGen ELISA | Commercial ELISA |
|---|---|---|---|
| Anigen | + | 20 | 20 |
| Rapid | - | 1 | 2 |
| | | 21 | 22 |

2) Specimen collected in FMD free region(Specificity)

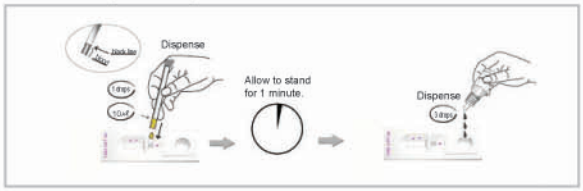
| | | |
|---|---|---|
| Anigen | + | 566 |
| Rapid | - | 9 |
| | | 575 |

3) Result

| | Anigen Rapid FMD NSP | |
|---|---|---|
| | Sensitivity | Specificity |
| AniGen ELISA | 95.2% (20/21) | 98.4% |
| Commercial ELISA | 90.9% (20/22) | |

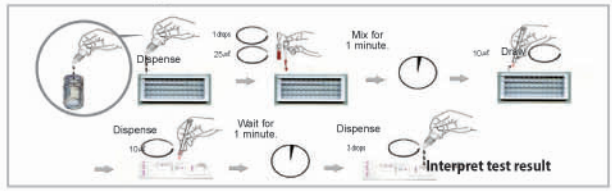
## Test Procedures

(1) Serum & plasma specimen




•Add 5 ul of serum or plasma to the sample hole with a capillary tube
•Wait 1 minute
•Add 3 drops of the buffer
•Read the test result at 20~30 minutes

(2) Whole blood specimen




•Dispense 3 drops of the whole blood diluent into the dilution well
•Add 1 drop(25ul) of a whole blood sample with a disposable dropper
•Mix them 1 minute
•Extract the mixture, and add 5ul of the mixed sample to the sample hole with a capillary tube
•Wait 1 minute
•Dispense 3 drops of the buffer into the buffer well
•Read the test result at 20~30 minutes

# Bovine
# Rota Ag

**Anigen Rapid Rota Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of Rotavirus group A antigen in porcine, bovine, or canine feces


CAT.No.: RG18-03

## Background

Rotavirus is the most common viral causative agent of diarrhea in pigs, cattle and dogs. Group A and B rotavirus are involved with group A being most prevalent and clinically important, containing several serotypes of differing virulence. All ages are susceptible. Dogs show somewhat opportunistic clinical signs. If neonatal pigs and cattle do not receive protective levels of maternal antibody, they are likely to develop profuse watery diarrhea in 12-48 hr. More commonly, the infection is endemic in a herd. Differential diagnosis of Rotavirus, TGEV and PEDV is important.Usually confirmatory diagnosis is based on histologic demonstration of villous atrophy in the jejunum or electron microscopy demonstration of virions in the intestinal contents. These methods are slow and require high priced specialized equipment and expertise. The Anigen Rapid Rota Ag test kit has been developed to provide fast, reliable, simple and sensitive detection of viral antigen in the intestinal mucosa or feces.

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-Rotavirus (Capture ) – Rotavirus – Monoclonal anti-Rotavirus (Detector)
  - •Monoclonal antibody against VP6 of Rotavirus
- Purpose: Detection of Rotavirus Group A antigen in pig, cattle and canine animal
- Specimen: Diarrheal feces
- Reading time: 10 minutes
- Sensitivity: 100% vs. RT-PCR
- Specificity: 98.5% vs. RT-PCR
- No cross reaction against PEDV, TGEV, PRC virus, BCV, E.coli, K88ab, K88ac, 987P, F41, Salmonella spp. Brachyspira hyodysenteriae, Clostridium perfringens, Coccidium, CPV, CCV
- Shelf life: 24 months
- Storage Temperature: 2~30℃
- Packing size: 10 individual devices/Kit

## Independent Comparison Study

Clinical evaluation study of Anigen Rapid Rota Ag Test Kit

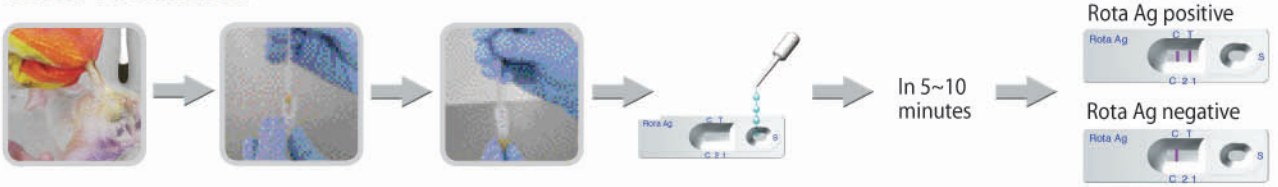
| | Suckling pig | Calf |
|---|---|---|
| No of specimen | 12 | 18 |
| No. of positive result of Antigen Rapid Rota Ag Test | 5 | 6 |
| No. of positive result of RT-PCR | 5 | 6 |
| Positive rate of Antigen Rapid Rota Ag Test | 44% | 33% |
| Positive result rate of RT-PCR | 44% | 33% |
| Agreement rate between Anigen Rota Ag Test and RT-PCR assay | 100% | 100% |

## Special Features

- Optimal detection method of Rotavirus group A antigen in the farm or laboratory.
- High sensitivity Vs RT-PCR
- Quick test result allows immediate preventive action to be taken.
- World's first commercialized rapid test kit for detection of Rotavirus antigen.
- Easy test procedure: No technical expert is required, saving labor & time
- All components are included in the test kit: Non-expert can perform testing.
- Fast diagnosis helps to decreases herd losses.

**[Proper sample amount collected by a swab]**


## Test Procedures




RAPID

Swine

# PED Ag

**Anigen Rapid PED Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of Porcine Epidemic Diarrhea virus antigen in porcine feces.


CAT.No.: RG14-01

## Background

Porcine epidemic diarrhea virus (PEDV) is a member of the coronavirus group which causes watery diarrhea, dehydration and high mortality in suckling pigs. Porcine Transmissible Gastroenteritis (TGE) virus is serologically unrelated with PEDV, but clinically these two virus infections are difficult to differentiate. The PEDV is transmitted by feces from infected pigs after oral uptake. Current available laboratory diagnosis in neonates is by direct immunofluorescence on cryostat sections of the small intestine or colon. ELISA and RT-PCR assays to detect viral antigens in feces or intestinal contents are useful, but require specialized instruments and laboratory personnel. The Anigen Rapid PED Ag Test Kit was developed for a non-expert to rapidly diagnose PEDV in farms or the laboratory.

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-PEDV (Capture) – PEDV – Monoclonal anti-PEDV (Detector)
  - •Monoclonal antibody against Porcine Epidemic Diarrhea virus
- Purpose: Detection of Porcine Epidemic Diarrhea virus antigen in pig
- Specimen: Diarrhea feces
- Reading time: 10 minutes
- Sensitivity: 92% vs. RT-PCR.
- Specificity: 98% vs. RT-PCR
- No cross reaction against TGE virus, Rota virus, PRC virus, BCV, E.coli, K88ab, K88ac, 987P, F41, Salmonella spp. Brachyspira hyodysenteriae, Clostridium perfringens, Coccidium
- Shelf life: 24 months
- Detection limit: 1.0 x $10^3$ $TCID_{50}$/ml or 0.5 HAU
- Storage Temperature: 2~30℃
- Packing size: 10 individual devices/Kit

## Independent Clinical Evaluation Study

1. The Anigen Rapid PED Ag have tested with PED positive and negative clinical samples confirmed by RT-PCR at Korean National Veterinary Quarantine Service.

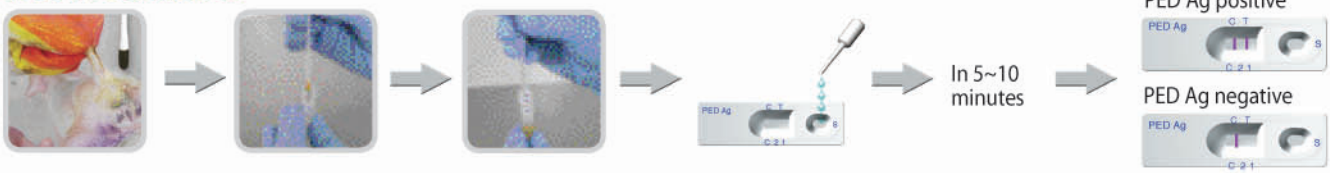
| | | RT-PCR | | |
|---|---|---|---|---|
| | | Positive | Negative | |
| Anigen Rapid PED Ag | Positive | 164 | 4 | Sensitivity: 92% |
| | Negative | 15 | 184 | Specificity: 98% |

**[Proper sample amount collected by a swab]**


## Special Features

- It is the easiest way to confirm the cause of pig diarrhea
- Quick test results allow immediate preventive action to be taken
- High sensitivity gives confidence in results
- High specificity with no cross-reactivity
- No specialised equipment or personnel required
- One Step Testing - easy to use, Saving labor & time
- World's first & sole PED virus antigen Rapid Test Kit

## Test Procedures



Swine

# TGE Ag

**Anigen Rapid TGE Ag Test Kit** is a solid phase chromatographic immunoassay for the qualitative detection of Porcine Transmissible Gastroenteritis (TGE) Virus antigen in porcine diarrhea feces


CAT.No.: RG14-02

## Background

Transmissible gastroenteritis (TGE) is a viral disease of the small intestine that causes vomiting and diarrhea in pigs of all ages. The infection spreads rapidly by aerosol or contact exposure. Severe epidemics are more common during winter due to survival of the virus in colder temperatures. Depending on the level of immunity and exposure, diarrhea may be mild in some litters but severe in others. Because TGE virus is easily spread during an epidemic by persons, animals, and other means, fast diagnosis and special care should be taken to prevent spread to unexposed groups of pigs and to neighboring herds. Current clinical signs in the epidemic form of TGE usually justify a presumptive diagnosis. In the mild endemic form, laboratory confirmation is required. The Anigen Rapid TGE Ag Test Kit provides fast and accurate confirmation of the presence of TGE viral antigens.

## Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-TGEV (Capture) – TGEV – Monoclonal anti-TGEV(Detector)
  - •Monoclonal antibody against S protein of Transmissible gastroenteritis virus
- Purpose: Detection of Transmissible gastroenteritis virus antigen in pig
- Specimen: Diarrhea feces
- Reading time: 10 minutes
- Sensitivity: 92.1% vs. RT-PCR &IFA
- Specificity: 95.2% vs. RT-PCR &IFA
- No cross reaction against PEDV, Rota virus, PRC virus, BCV, E.coli, K88ab, K88ac, 987P, F41, Salmonella spp. Brachyspira hyodysenteriae, Clostridium perfringens, Coccidium
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 10 individual devices/Kit

## Special Features

- Optimal detection method of TGEV antigen in the farm or laboratory
- High sensitivity Vs current confirmatory RT-PCR
- Quick test result: Immediate preventive action is possible
- World's first commercialized rapid test kit for detection of TGEV antigen
- Easy test procedure: No technical expert is required, labor & time saving.
- All components are included in the test kit
- Fast diagnosis helps to decrease herd losses.

## Independent Comparison Study

1. Sensitivity Study: The Anigen Rapid TGE Ag Test Kit was tested with diarrhea feces to compare RT-PCR, IFA test result at Korean National Veterinary Quarantine Service

| Pig Farm | No. of feces | Final diagnosis | No. of positive result | |
|---|---|---|---|---|
| | | | Anigen TGE Ag Kit | RT-PCR and IFA |
| A | 12 | TGEV | 11 | 12 |
| B | 5 | E.coli | 0 | 0 |
| C | 12 | TGEV | 10 | 12 |
| D | 6 | E.coli | 0 | 0 |
| E | 14 | TGEV | 14 | 14 |
| F | 13 | TGEV | 11 | 13 |
| G | 15 | TGEV + E.coli | 14 | 15 |
| H | 9 | TGEV | 9 | 9 |
| I | 3 | TGEV + E.coli | 3 | 3 |
| J | 11 | TGEV + E.coli | 10 | 11 |
| Total | 100 | | 82 | 89 |

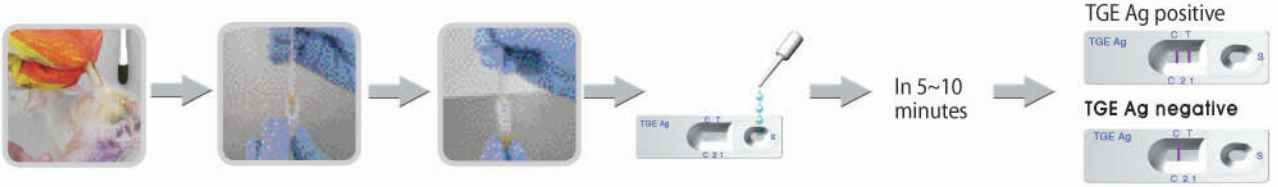
- Sensitivity: 82/89=92.1% vs. RT-PCR and IFA

2. Specificity Study: The Anigen Rapid TGE Ag Test Kit was tested with diarrhea feces to compare RT-PCR, IFA test result at Korean National Veterinary Quarantine Service

| Age of pig | No. of specimens | No. of negative results | |
|---|---|---|---|
| | | Anigen TGE Ag | RT-PCR and IFA |
| Suckling pig | 173 | 165 | 173 |
| Growing pig | 37 | 35 | 37 |
| Total | 210 | 200 | 210 |

- Specificity: 200/210=95.2% vs. RT-PCR and IFA

## Test Procedures




RAPID

Swine

# TGE/PED Ag

**Anigen Rapid TGE/PED Ag Test Kit** is a solid phase chromatographic immunoassay for the simultaneously qualitative detection of Transmissible Gastroenteritis (TGE) virus antigen and Porcine Epidemic Diarrhea (PED) Virus antigen in porcine diarrhea feces.

CAT.No.: RG14-03

## Background

TGE and PED have a similar pathogenesis. The TGE and PED virus are excreted in feces. An acute outbreak of PED resembles the TGE outbreak. Clinical differentiation between TGE and PED is very difficult. However, as compared with TGE, the incubation period is longer (3-4 days), not all the litters of suckling pigs may become sick, and mortality in neonatal pigs is lower (average 50%).

TGE in its typical epidemic form causes a rapidly spreading diarrhea in animals of all ages with high mortality in neonates. With PED, the diarrhea spreads at a slower rate, and although diarrhea is seen in most of the litters, some litters may remain healthy even in the absence of immunity. Morbidity is 100% in older pigs. The Anigen Rapid TGE/PED Ag Test Kit detects viral antigens in feces or intestinal contents and easily differentiates between the PEDV and TGEV in pigs of all ages.

## Specifications of TGE Ag

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-TGEV (Capture) – TGEV – Monoclonal anti-TGEV (Detector)
  - •Monoclonal antibody against Transmissible Gastroenteritis virus
- Purpose: Detection of Porcine Transmissible Gastroenteritis virus antigen in pig
- Specimen: Diarrheal feces
- Reading time: 10 minutes
- Sensitivity: 92.1% vs. RT-PCR &IFA
- Specificity: 95.2% vs. RT-PCR &IFA
- No cross reaction against PEDV, Rota virus, PRC virus, BCV, E.coli, K88ab, K88ac, 987P, F41, Salmonella spp, Brachyspira hyodysenteriae, Clostridium perfringens, Coccidium
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 10 individual devices/Kit

## Specifications of PED Ag

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - •Monoclonal anti-PEDV(Capture) – PEDV – Monoclonal anti-PEDV(Detector)
  - •Monoclonal antibody against PED Virus
- Purpose: Detection of Porcine Epidemic Diarrhea virus antigen in pig
- Specimen: Diarrheal feces
- Reading time: 10 minutes
- Sensitivity: 92% vs. RT-PCR
- Specificity: 98% vs. RT-PCR
- No cross reaction against TGEV, Rota virus, PRC virus, BCV, E.coli, K88ab, K88ac, 987P, F41,Salmonella spp. Brachyspira hyodysenteriae, Clostridium perfringens, Coccidium
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 10 individual devices/Kit

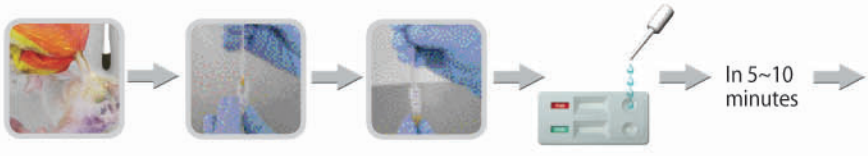
## Special Features

- World's first and sole rapid test kit for differential detection of TGEV and PEDV antigen.
- High sensitivity Vs current confirmatory RT-PCR
- Quick test result allows immediate preventive action to be taken.
- Easy test procedure: No technical expertise is required, saving labor & time
- Only one test sample is required for the differential testing.
- All components are included in the test kit
- Fast diagnosis helps reducing losses to herds.
- Anigen serves the first step to identify the virus causing the pig diarrhea

## Result Interpretation

| |
|---|
| 1) TGE Ag and PED Ag Negative result |
|  |
| 2) Simultaneous TGE Ag and PED Ag Positive result |
|  |
| 3) TGE Ag Positive result |
|  |
| 4) PED Ag Positive result |
|  |

## Test Procedures



# Avian
# AIV Ab ELISA

**AniGen AIV Ab ELISA** is a competitive Enzyme Linked Immnosorbent Assay for the qualitative detection of antibody against Avian Influenza A in serum, plasma and egg yolk.

## Background

Wild birds and some poultry infected by HPAI show no clinical signs, and their virus excretion is too be detected by an antigen capture immunoassay. To detect these latent AIV carriers, BIONOTE has developed the AniGen AIV Ab ELISA as another for detecting AIV antibodies in these bird populations.

## Specifications

- Principle: Competitive Enzyme Linked Immnosorbent Assay [ Nucleoprotein(NP) capture]-[AIV Ab in serum]-[Monoclonal NP Ab-HRP detector]
- Purpose: Qualitative detection of AIV type A antibody
- Species: Chicken, duck, turkey, Geese, Swans, Quails, Guinea fowls Grey partridges, Red partridges, Pheasnats, Horses, pigs, Tern, Seal, Gull, Mallard, Bar-headed Gull
- Specimen: Serum, plasma or egg yolk.
- Reading time: 45 minutes
- Sensitivity: Chicken 98.2%, Duck 97.5%, Turkey 97.1%
- Specificity: Chinken 97.3%, Duck 93.8%, Turkey 100%
- No cross reaction against NDV, IBV, IBDV or MDV positive sera
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

## Quick Procedure

1. Prepare AIV NP antigen coated test plate
2. Add 50ul of controls and sample to wells
3. Add 50ul of diluted enzyme conjugate to wells
4. Incubated plated for 30 minutes at 37℃
5. Wash plate 6 times
6. Add 100ul of substrate solution and incubated for 10 minutes at room temperature
7. Add 100ul of stop solution
8. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
9. PI value=[1-(OD sample/mean OD negative)] x 100

## Special Features

- Optimal screening method of High pathogenic AIV in carrier birds
- Easy Test procedure : No sample dilution required
- Suitable test method at the lab.
- Applicable to various species
- Fast Test Result: Complete within 45 minutes
- High sensitivity and specificity compared with the HI test

## Sensitivity and Specificity

| | Chicken | Duck | Turkey | Goose | Swan | Quail |
|---|---|---|---|---|---|---|
| Total No. of sera | 1,613 | 178 | 213 | 25 | 4 | 46 |
| PI value | 50 | 50 | 85 | 50 | 50 | 51 |
| Sensitivity (%) | 98.2 | 97.5 | 97.1 | 100 | 100 | 100 |
| Specificity (%) | 97.3 | 93.8 | 100 | 100 | 100 | 97 |

| | Guinea fowl | Grey Partridge | Red Partridge | Pheasant | Horse | Swine |
|---|---|---|---|---|---|---|
| Total No. of sera | 19 | 38 | 5 | 18 | 63 | 266 |
| PI value | 19 | 50 | 50 | 50 | 50 | 50 |
| Sensitivity (%) | 87.5 | 100 | Not tested | 100 | 100 | 91.1 |
| Specificity (%) | 100 | 100 | 100 | 62.5 | Not tested | 97.4 |

*Validated of OIE AIV Reference Laboratory (IZS, Italy)


CAT.No.: EB45-02

## Serotype Validation : This kit is valid in all subtype of AIV

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| H1N1 | H2N2 | H2N3 | H3N2 | H3N8 | H4N6 | H4N8 | H5N1 | H5N2 | H5N3 | H6N2 |
| H7N1 | H7N3 | H7N7 | H8N4 | H9N2 | H9N7 | H10N1 | H10N7 | H11N6 | H12N5 | H13N6 |
| H14N5 | H15N6 | H15N8 | H16N3 | | | | | | | |

[ Detection of AIV Ab in serum of Chicken that immunized purifled inactivation virus ]

| Serum | Anigen Ab ELISA kit | HI* |
|---|---|---|
| PR/8/34 (H1N1) | + (98) | 102,400 |
| Singapore/1/57 (H2N2) | + (97) | 16,384 |
| Duck/Ukraine/1/63 (H3N8) | + (99) | 40,960 |
| Duck/Czechoslovakia/56 (H4N6) | + (99) | 16,384 |
| Tern/South Africa/61 (H5N3) | + (99) | 10,240 |
| Turkey/Massachusetts/3740/65 (H6N2) | + (94) | 10,240 |
| Seal/Massachusetts/1/80 (H7N7) | + (98) | 12,800 |
| Turkey/Ontario/6118/68 (H8N4) | + (99) | 8,000 |
| Turkey/Wisconsin/66 (H9N2) | + (99) | 16,000 |
| Chicken/Germany/N/49 (H10N7) | + (99) | 51,200 |
| Duck/England/1/56 (H11N6) | + (99) | 10,240 |
| Duck/Alberta/60/76 (H12N5) | + (99) | 16,834 |
| Gull/Maryland/704/77 (H13N6) | + (84) | 51,200 |
| Mallard/Astrakhan/263/82 (H14N5) | + (99) | 10,240 |
| Duck/Austalia/341/83 (H15N8) | + (98) | 5,120 |
| Bar-headed Gull/Sweden/5/99 (H16N3) | + (99) | 16,384 |
| NDV Miyadera | - (-20) | 131,072 |

*HI used each virus antigen that immunized

[ Detection of AIV Ab in serum post experimental infection ]

| Serum | No | Anigen Ab ELISA kit | | | | HI* | | |
|---|---|---|---|---|---|---|---|---|
| | | pre | 1w | 2w | 3w | pre | 1w | 2w |
| Turkey/England/63 (H7N3) (HP AI) | 1 | - (-27) | + (96) | + (95) | + (98) | <20 | 320 | 640 |
| | 2 | - (-23) | + (97) | + (98) | + (99) | <20 | 320 | 640 |
| | 6 | - (-25) | + (95) | + (97) | + (98) | <20 | 320 | 640 |
| | 7 | - (-26) | + (98) | + (98) | + (99) | <20 | 320 | 1280 |
| | 8 | - (-22) | + (90) | + (96) | + (98) | <20 | 320 | 640 |
| | 9 | No test | + (97) | + (97) | + (99) | <20 | 160 | 320 |
| Chicken/Tbaraki/1/05 (H5N2) (LPAI) | 11 | No test | - (41) | + (58) | + (98) | <20 | 160 | 640 |
| | 12 | No test | + (58) | + (69) | + (99) | <20 | 160 | 640 |

*HI used each virus antigen that immunized *Pre : Pre immunization, W : week(s) *Validated of OIE AIV Reference Laboratory (Hokkaido Univ. Japan)

Avian

# H5 AIV Ab ELISA

**AniGen H5 AIV Ab ELISA** is a competitive Enzyme Linked Immnosorbent Assay for the qualitative detection of antibody against Avian Influenza A, H5 subtype in serum, plasma and egg yolk.

CAT.No.: EB 45-03

## Background

Wild birds and some poultry infected by HPAI subtype H5 show no clinical signs, and their virus excretion is too be detected by an antigen capture immunoassay. To detect these latent H5 AIV carriers, BIONOTE has developed the AniGen H5 AIV Ab ELISA as another for detecting AIV subtype H5 antibodies in these bird populations.

## Specifications

- Principle: Competitive Enzyme Linked Immnosorbent Assay [ Hemagglutinin 5 capture]-[H5 AIV Ab in serum]-[Monoclonal Hemagglutinin 5 Ab-HRP detector]
- Purpose: Qualitative detection of AIV subtype H5 antibodies
- Species: Chicken, duck, Quail
- Specimen: Serum, plasma or egg yolk.
- Reading time: 45 minutes
- Sensitivity: Chicken 96.9% (Vs HI)
- Specificity: Chicken 100 % (Vs HI)
- No cross reaction against other AIV subtype antibodies
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

## Quick Procedure

1. Prepare AIV H5 antigen coated test plate
2. Add 50ul of controls and sample to wells
3. Add 50ul of diluted enzyme conjugate to wells
4. Incubated plated for 30 minutes at 37℃
5. Wash plate 6 times
6. Add 100ul of substrate solution and incubated for 10 minutes at room temperature
7. Add 100ul of stop solution
8. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
9. PI value=[1-(OD sample/mean OD negative)] x 100

## Special Features

- Optimal screening method of High pathogenic AIV, H5 in carrier birds and vaccination
- Easy Test procedure : No sample dilution required
- Suitable test method at the lab.
- Applicable to various species
- Fast Test Result: Complete within 45 minutes
- High sensitivity and specificity compared with the HI test Serotype Validation

## Serotype Validation

| Antibody | PI | Interpretation | Antibody | PI | Interpretation |
|---|---|---|---|---|---|
| **H1N1** | 5 | - | **H5N2** | 95 | + |
| **H2N9** | 7 | - | **H5N3** | 98 | + |
| **H3N2** | 10 | - | **H7N7** | 11 | - |
| **H5N1** | 92 | + | **H9N2** | 13 | - |

Avian

# NDV velo Ab ELISA

**AniGen NDV Velo Ab ELISA** is an Indirect Enzyme Linked Immnosorbent Assay for the qualitative detection of antibodies against Velogenic Newcastle disease virus in avian serum or plasma


CAT.No.: EB45-01

## Background

**Newcastle disease** is a contagious bird disease affecting many domestic and wild avian species. NDV strains can be categorised as velogenic (highly virulent), mesogenic (intermediate virulence) or lentogenic (nonvirulent). Velogenic strains produce severe nervous and respiratory signs, spread rapidly and cause up to 90% mortality. Mesogenic strains cause coughing, affect egg quality and production and result in up to 10% mortality. Lentogenic strains produce mild signs with negligible mortality.
In acute cases, the death is very sudden, and, in the beginning of the outbreak, the remaining birds do not seem to be sick. In flock with good immunity, however, the signs (respiratory an digestive) are mild and progressive, and are followed after 7 days by nervous symptoms, especially twisted heads.

## Specifications

- Principle: Indirect Enzyme Linked Immnosorbent Assay [Recombinant NDV antigen (Capture)]-[velogenic NDV antibodies in sample]-[Anti Avian IgG-HRP detector]
- Purpose: Qualitative detection of antibodies against Velogenic Newcastle disease virus
- Specimen: Serum or plasma
- Reading time: 105 minutes
- Sensitivity: 95.0%
- Specificity: 98 %
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

## Special Features

- Differential test of Velogenic strain and other strains
- The first ELISA test kit for detection of antibodies against velogenic NDV virus
- Simple test procedure
- High sensitivity and specificity
- Fast Test result: Within 2 hours

## Quick Procedure

1. Prepare NDV velo antigen coated test plate
2. Dilute test sample and control with sample diluents
3. Add 100ul of diluted sample and control to wells
4. Incubated plated for 60 minutes at room temperature.
5. Wash plate 5 times
6. Add 100ul of enzyme conjugate to wells
7. Add 100ul of substrate solution and incubated for 30 minutes at room temperature
8. Add 100ul of stop solution
9. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
10. S/P value=[OD sample-mean OD negative]/ [ mean OD positive- mean OD negative x 100

## Performance study

| | NDV Velogenic strain inoculation to vaccinated chickens | | | | | |
|---|---|---|---|---|---|---|
| | DPI 0 | DPI 5 | DPI 7 | DPI 10 | DPI 14 | DPI 18 |
| **AniGen NDV Velo Ab ELISA** | 0% | 33% | 70% | 58% | 25% | 25% |

*** Test group: 12 chickens * Control group: 3 chickens**

It is almost not possible to study sensitivity because there are no commercial tests or method confirmed for detection of the antibody by NDV strains.

Bovine

# B.brucella Ab ELISA

**AniGen B. Brucella Ab ELISA** is an Indirect Enzyme Linked Immnosorbent Assay for the qualitative detection of Brucella abortus and melitenis antibody in bovine plasma, serum or milk.


CAT.No.: EB43-01

## Background

Bovine brucellosis is a highly contagious bacterial disease, almost exclusively caused by Brucella abortus causing late term-abortion and infertility in cattle. Theis disease that affecs many animal species is a zoonose of ecomomic importance, as well as economic importance, as well as a public health hazard.

## Specifications

- Principle: Indirect Enzyme Linked Immnosorbent Assay [ LPS of Brucella abortus (Capture)]-[Brucella antibody in sample]-[Monoclonal Anti Bovine IgG-HRP detector]
- Purpose: Qualitative detection of Brucella abortus and melitenis
- Species: Bovine
- Specimen: plasma, serum or milk
- Reading time: 120 minutes
- Sensitivity: serum 100%, milk 100% (Vs Commercial ELISA)
- Specificity: Serum 97.9 %, milk 99.1% (Vs Commercial ELISA),
- No cross reaction against yersinia enterocolitica
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

## Special Features

- High Sensitivity and Specificity in serum, plasma, or milk.
- Fully meets the requirement of EU Council Directive 64/432/EEC Annex C as last amended in March, 2002 and the OIE Manual od Diagnostics Tests and Vaccine Fifth Edition 2004 Chapter 2.3.1
- Standardized by OIE standard sera (OIESS and relevant OIE wp and OIEsp)
- Adapted to variety of automated robotic samplers and ELISA processor systems
- Individual or pool sample available

## Quick Procedure

1. Prepare LPS of B. abortus coated test plate
2. Dilute the test samples 1:50 with sample diluents (Do not dilute controls and Milk)
3. Add 100ul of positive control, negative control, and diluted test samples.
4. Incubated plate for 60 minutes at 37℃
5. Wash plate 5 times
6. Add 100ul of diluted enzyme conjugate to wells
7. Incubated plate for 30minutes at 37℃
8. Wash plate 5 times
9. Add 100ul of substrate solution and incubated for 15 minutes at room temperature
10. Add 100ul of stop solution
11. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
12. %P value=[OD sample/mean OD positive)] x 100

## Comparative Sensitivity and Specificity study

**(1) Study in serum**

**Specimens :** Total 271 of positive and negative cow serum from KNVRQS*

| | | AniGen ELISA | | |
|---|---|---|---|---|
| | | + | - | |
| Commercial ELISA | + | 127 | 0 | 127 |
| | - | 3 | 141 | 144 |
| | | 130 | 141 | |

**Reseult**

| | |
|---|---|
| Sensitivity | 100% |
| Specificity | 97.9% |

**(2) Study in raw milk**

**Specimens :** Total 271 of positive and negative cow milk from KNVRQS*

| | | AniGen ELISA | | |
|---|---|---|---|---|
| | | + | - | |
| Commercial ELISA | + | 68 | 0 | 68 |
| | - | 1 | 116 | 117 |
| | | 69 | 116 | |

**Reseult**

| | |
|---|---|
| Sensitivity | 100% |
| Specificity | 99.1% |

Bovine

# BTB Ab ELISA

**AniGen BTB Ab ELISA** is a direct Enzyme Linked Immnosorbent Assay for the qualitative detection of M. bovis antibodies in bovine serum

CAT.No.: EB43-03

## Background

Bovine tuberculosis infection in cattle is usually diagnosed in live anmals on the basis of delayed hypersensitivity reactions (Intradermal skin test). The infection is often subclinical; ehen present, clinical signs are not specifically distinctive of this disease and might include weakness, anorexia, emaciation, dyspnoea, enlargement of lymphnodes, and cough, particularly with advanced tuberculosis. After death, it is diagnosed by post-mortem examination and histopathological and bacteriological techniques. DNA probe and polymerase chain reaction(PCR) techniques may also be used. Traditionl bacterial culture diagnosis remains the routine method for confirmation of infection. The intradermal skin test is the method of choice for routine screening although it time and labor intensive. The Anigen BTB Ab ELISA is an easy and fast serological diagnostic test intended for bovine tuberculosis mass screening before the intradermal skin test; the kit detects *M. bovis* antibody in bovine serum

## Specifications

- Principle: Direct Enzyme Linked Immnosorbent Assay [Recombinant M. bovis antigen (Capture)]-[M. bovis antibody in sample]-[Recombinant M. bovis antigen -HRP detector]
- Purpose: Qualitative detection of M. bovis antibody
- Species: Bovine
- Specimen: serum
- Reading time: 75 minutes
- Sensitivity: 87.3% (Vs isolation or intradermal skin test)
- Specificity: 98.9% (Vs isolation or intradermal skin test)
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

## Special Features

- The world's first reliable BTB Ab ELISA for serological diagnosis
- Useful mass screening method for Bovine tuberculosis before intradermal skin test: Save time and labor cost
- Unique recombinant specific antigens provide high sensitivity and specificity
- Fast test result without sample dilution and secondary washing

## Quick Procedure

1. Prepare BTB antigen coated test plate
2. Add 50ul of controls and sample to wells
3. Add 50ul of diluted enzyme conjugate to wells
4. Incubated plated for 60 minutes at 37℃
5. Wash plate 6 times
6. Add 100ul of substrate solution and incubated for 15 minutes at room temperature
7. Add 100ul of stop solution
8. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
9. S/P value=[OD sample-mean OD negative)]/[mean OD positive – mean negative] x 100

## Diagnosis Flow

How can the AniGen BTB Ab ELISA by used effectively?

The individual Intradermal skin test is the standard screening method of diagnosis in the presence of live cattle. However, Intradermal skin test is more time and labor intensive compared to ELISA test. Therefore, it is recommended to use Anigen BTB Ab ELISA as a mass screening diagnostic method. ELISA positive cases are recommended to be tested again by Intradermal skin test.

1. Anigen BTB Ab ELISA test for mess screening
2. Intradermal skin test for suspected cattle
3. IFN-v test for confirmation

# Bovine BTB Ab ELISA

## Performance data

### Sensitivity

| | AniGen BTB Ab ELISA | | | |
|---|---|---|---|---|
| | Positive | Negative | Total | Sensitivity |
| Positive serum confirmed by virus isolation | 18 | 2 | 20 | 90.0%(18/20) |
| Positive serum confirmed by Intradermal skin test | 113 | 17 | 130 | 86.9%(113/130) |
| Total | 131 | 19 | 150 | 87.3%(131/150) |

### Specificity

| | AniGen BTB Ab ELISA | | | |
|---|---|---|---|---|
| | Positive | Negative | Total | Specificity |
| Negative serum confirmed by epidemiological study | 12 | 754 | 766 | 98.4%(754/766) |
| Negative serum confirmed by Intradermal skin test | 80 | 8,220 | 8,300 | 99.0%(8,220/8,300) |
| Total | 92 | 8,974 | 9,066 | 98.9%(8,974/9,066) |

## Q & A

**1.When can the M. Bovis be detected by Intradermal skin test after M. Bovis infection?**

Generally, the bovine tuberculdsis can be detected by the intradermal skin test from 3~6 weeks after infection.
The Intradermal skin test can detect M. Bovisat the early, middle, and late stage of a disease but not during the early stage.

**2. When can the AniGen BTB Ab ELISA detect the anti- M. bovis antibody after M. bovis infection?**

Generally, the bovine tuberculosis can be detected by the Anigne BTB Ab ELISA from 4~8.5 weeks afteri nfection.
The AniGen BTB ELISA can detect at the middle, late stage, and the last stage of a disease but not during the early stage.

**3. What are the reasons for possible discrepancies between AniGen BTB Ab ELISA result and Interadermal skin test result?**

1) In the case of a positive intradermal skin test,and a nerative ELISA results.
- If the cattle is trulye infected, the early stage of M. bovis infection is stronger in cellular immunity, while it is weak in humoral immunity. Therefore, it is posssible that Interadermal skin test that detects cellular immunity is positive and ELISA which detects humoral immunity is negative.
- If the cattle is not infected, the false positive result is due to a non-specific response of the Intradermal skin test.

2)In the case of a negative Intradermal skin test, and a positive ELISA results.
- If the cattle is truly infected, the last stage of M. bovis infection is stronger in humeral immunity, while it is weak in cellular immunity. Therefore, it is possible that Intrademal skin test that detect cellular immunity is negative and ELISA that detects humeral immunity is positive.
- If the cattle is not infected, the false positive result is due to a non-specific response of ELISA.

Bovine

# FMD NSP Ab ELISA

**AniGen FMD NSP Ab ELISA** is a Competitive Enzyme Linked Immnosorbent Assay for the qualitative detection of FMD NSP antibodies in Cattle, Sheep, Goat, Pig serum or plasma.

CAT.No.: EB48-01

## Background

Foot-and-mouth disease (FMD) is a highly contagious viral infection primarily of cloven-hoofed domestic animals, such as cattle, pigs, sheep, goats, deer, and water buffalo. The FMD virus has seven serotypes : A, O, C, Asia 1, and Southern African Territories (SAT) 1,2 and 3.
In many countries the disease is controlled by vaccinations that consist of (partly) purified structural proteins (SP) of the FMD virus, and therefore vaccinated animals only elicit antibodies directed against the structural proteins.
Non structural protein (NSP) is expressed only by replicating viruses, and inactivated vaccines are purified to romove the cellular proteins and NSP. Therefore only animals that have been infected with live virus should develop antibodies against NSP.
The detection of antibody to the NSP is the single most reliable indicator of FMDV infection (Lubroth, 1995, De Diego, 1997)
It is known that vaccinated animals, which are exposed to infection, can become persistently infected with FMDV without ever showing clinical signs (Mackay, D.K.J., et. Al., 1998)
In countries that use vaccination to control FMDV outbreaks, it is important to differentiate between antibodied against SP and NSP in to discriminate between infections from the field and immune response to vaccination.

## Specifications

- Principle: Competitive Enzyme Linked Immnosorbent Assay [Recombinant FMD 3 ABC antigen (Capture)]-[FMD NSP antigen in sample]-[Monoclonal anti-FMD NSP antibody -HRP detector]
- Purpose: Qualitative detection of FMD NSP antibodies
- Species: Cattle, Sheep, Goat, Pig
- Specimen: serum or plasma
- Reading time: 120 minutes
- Sensitivity: Cattle 93.8%
- Specificity: Cattle 99.9%, Pig 99.9%, Sheep& goat 100%
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

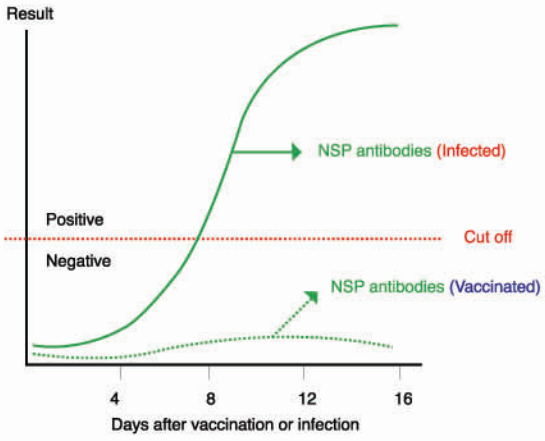
## Special Features

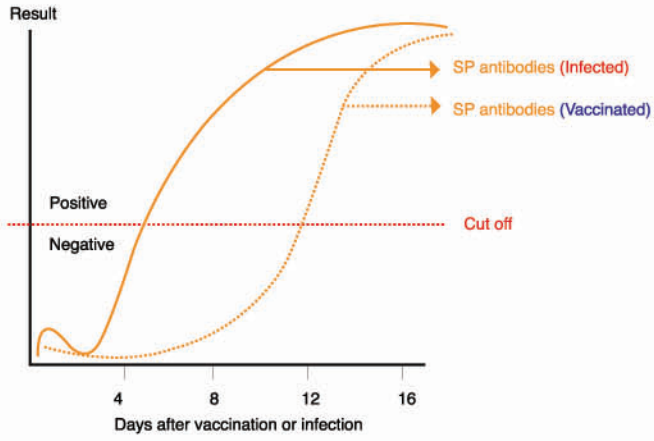
- Differential test of FMD infected or vaccinated
- High accuracy equivalent to a world standard ELISA kit
- Easy test procedure: No serum pre-dilution required
- Cost effective: No requirement for an uncoated microplate for serum pre-dilution
- Fast Test result: Within 2 hours

## Quick Procedure

1. Prepare FMD NSP antigen coated test plate
2. Add 50ul of controls and sample to wells
3. Add 50ul of diluted enzyme conjugate to wells
4. Incubated plated for 90 minutes at 37℃
5. Wash plate 6 times
6. Add 100ul of substrate solution and incubated for 15 minutes at room temperature
7. Add 100ul of stop solution
8. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
9. PI value=[1-(OD sample/mean OD negative)] x 100

## FMD Immune response of infected & vaccinated cattle



Bovine

# FMD NSP Ab ELISA

## Differentiation Infected and Vaccinated.

| FMDV Status | Serological Test result | |
|---|---|---|
| | LPB,VN Test | NSP test |
| Vaccinated, infected | Positive | Positive |
| Vaccinated, Not infected | Positive | Negative |
| Non vaccinated, Infected | Positive | Positive |
| Non vaccinated, Not infected | Negative | Negative |

## Performance characteristics

### 1) Cross reactivity to each FMDV serotype

| Serotype | Detection Rate (positive no./ tested no.) |
|---|---|
| Asia 1 | 2/2 |
| SAT 1 | 3/3 |
| SAT 2 | 5/5 |
| SAT 3 | 2/2 |
| Type A | 13/13 |
| Type C | 3/3 |
| Type O | 6/6 |

**AniGen FMD NSP Ab ELISA detects antibodies against all FMDV serotypes**
(The performance evaluation was performed in OIE FMD Ref. Laboratory)

### 2) Comparative Sensitivity study in experimentally infected animals

| Species | Post Infection | Detection Rate (positive no./ tested no.) | | |
|---|---|---|---|---|
| | | AniGen | Company I | Company A |
| Cattle | 5days | 0/17 | - | 0/17 |
| | 7days | 70/92(76.1%) | 18/47 (38.3%) | 54/92 (58.7%) |
| | 14~26 days | 30/32(93.8%) | 30/32(93.8%) | 31/32 (96.9%) |
| Sheep and Goat | 7 months | 3/6 | - | 3/6 |
| | 10-12 days | 5/5 | 2/5 | 5/5 |
| | | 0/3* | 0/3* | 0/3* |
| | 21 days | 3/3 | 2/3 | 3/3 |
| | | 1/1* | 1/1* | 1/1* |
| | 7months | 7/10 | - | 7/10 |
| Pig | 10-12 days | 4/5 | - | - |

**AniGen FMD NSP Ab ELISA detects antibodies against nonstructural proteun the from 7 days to 7 months after infection**
(*Experimentally contact challenge animal group, The performance evaluation was performed in OIE FMD Ref. Laboratory)

Swine

# CSFV Ab ELISA

**AniGen CSFV Ab ELISA** is an Indirect Enzyme Linked Immnosorbent Assay for the qualitative detection of antibodies against classical swine fever virus in swine serum


CAT.No.: EB44-13

## Background

The infectious agent responsible is a virus CSFV (previously called hog cholera virus) of the genus Pestivirus in the family Flaviviridae. CSFV is closely related to the ruminant pestiviruses which cause Bovine Viral Diarrhoea (BVDV) and Border Disease (BDV). The effect of different CSFV strains varies widely, leading to a wide range of clinical signs. Highly virulent strains correlate with acute, obvious disease and high mortality, including neurological signs and hemorrhages within the skin. Less virulent strains can give rise to subacute or chronic infections that may escape detection, while still causing abortions and stillbirths . In these cases herds in high risk areas are usually serologically tested on a thorough statistical basis. Infected piglets born to infected but subclinical sows help maintain the disease within a population. Other signs can include lethargy, fever, immunosuppression, chronic diarrhea and secondary respiratory infections.

## Specifications

- Principle: Indirect Enzyme Linked Immnosorbent Assay [Recombinant CSFV antigen (Capture)]-[CSFV antibodies in sample]-[Anti swine IgG-HRP detector]
- Purpose: Qualitative detection of antibodies against classical swine fever virus
- Species: Swine
- Specimen: Serum
- Reading time: 75 minutes
- Sensitivity: 99.3% (Vs Commercial ELISA)
- Specificity: 99.7 % (Vs Commercial ELISA)
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Tests/kit, 960 Test/ kit

## Special Features

- No cross reaction with other swine disease positive sera.
- Simple test procedure
- High sensitivity and specificity
- Fast Test result: Within 2 hours

## Quick Procedure

1. Prepare CSFV antigen coated test plate
2. Dilute test sample and control with sample diluents
3. Add 100ul of diluted sample and control to wells
4. Incubated plated for 30 minutes at room temperature.
5. Wash plate 5 times
6. Add 100ul of enzyme conjugate to wells
7. Wash plate 5 times
8. Add 100ul of substrate solution and incubated for 15 minutes at room temperature
9. Add 100ul of stop solution
10. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
11. S/P value=[OD sample-mean OD negative]/ [ mean OD positive- mean OD negative x 100

## Sensitivity and specificity

| | | Comnercial ELISA | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| AniGen CSFV Ab ELISA | Positive | 156 | 0 | 156 |
| | Negative | 1 | 210 | 211 |
| | Total | 157 | 210 | 367 |

AniGen CSFV Ab ELISA has high Sensitivity 99.3% and high Specificity 99.7

Swine

# PRRS Ab ELISA 4.0

**AniGen PRRS Ab ELISA 4.0** is an Indirect Enzyme Linked Immnosorbent Assay for the qualitative detection of antibodies against PRRSV(EU, NA, and Korean strain) in swine serum.

## Background

**Porcine reproductive and respiratory syndrome (PRRS)** is characterized by reproductive failure of sows and respiratory problems of piglets and growing pigs. The disease is caused by the PRRS virus, a virus currently classified as a member of the order Nidovirales, family Arteriviridae, genus Arterivirus. The primary target cell of the virus is the alveolar macrophage of the pig. Two major antigenic types of the virus exist, the European(EU) and the North American(NA) strain. The virus is primarily transmitted via infected pigs but also by feces, urine, semen and fomites.

## Specifications

- Principle: Indirect Enzyme Linked Immnosorbent Assay [Recombinant PRRSV antigen (Capture)]-[PRRS Ab in sample]-[Polyclonal anti-swine IgG -HRP detector]
- Purpose: Qualitative detection of antibodies against PRRSV(EU, NA, and Korean strain) -Species: Cattle, Sheep, Goat, Pig
- Specimen: serum
- Reading time: 75 minutes
- Sensitivity: 98.7 (Vs IFA)
- Specificity: 99.7 (Vs IFA)
- Shelf life: 12 months
- Storage temperature: 2~8℃
- Packing size: 96 Tests/kit, 480 Test/kits, 960 Test/ kit

## Special Features

- Antibodies against European strain, North America strain and Korean Strain can be detected.
- No cross reaction with other swine disease positive sera.
- Simple test procedure
- High sensitivity and specificity
- No more singleton reactor (false positive)
- Fast Test result: Within 2 hours

## Quick Procedure

1. Prepare PRRSV antigen coated test plate
2. Dilute test sample and controls with sample diluents
3. Add 100ul of diluted sample and controls to wells
4. Incubated plated for 30 minutes at room temperature.
5. Wash plate 5 times
6. Add 100ul of enzyme conjugate to wells
7. Wash plate 5 times
8. Add 100ul of substrate solution and incubated for 15 minutes at room temperature
9. Add 100ul of stop solution
10. Measure the optical density (OD) at 450 nm with reference wavelength at 620nm
11. S/P value=[OD sample-mean OD negative]/ [ mean OD positive- mean OD negative x 100

## PRRS strain detectability study

### 1) PRRS European strain

| | Farm | No.of Samples | AniGen % | Commercial Kit A % |
|---|---|---|---|---|
| Sensitivity | EU-1 | 10 | 100% (10/10) | 90% (9/10) |
| | EU-2 | 6 | 100% (6/6) | 100% (6/6) |
| | EU-3 | 9 | 100% (9/9) | 100% (9/9) |
| | EU-4 | 8 | 87.5% (7/8) | 100% (8/8) |
| | EU-5 | 8 | 100% (8/8) | 75% (6/8) |
| | EU-6 | 28 | 64.3% (18/28) | 75% (21/28) |
| | EU-7 | 29 | 100% (29/29) | 96% (28/29) |
| Specificity | Farm A[1)] | 14 | 93% (13/14) | 93% (13/14) |
| | Multiple farms[2)] | 17 | 100% (17/17) | 23.5% (4/17) |

1) Farm A : 14 Samples from 1 farm show singleton reactor.
2) Multiple Farms : 17 Samples from several farms show singleton reactor.

### 2) PRRS Korean strain

| Inoculation strain | | DPI 3 weeks | | |
|---|---|---|---|---|
| | | IFA | AniGen PRRS Ab ELISA 4.0 | |
| | | | S/P | Results |
| VR2332 like virus | No.1 | 1:64 | 1.5 | Positive |
| | No.2 | 1:64 | 1.4 | Positive |
| NSP2-deleted mutant | | 1:64 | 1.0 | Positive |
| NA mutant (ORF5 mutant, Prevalent in Korea) | No.1 | 1:64 | 1.2 | Positive |
| | No.2 | 1:64 | 1.3 | Positive |
| EU Lelystad like virus | | 1:64 | 0.8 | Positive |


CAT.No.: EB44-04

## Study on PRRS standard antisera

| Standard Sera | IFA | | AniGen PRRS Ab ELISA 4.0 | | | Commercial Kit A | | |
|---|---|---|---|---|---|---|---|---|
| | Titer | Result | OD | S/P | Result | OD | S/P | Result |
| Standard antiserum (European strain) | >256 | Positive | 3.0060 | 4.8 | Positive | 0.8830 | 2.1 | Positive |
| Standard antiserum (North American stain) | >256 | Positive | 2.2350 | 3.5 | Positive | 1.0270 | 2.4 | Positive |
| Negative control serum | <20 | Negative | 0.1550 | 0.0 | Negative | 0.1440 | 0.0 | Negative |

**AniGen PRRS Ab ELISA 4.0 can detect standard antiserum from both European and North American strain.** •S/P ratio≥0.4:positive

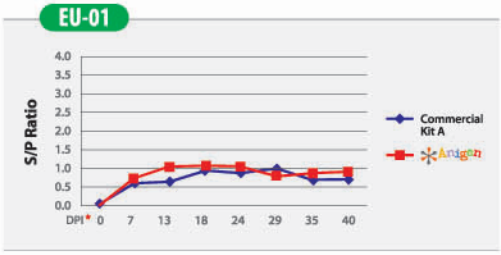
## Sensitivity and specificity study

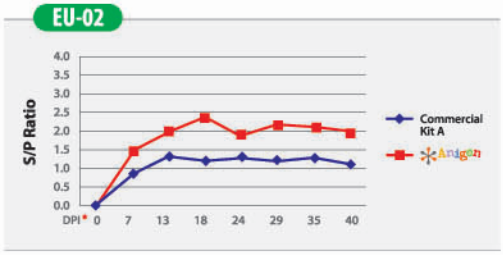
| | | IFA | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| AniGen PRRS Ab ELISA 4.0 | Positive | 324 | 1 | 325 |
| | Negative | 4 | 333 | 337 |
| | Total | 328 | 334 | 662 |

**AniGen PRRS Ab ELISA 4.0 has high Sensitivity, 98.7% and high Specificity, 99.7%**

## Seroconversion study after challenge of PRRSV

1) **EU strain** Antibody response after challenge with PRRS European strain
(Sample No. EU-01, EU-02)

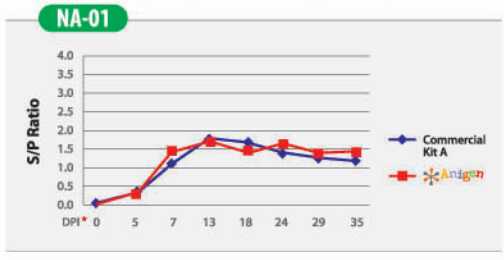


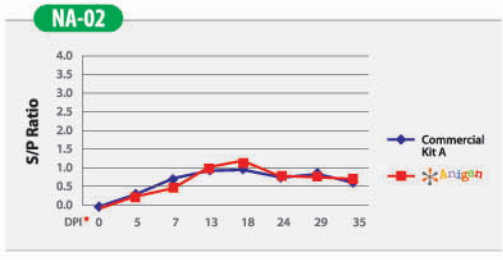




* DPI: Day Post Inoculation

**AniGen PRRS Ab ELISA 4.0 can detect PRRS Ab from DPI 7 with PRRS European strain.**

2) **NA strain** Antibody response after challenge with PRRS North American strain
(Sample No. NA-01, NA-02)




**AniGen PRRS Ab ELISA 4.0 can detect PRRS Ab from DPI 7 with North American strain.**

# Avian General PCR Kits
# AIV detection Kit


## Background

Avian Influenza virus are divided into subtypes based on two proteins, hemagglutinin(HA) and neuraminidase(NA), on the surface of the virus. AIV is spread primarily through direct form infected birds to healthy birds, and through indirect contact with contact with contaminated equipment and materials. The virus is excreted through infected birds' feces and secretions form their noses, mouths, and eyes. BIONOTE AIV Detection Test Kit is a complete, easy PCR kit for detection of Sepcific protein gene from Avian influenza type A virus (H1~H16 genes) BIONOTE AIV detection Kit is very accurate and high efficient, and RT-reaction can be done from 50fg to 500ng of template RNA. It is developed with the best condition of synthesis first-strand cDNA, so it is useful for check a low copy of DNA transcription.

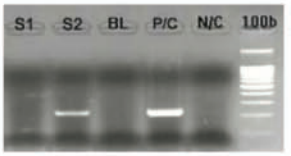
## Specifications

- ☑ **High Sensitivity and Specificity : BIONOTE owning optimal& unique primers and probes system guarantees a highly specific result.**
- ☑ **Excellent reproducibility**
- ☑ **Easy to use : BIONOTE AIV Detection Kits contain all components for the detection of AIV.**
- ☑ **Saving labor costs& time in the laboratory**
- ☑ **Includes positive and negative control**

## Materials in AIV Detection kit (96tests/Kits)

| Contents | Volume |
|---|---|
| Negative Control | 0.5ml |
| Positive Control | 0.5ml |
| 20X RT Mix | 0.1ml |
| 20X PCR Enzyme Mix | 0.1ml |
| Detection Solution | 0.8ml |

## Interpretation of the AIV detection Kit




(S1: Negative sample, S2: Positive sample, BL: blank, P/C: Positive control, N/C: Negative control), 100b: 100bp ladder)

## Type of AIV General PCR Kit

| Product | Diagnosis | Cat.No. |
|---|---|---|
| AIV Detection Kit | AIV type A (Matrix gene) | PD55-01 |
| AIV H5 Detection Kit | Subtype H5 | PD55-02 |
| AIV H7 Detection Kit | Subtype H7 | PD55-03 |
| AIV H9 Detection Kit | Subtype H9 | PD55-04 |

## PCR Q & A

**Why do AIV PCR Kits require for AIV diagnosis?**

•Because the culture methods are time consuming and heavily contaminated (false negative)
•Because the serological methods are not specific enough (false positive) or when the delay of seroconversion is long

**What are the samples for PCR assays?**

•Sample: RNA extracted from blood, tissue, secretion of birds, horse, pig or human

**How accurate?**

•Sensitive: 5 fg of viral RNA detectable, detects early at onset of disease as early as 1~2 days
•Precise: Highly specific primers detect only avian influenza viruses.

**Advantage**

•More sensitivity than general PCR
•Simple and fast PCR procedures

Avian

# General PCR Kits

# NDV, IBDV detection Kit


## Background

BIONOTE NDV and IBDV Detection Test Kit is a complete, easy PCR kit for detection of Sepcific protein gene from Newcastle disease virus and Infectious Bursal Disease virus. Therse detection Kit are very accurate and high efficient, and RT-reaction can be done from 50fg to 500ng of template RNA. It is developed with the best condition of synthesis first-strand cDNA, so it is useful for check a low copy of DNA transcription.



## Specifications

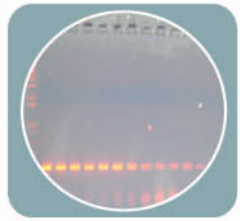
- **High Sensitivity and Specificity : BIONOTE has specific Primer and Probes system**
- **Excellent reproducibility**
- **Easy to use: BioNote Detection Kits contain all components for the detection of NDV or IBDV.**
- **Saving labor costs& time in the laboratory**
- **Includes positive and negative control**

## NDV or IBDV Detection Kits Procedure

1. Sampling

2. RNA Extraction

3. Amplification



4. Detection

## Materials in NDV or IBDV Detection kit (96tests/Kit)

| Contents | Volume |
|---|---|
| Negative Control | 0.5ml |
| Positive Control | 0.5ml |
| 20X RT Mix | 0.1ml |
| 20X PCR Enzyme Mix | 0.1ml |
| Detection Solution | 0.8ml |

## Type of NDV, and IBDV Real-Time detection Kit

| Product | Diagnosis | Cat.No. |
|---|---|---|
| Lento NDV Detection Kit | Lentogenic Newcastle Disease virus | PD55-07 |
| Velo NDV Detection Kit | Velogenic Newcastle Disease virus | PD55-08 |
| IBDV Detection Kit | Infectious Bursal Disease virus | PD55-11 |

# Avian
# Real-Time PCR Kit
# AIV detection Kit



## Background

AIV Real-Time Detection Kit from BIONOTE is useful for detecting the infection of avian influenza A viruses. The kit can be exactly performed to detect RNA of avian influenza A virus, H5, H7, H9 according to subtype, so it can be used for both qualitative and quantitative analysis. It works most of Real-Time PCR apparatuses of block and capillary type.

## Specifications

- **High Sensitivity : Each BIONOTE Real-Time Detection Kit provides highly effective pathogen detection in a sample material.**
  **→ Possible detection up to 10 copies/ul**
- **High Specificity: BIONOTE owing optimal& unique primers and probes system guarantees a highly specific result**
- **Excellent reproducibility: One step Real-Time PCR Kit using Taqman probe**
- **Quantitative and qualitative analysis.**
- **Complete result within 2 hours for after RNA extraction**
- **Higher detection limit than general PCR : 100~1,000 times more sensitive**
- **Simple test procedure: Adding only detection solution and enzyme**
- **BioNote AIV Detection Kits for AIV contain all component for detection from sample.**
- **Feces, cloaca, and organ homogenates samples are recommended**

## Materials in AIV Detection Kit (96tests/Kit)

| Contents | Volume |
|---|---|
| Standard 1 (1x104 copies/μl) | 200μlx1 |
| Standard 2 (1x105 copies/μl) | 200μlx1 |
| Standard 3 (1x106 copies/μl) | 200μlx1 |
| Standard 4 (1x107 copies/μl) | 200μlx1 |
| Detection Solution*1 | 460μlx1 |
| Nuclease Free buffer | 1500μlx1 |
| 2X Enzyme buffer | 1000μlx1 |
| Enzyme Mix | 40μlx1 |
| Rox Reference Dye *2 | 40μlx1 |

*1: Probe is labeled at the 5'-end with the reporter molecule 6-carboxyfluorescein (**FAM**).
*2: The kits is provided extra Rox dye for ABI real-time PCR

## Real-Time Detection Kits Procedure

1. Extraction the template RNA
2. Prepare the PCR MiX
3. React the testing sample, Standard 1,2,3,4 and negative control at each test tube
4. Set up the cycle program as following the Applicable Real-Time PCR machine
5. Set up the report dye as FAM

## List of AIV Real-Time Detection Kit

| Product | Diagnosis | Cat.No. |
|---|---|---|
| AIV A Real -Time Detection Kit | All type A (Matrix gene) | PD65-01 |
| AIV H5 Real -Time Detection Kit | Subtype H5 | PD65-02 |
| AIV H7 Real -Time Detection Kit | Subtype H7 | PD65-03 |
| AIV H9 Real -Time Detection Kit | Subtype H9 | PD65-04 |
| AIV H5/N1 Real-Time Detection Kit | Subtype H5 N1 | PD65-016 |
| AIV N1 Real-Time Detection Kit | Subtype N1 | PD65-017 |
| AIV H5/N1 Duplex Detection Kit | Subtype H5 and N1 | PD65-051 |

# Avian
# Real-Time PCR Kit
# Other poultry disease virus detection Kit

## Background

Other poultry disease virus Real-Time Detection Kit from BIONOTE is useful for detecting the infection of REV, MDV, NDV, IBV, TRT, IBDV, REO, ORT, Myco or ALV. The kit can be exactly performed to detect RNA or DNA of each virus according to disease, so it can be used for both qualitative and quantitative analysis. It works most of Real-Time PCR apparatuses of block and capillary type.



## Specifications

- ☑ **High Sensitivity : Each BIONOTE Real-Time Detection Kit provides highly effective pathogen detection in a sample material. → Possible detection up to 10 copies/ul**
- ☑ **High Specificity: BIONOTE owing optimal& unique primers and probes system guarantees a highly specific result**
- ☑ **Excellent reproducibility: One step Real-Time PCR Kit using Taqman probe**
- ☑ **Quantitative and qualitative analysis.**
- ☑ **Complete result within 2 hours for after RNA or DNA extraction**
- ☑ **Higher detection limit than general PCR : 100~1,000 times more sensitive**
- ☑ **Simple test procedure: Adding only detection solution and enzyme**
- ☑ **BioNote Detection Kits for each virus contain all component for detection from sample.**

## Specifications

- Reaction Buffer
- dNTP
- Sense Primer
- Anti Sense Primer
- Taqman probe
- UNG
- Rox reference dye

- Easy handling
- Fast procedure
- Low contamination risk
- High reproducibility

## List of Other poultry disease Real-Time Detection Kit

| Product | Diagnosis | Cat.No. |
|---|---|---|
| REV Real-TIme Detection Kit | Reticuloendotheliosis Virus | PD65-05 |
| MDV Real-TIme Detection Kit | Marek's disease virus | PD65-06 |
| Lento NDV Real-Time Detection Kit | low pathogenci NDV virus (Lentogenic) | PD65-07 |
| Velo NDV Real-Time Detection Kit | high pathogenic NDV virus (Velogenic) | PD65-08 |
| IBV Real-Time Detection Kit | Infectious Bronnchitis Virus | PD65-09 |
| TRT Real-Time Detection Kit | Infectious Turkey Rhinotracheitis | PD65-10 |
| IBDV Real-Time Detection Kit | Infectious Bursal Disease Virus | PD65-11 |
| REO Real-Time Detection Kit | Avian Reovirus | PD65-12 |
| ORT Real-Time Detection Kit | Ornthobacterium rhinotracheale | PD65-13 |
| MYCO G/S Real-Time Detection Kit | Avian Mycoplasma gallisepticum, and M. iowae, M. meleagridis , M. synoviae | PD65-14 |
| ALV Real-Time Detection Kit | Avian Leukosis Virus | PD65-15 |

# Swine
# Real-Time PCR Kit
# PRRSV, PCV2, CSFV detection Kit

## Background

***PCV-2 Real –Time Detection Kit and *CSFV Real –Time Detection Kit from BIONOTE are** useful for detection the infection of Porcine Circovirus or Classical swine fever virus. The Kit cane be exactly performed to detect DNA of Porcine Circovirus or Classical swine fever virus, so it can be used for both qualitative and quantitative analysis. It works most of Real-Time PCR apparatuses of block and capillary tubes

***PRRSV Real –Time Detection Kit from BIONOTE is** useful for **differential** detection the infection of EU/US strain of Porcine Reproductive and Respiratory Syndrome Virus. The Kit cane be exactly performed to detect DNA of Porcine Reproductive and Respiratory Syndrome Virus (EU/US), so it can be used for both qualitative and quantitative analysis. It works most of Real-Time PCR apparatuses of block and capillary tubes

## PCV-2 or CSFV Real-Time Detection Kit

| Contents | Volume |
|---|---|
| Standard 1 (1x104 copies/μl) | 200μlx1 |
| Standard 2 (1x105 copies/μl) | 200μlx1 |
| Standard 3 (1x106 copies/μl) | 200μlx1 |
| Standard 4 (1x107 copies/μl) | 200μlx1 |
| Detection Solution PCV-2 | 500μlx1 |
| Nuclease Free Water | 1500μlx1 |
| 2X Master Mix | 1000μlx1 |
| Rox Reference Dye | 40μlx1 |

## PRRSV Real-Time Detection Kit

| Contents | Volume |
|---|---|
| Standard 1 (1x104 copies/μl) | 200μlx1 |
| Standard 2 (1x105 copies/μl) | 200μlx1 |
| Standard 3 (1x106 copies/μl) | 200μlx1 |
| Standard 4 (1x107 copies/μl) | 200μlx1 |
| Detection Solution PRRS EU | 460μlx1 |
| Detection Solution PRRS US | 460μlx1 |
| Nuclease Free Water | 1500μlx1 |
| 2X Enzyme buffer | 1000μlx1 |
| Enzyme Mix | 40μlx1 |
| Rox Reference Dye | 40μlx1 |

## Swine Real-Time Detection Kits Procedure

1. Extraction the template DNA
2. Prepare the PCR MiX
3. React the testing sample, Standard 1,2,3,4 and negative control at each test tube
4. Set up the cycle program as following the Applicable Real-Time PCR machine
5. Set up the report dye as FAM

## List of PCV and PRRSV Real-Time Detection Kit

| Product | Diagnosis | Cat.No. |
|---|---|---|
| PCV-2 Real-Time Detection Kit | Porcine Circovirus | PD64-03 |
| PRRSV Real-Time Detection Kit | Porcine Reproductive and Respiratory Syndrome Virus (Differential diagnosis of EU/US strain) | PD64-04 |
| CSFV Real-Time Detection Kit | Classical swine fever virus | PD64-05 |

# Swine
# Real-Time PCR Kit
# SIV Detection Kit




## Background

***SIV Real –Time Detection Kit from BIONOTE is** useful for detection the infection of Swine Influenza Virus. There are 2 types of SIV Real-Time Detection Kit. One is Swine Influenza Virus (Influenza A H1N1) detection Kit and the other distinguishes Classical Swine Influenza virus between and Novel Swine Influenza virus. These Kits can be exactly performed to detect RNA of Swine Influenza virus according to subtype, so it can be used for both qualitative and quantitative analysis. It works most of Real-Time PCR apparatuses of block and capillary tubes.

## Specifications

- High Sensitivity : Each BIONOTE Real-Time Detection Kit provides highly effective pathogen detection in a sample material.
  → Possible detection up to 10 copies/ul
- High Specificity: BIONOTE owing optimal& unique primers and probes system guarantees a highly specific result
- Differential Diagnosis: Original Swine Influenza and Novel Influenza (H1N1) are easily distinguished by SIV Real-Time Detection Kit (PD64-02)
- Excellent reproducibility: One step Real-Time PCR Kit using Taqman probe
- Quantitative and qualitative analysis.
- Complete result within 2 hours for after RNA extraction
- Higher detection limit than general PCR : 100~1,000 times more sensitive

## SIV Real -Time Detection Kit

| Contents | Volume |
|---|---|
| Standard 1 (1x104 copies/μl) | 200μlx1 |
| Standard 2 (1x105 copies/μl) | 200μlx1 |
| Standard 3 (1x106 copies/μl) | 200μlx1 |
| Standard 4 (1x107 copies/μl) | 200μlx1 |
| Detection Solution<br>Swine Influenza virus | 500μlx1 |
| Nuclease Free Water | 1500μlx1 |
| 2X Master Mix | 1000μlx1 |
| Rox Reference Dye | 40μlx1 |

## Influenze A(H1N1)-Swine Real-Time Detection Kit

| Contents | Volume |
|---|---|
| Positive control | 200μlx1 |
| Detection Solution<br>Influenza A (M gene) | 460μlx1 |
| Detection Solution<br>Novel Influenza A (H1 gene) | 460μlx1 |
| Nuclease Free Water | 1500μlx1 |
| 2X Enzme buffer | 1000μlx1 |
| Enzyme Mix | 80μlx1 |
| Rox Reference Dye | 800μlx1 |

## List of SIV Real-Time detection Kit

| Product | Diagnosis | Cat.No. |
|---|---|---|
| Influenza A(H1N1)-Swine Real-Time Detection Kit | Novel Influenza A (H1n1) | PD64-01 |
| SIV Real-Time Detection Kit | Original Swine Influenza virus | PD64-02 |

## Real-Time Fluorescence Detection System

# CURRENT AVAILABLE PRODUCT LIST

## Rapid

| | Species | Product | Cat. No. | Type | Packing Size | Description | Sample |
|---|---|---|---|---|---|---|---|
| PET Animal |  | Rapid CPV Ag Test Kit | RG11-01 | Device | 1Test x 10/Kit | Detection of Canine Parvovirus antigen | Feces |
| | | Rapid Canine Heartworm Ag Test Kit | RG11-02 | Device | 1Test x 10/Kit | Detection of Canine Heartworm antigen | Whole blood, plasma or serum |
| | | Rapid CDV Ag Test Kit | RG11-03 | Device | 1Test x 10/Kit | Detection of Canine Distemper virus antigen | Conjunctiva, feces, saliva, urine, plasma, or serum |
| | | Rapid CCV Ag Test Kit | RG11-04 | Device | 1Test x 10/Kit | Detection of Canine Coronavirus antigen | Feces |
| | | Rapid CPV Ag/CCV Ag Test Kit | RG11-05 | Dual device | 1Test x 10/Kit | Detection of Parvovirus antigen/Coronavirus antigen | Feces |
| | | Rapid CIV Ag Test Kit | RG11-07 | Device | 1Test x 10/Kit | Detection of Canine influenza virus antigen | Conjunctiva and nasal swab |
| | | Rapid CDV Ag/CAV Ag Test Kit | RG11-08 | Dual device | 1Test x 10/Kit | Detection of Distemper antigen/Canine adenovirus antigen | Conjunctiva and nasal swab |
| | | Rapid CIRD-3 Ag Test Kit | RG11-09 | Dual device | 1Test x 10/Kit | Detection of Distemper antigen/Canine adenovirus/Canine influenza virus antigen | Conjunctiva and nasal swab |
| | | Rapid CDV Ag/CIV Ag Test Kit | RG11-10 | Dual device | 1Test x 10/Kit | Detection of Distemper antigen/Canine Influenza antigen | Conjunctiva and nasal swab |
| | | Rapid CPV/CCV/Giardia Ag Test Kit | RG11-12 | Triple Device | 1Test x 5/Kit | Detection of Parvovirus antigen/Coronavirus antigen/ Giardia antigen | Feces |
| | | Rapid Rabies Ag Test Kit | RG18-01 | Device | 1Test x 10/Kit | Detection of Rabies virus antigen | Saliva & brain homogenates |
| | | Rapid Rota Ag Test Kit | RG18-03 | Device | 1Test x 10/Kit | Detection of Rotavirus antigen in bovine, porcine, canine | Diarrheal faeces |
| | | Rapid Giardia Ag Test kit | RG18-04 | Device | 1Test x 10/Kit | Detection of Giardia antigen | Feces |
| | | Rapid CPV Ab Test Kit | RB21-01 | Device | 1Test x 10/Kit | Titration of Parvovirus antibody for vaccination & prognosis | Whole blood, plasma or serum |
| | | Rapid CDV Ab Test Kit | RB21-02 | Device | 1Test x 10/Kit | Titration of Distemper virus antibody for vaccination & prognosis | Blood |
| | | Rapid Canine Brucella Ab Test Kit | RB21-03 | Device | 1Test x 10/Kit | Detection of Brucella canins antibody | Whole blood, plasma or serum |
| | | Rapid Leishmania Ab Test Kit | RB21-04 | Device | 1Test x 10/Kit | Detection of Leishmania antibody | Whole blood, plasma or serum |
| |  | Rapid FeLV Ag Test Kit | RG12-01 | Device | 1Test x 10/Kit | Detection of Feline Leukemia virus antigen | Whole blood, plasma or serum |
| | | Rapid FPV Ag Test Kit | RG12-03 | Device | 1Test x 10/Kit | Detection of Feline Panleukopaenia virus antigen | Feces |
| | | Rapid FIV Ab/FeLV Ag Test Kit | RC12-04 | Dual Device | 1Test x 10/Kit | Detection of Feline Leukemia virus antigen and Feline Immunodeficiency virus antibody | Whole blood, plasma or serum |
| | | Rapid FCoV Ag Test Kit | RG12-05 | Device | 1Test x 10/Kit | Detection of Feline Corona virus antigen | Feces |
| | | Rapid FIV Ab Test Kit | RB22-01 | Device | 1Test x 10/Kit | Detection of Feline Immunodeficiency virus antibody | Whole blood, plasma or serum |
| | | Rapid FCoV Ab Test Kit | RB22-03 | Device | 1Test x 10/Kit | Detection of Feline Corona virus antibody | Whole blood, plasma or serum |
| Industrial Animal |  | Rapid Rota Ag Test Kit | RG18-03 | Device | 1Test x 10/Kit | Detection of Rotavirus antigen in bovine, porcine, canine | Diarrheal faeces |
| | | Rapid Bovine Brucella Ab Test Kit | RB23-01 | Device | 1Test x 10/Kit | Detection of Brucella abortus antibody | Whole blood, plasma, serum or milk |
| | | Rapid Bovine TB Ab Test Kit | RB23-02 | Device | 1Test x 10/Kit | Detection of Mycobacterium bovis antibody | Plasma, serum |
| | | Rapid FMD NSP Ab Test Kit | RB28-02 | Device | 1Test x 10/Kit | Detection of Foot and mouth disease virus antibody field infected | Whole blood, plasma or serum |
| |  | Rapid PED Ag Test Kit | RG14-01 | Device | 1Test x 10/Kit | Detection of Porcine Epidemic Diarrhea virus antigen | Diarrheal faeces |
| | | Rapid TGE Ag Test Kit | RG14-02 | Device | 1Test x 10/Kit | Detection of Transmissible Gastroenteritis virus antigen | Diarrheal faeces |
| | | Rapid TGE Ag/PED Ag Test Kit | RG14-03 | Dual device | 1Test x 10/Kit | Detection of TGE Ag and PED Ag | Diarrheal faeces |
| | | Rapid PED Ag/Rota Ag Test Kit | RG14-04 | Dual device | 1Test x 10/Kit | Detection of PED antigen and Rotavirus antigen in pig | Diarrheal faeces |
| | | Rapid Rota Ag Test Kit | RG18-03 | Device | 1Test x 10/Kit | Detection of Rotavirus antigen in bovine, porcine, canine | Diarrheal faeces |
| | | Rapid FMD NSP Ab Test Kit | RB28-02 | Device | 1Test x 10/Kit | Detection of Foot and mouth disease virus antibody field infected | Whole blood, plasma or serum |
| | | Rapid SIV Ag Test Kit | RG14-05 | Device | 1Test x 10/Kit | Detection of Swine Influenza virus antigen | Nasal fluid or tracheal swab and lung tissue |
| |  | Rapid AIV Ag Test Kit | RG15-01 | Multidevice | 10Tests x 3/Kit | Detection of Avian influenza type A virus antigen | Diarrhoea faeces, Cloaca Feces, or Trachea swab |
| | | Rapid NDV Ag Test Kit | RG15-03 | Device | 1Test x 10/Kit | Detection of Newcastle Disease virus antigen | Cloaca Feces, Trachea |
| | | Rapid IBDV Ag Test Kit | RG15-04 | Device | 1Test x 10/Kit | Detection of Infectious Bursal Disease virus antigen | Bursa of Fabricious, Feces |
| | | Rapid H5 AIV Ag Test Kit | RG15-05 | Device | 1Test x 25/Kit | Detection of avian influenza type A subtype H5 virus antigen | Diarrhoea faeces, Cloaca Feces, or Trachea swab |
| | | Rapid AIV type A/H5 AIV Ag Test Kit | RG15-06 | Dual device | 1Test x 10/Kit | Detection of avian influenza type A and H5 antigen | Diarrhoea faeces, Cloaca Feces, or Trachea swab |
| | | Rapid AIV Ag/NDV Ag Test Kit | RG15-09 | Dual device | 1Test x 10/Kit | Detection of avian influenza type A and NDV antigen | Diarrhoea faeces, Cloaca Feces, or Trachea swab |
| | | Rapid AIV Ab Test Kit | RB25-01 | Multidevice | 10Tests x 3/Kit | Detection of Avian Influenza Virus Type A Antibody | Plasma, serum |

## ELISA

| | Species | Product | Cat. No. | Type | Packing Size | Description | Sample |
|---|---|---|---|---|---|---|---|
| Industrial Animal |  | Bovine Brucella Ab ELISA | EB43-01 | Microplate | 480 wells/Kit | Detection of Brucella abortus antibody | Serum, Plasma, Raw milk |
| | | | EB43-02 | | 960 wells/Kit | | |
| | | BTB Ab ELISA | EB43-03 | Microplate | 480 wells/Kit | Detection of Mycobacterium bovis antibody | Serum |
| | | FMD NSP Ab ELISA | EB48-01 | Microplate | 480 wells/Kit | Detection of Foot-and-mouth disease virus antibody field infected in cattle, pig, goat, sheep | Serum, Plasma |
| |  | CSFV Ab ELISA | EB44-13 | Microplate | 480 wells/Kit | Detection of Classical swine fever virus antibody for routine screening | Serum, Plasma |
| | | PRRS Ab ELISA | EB44-04 | Microplate | 480 wells/Kit | Detection of Porcine Reproductive and Respiratory Syndrome (PRRS) antibody | Serum, Plasma |

## ELISA

| | Species | Product | Cat. No. | Type | Packing Size | Description | Sample |
|---|---|---|---|---|---|---|---|
| Industrial Animal |  | AIV Ab ELISA | EB45-02 | Microplate | 480 wells/Kit | Detection of AIV type A antibody in chicken, duck, goose. | Serum |
| | | | EB45-52 | | 96 wells/Kit | | |
| | | H5 AIV Ab ELISA | EB45-03 | Microplate | 480 wells/Kit | Detection of AIV subtype H5 antibody in chicken, duck, goose. | Serum |
| | | | EB45-53 | | 96 wells/Kit | | |
| | | NDV Velo Ab ELISA | EB45-01 | Microplate | 480 wells/Kit | Detection of NDV velogenic virus antibody in chicken | Serum |
| | | | EB45-51 | | 96 wells/Kit | | |

## Conventional PCR

| | Species | Product | Cat. No. | Type | Packing Size | Description | Sample |
|---|---|---|---|---|---|---|---|
| Industrial Animal |  | AIV Detection Test Kit | PD55-01 | Conventional PCR | 96Tests/kit | Detection of AIV type A | sercetion, organ, blood, feces, fluid etc. |
| | | H5 AIV Detection Test Kit | PD55-02 | Conventional PCR | 96Tests/kit | Detection of AIV subtype H5 | sercetion, organ, blood, feces, fluid etc. |
| | | H7 AIV Detection Test Kit | PD55-03 | Conventional PCR | 96Tests/kit | Detection of AIV subtype H7 | sercetion, organ, blood, feces, fluid etc. |
| | | H9 AIV Detection Test Kit | PD55-04 | Conventional PCR | 96Tests/kit | Detection of AIV subtype H9 | sercetion, organ, blood, feces, fluid etc. |
| | | Lento NDV Detection Test Kit | PD55-07 | Conventional PCR | 96Tests/kit | Detection of low pathogenci NDV virus (Lentogenic) | sercetion, organ, blood, feces, fluid etc. |
| | | Velo NDV Detection Test Kit | PD55-08 | Conventional PCR | 96Tests/kit | Detection of high pathogenic NDV virus (Velogenic) | sercetion, organ, blood, feces, fluid etc. |
| | | IBDV Detection Test Kit | PD55-11 | Conventional PCR | 96Tests/kit | Detection of Infectious Bursal Disease Virus | sercetion, organ, blood, feces, fluid etc. |
| PET Animal |  | CDV Detection Test Kit | PD 51-03 | Conventional PCR | 25Tests/kit | Detection of Canine Destemper Virus | Conjunctiva, feces, saliva, urine, plasma, or serum |
| | | Leishmaniasis Detection Test Kit | PD 51-04 | Conventional PCR | 25Tests/kit | Detection of Leishmania | Whole blood, plasma or serum |
| | | E.canis Detection Test Kit | PD 51-05 | Conventional PCR | 25Tests/kit | Detection of E.canis | Whole blood, plasma or serum |

## Real-Time PCR

| | Species | Product | Cat. No. | Type | Packing Size | Description | Sample |
|---|---|---|---|---|---|---|---|
| Industrial Animal |  | AIV A Real-Time Detection Test Kit | PD65-01 | Real-Time PCR | 96Tests/kit | Detection of AIV type A | sercetion, organ, blood, feces, fluid etc. |
| | | H5 AIV Real-Time Detection Test Kit | PD65-02 | Real-Time PCR | 96Tests/kit | Detection of AIV subtype H5 | sercetion, organ, blood, feces, fluid etc. |
| | | H7 AIV Real-Time Detection Test Kit | PD65-03 | Real-Time PCR | 96Tests/kit | Detection of AIV subtype H7 | sercetion, organ, blood, feces, fluid etc. |
| | | H9 AIV Real-Time Detection Test Kit | PD65-04 | Real-Time PCR | 96Tests/kit | Detection of AIV subtype H9 | sercetion, organ, blood, feces, fluid etc. |
| | | REV Real-TIme Detection Test Kit | PD65-05 | Real-Time PCR | 96Tests/kit | Detection of Reticuloendotheliosis Virus | sercetion, organ, blood, feces, fluid etc. |
| | | MDV Real-TIme Detection Test Kit | PD65-06 | Real-Time PCR | 96Tests/kit | Detection of Marek's disease virus | sercetion, organ, blood, feces, fluid etc. |
| | | Lento NDV Real-Time Detection Test Kit | PD65-07 | Real-Time PCR | 96Tests/kit | Detection of low pathogenci NDV virus (Lentogenic) | sercetion, organ, blood, feces, fluid etc. |
| | | Velo NDV Real-Time Detection Test Kit | PD65-08 | Real-Time PCR | 96Tests/kit | Detection of high pathogenic NDV virus (Velogenic) | sercetion, organ, blood, feces, fluid etc. |
| | | IBV Real-Time Detection Test Kit | PD65-09 | Real-Time PCR | 96Tests/kit | Detection of Infectious Bronnchitis Virus | sercetion, organ, blood, feces, fluid etc. |
| | | TRT Real-Time Detection Test Kit | PD65-10 | Real-Time PCR | 96Tests/kit | Detection of Infectious Turkey Rhinotracheitis | sercetion, organ, blood, feces, fluid etc. |
| | | IBDV Real-Time Detection Test Kit | PD65-11 | Real-Time PCR | 96Tests/kit | Detection of Infectious Bursal Disease Virus | sercetion, organ, blood, feces, fluid etc. |
| | | REO Real-Time Detection Test Kit | PD65-12 | Real-Time PCR | 96Tests/kit | Detection of Avian Reovirus | sercetion, organ, blood, feces, fluid etc. |
| | | ORT Real-Time Detection Test Kit | PD65-13 | Real Time-PCR | 96Tests/kit | Detection of Ornthobacterium rhinotracheale | sercetion, organ, blood, feces, fluid etc. |
| | | MYCO G/S Real-Time Detection Test Kit | PD65-14 | Real-Time PCR | 96Tests/kit | Detection of Avian Mycoplasma gallisepticum, and M. iowae, M. meleagridis , M. synoviae | sercetion, organ, blood, feces, fluid etc. |
| | | ALV Real-Time Detection Test Kit | PD65-15 | Real-Time PCR | 96Tests/kit | Detection of Avian Leukosis Virus | sercetion, organ, blood, feces, fluid etc. |
| | | AIV H5/N1 Real-Time Detection Test Kit | PD65-16 | Real-Time PCR | 96Tests/kit | Detection of AIV H5N1 (Only FAM) | sercetion, organ, blood, feces, fluid etc. |
| | | AIV N1 Real-Time Detection Test Kit | PD65-17 | Real-Time PCR | 96Tests/kit | Detection of AIV N1 | sercetion, organ, blood, feces, fluid etc. |
| | | AIV H5/N1 Duplex Real-Time Detection Test Kit | PD65-51 | Real-Time PCR | 96Tests/kit | Detection of AIV H5 and N1 | sercetion, organ, blood, feces, fluid etc. |
| |  | Influenza A(H1N1)-Swine Real-Time Detection Test Kit | PD64-01 | Real-Time PCR | 96Tests/kit | Detection of Novel Influenza A(H1N1) Virus (Swine) | sercetion, organ, blood, feces, fluid etc. |
| | | SIV Real-Time Detection Test Kit | PD64-02 | Real-Time PCR | 96Tests/kit | Detection of Swine Influenza Virus | sercetion, organ, blood, feces, fluid etc. |
| | | PCV-2 Real-Time Detection Kit | PD64-03 | Real-Time PCR | 96Tests/kit | Detection of Procine Circovirus | sercetion, organ, blood, feces, fluid etc. |
| | | PRRSV Real-Time Detection Kit | PD64-04 | Real-Time PCR | 96Tests/kit | Detection of Procine Reproductive and Respiratory syndrome Virus | sercetion, organ, blood, feces, fluid etc. |
| | | CSFV Real-Time Detection Kit | PD64-05 | Real-Time PCR | 96Tests/kit | Detection of Classical swine fever virus | sercetion, organ, blood, feces, fluid etc. |
| PET Animal | | CHW Real-Time Detection Kit | PD61-02 | Real-Time PCR | 96Tests/kit | Detection of Canine Heartworm | |
| | | Influenza A(H1N1) Real-Time Detection Test Kit (2 Wells type) | PD65-18 | Real-Time PCR | 96Tests/kit | Detection of Novel Influenza A(H1N1) Virus (Human) | sercetion, organ, blood, fluid etc. |
| | | Influenza A(H1N1) Real-Time Detection Test Kit (4 Wells type) | PD65-19 | Real-Time PCR | 96Tests/kit | Detection of Novel Influenza A(H1N1) Virus (Human) | sercetion, organ, blood, fluid etc. |

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|---|---|---|---|---|---|---|---|
| | | OneStep RT-PCR Kit | RK50-01 | RT-PCR | 100 Reactions | | sercetion, organ, blood, fluid etc. |
| | | SYBR Green RT-PCR Kit | RK50-02 | RT-PCR | 1000 Reactions | | sercetion, organ, blood, fluid etc. |
| | | Viral RNA purification Kit | RK50-90 | | 250 Reactions | | sercetion, organ, blood, fluid etc. |

# BIONOTE Product catalog

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