ISO 9001&ISO 13485 certified

BIONOTE

Product Catalog(Ver.3.0)

Innovation & Standard of Rapid Immunoassays for Animal Disease

Anigen

Diagnostic Test Kits for PET Animals

BIONOTE
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COMPANY PROFILE

Introduction

BioNote, Inc. was established in the beginning of 2003, and is considered a pioneer of In-Vitro Diagnostics for human and veterinary in needs. We deliver inspirational, innovative and it's quality solutions for our customers and consumers to improve health care. BioNote, Inc. has own automated facility to manufacture a wide range of high value products developed by our high quality R&D center. BioNote, Inc. manufactures it's diagnostic products to accordance with ISO 9001:ISO13485 certification, and has expanded overseas sales network over 80 countries and is still continning to grow.

COMPANY HISTORY

2009 ~	**Expanding business**
2009.02	Company name was changed from Animal Genetics, Inc. to BioNote, Inc.
2007 ~2008	**Take-off stage**
2008. 12	Moved to current facility in 2-9, Seogu-dong, Hwaseong-si, Gyeonggi-do, Korea 445-170
2007. 12	Won a prize at the 2007 self-audit evaluation (NVRQS)
2007. 09	Acquired patent of HPAI H5 subtype and LPAI virus antigen diagnostic strip and manufacture method.
2007. 07	Certificated as a promising small & medium business of Gyeonggi province.
2005 ~ 2006	**Installing Base Profit**
2006. 06	Certified 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. 12	Acquired certificate of rapid avian influenza virus Ag test kit(NVRQS)
2004. 07	Acquired technical innovation subject of small & medium business
2003.12	Acquired certificate of rapid canine parvovirus Ag and canine heartworm Ag test kit(NVRQS)
2003.12	Acquired certificate of manufacture for animal health product (NVRQS)
2003.11	Acquired certificate of import for animal health product (NVRQS)
2003.03	Established "Animal Genetics, Inc."

CONTENTS

Canine Testing

Feline Testing

Anigen Check

Rapid Test Kit

CPV Ag

Anigen Rapid CPV Ag Test Kit is a solid phase chromatographic immunoassay for the qualitative detection of Canine Parvovirus antigen in canine feces.

Background

Canine Parvovirus is a virus that attacks the intestinal tract of dogs, causing severe vomiting and diarrhea. The diarrhea often has a very strong smell, and dogs show clinical signs usually within 7 - 10 days of the initial infection. CPV is extremely hardy, surviving extremes of heat and subzero temperatures for long periods of time, and is a deadly threat to an unvaccinated dog or puppy. Two slightly different strains of CPV that cause a similar disease state, CPV-2a and CPV-2b, have been identified and commercial vaccines give protection against both of these strains. Another subtype of Parvovirus (CPV-1) has been found in pups with diarrhea as well as adult dogs, this strain is not thought to be an important cause of disease.

Specifications

- Principle : Immunochromatographic assay using Direct Sandwich Method
  - Monoclonal anti - CPV (Capture) - CPV - Monoclonal anti-CPV (Detector)
- Purpose : Detection of canine parvovirus antigen
- Specimen : Canine feces
- Reading time : 5 -10 minutes
- Sensitivity : 100% (CPV 2, CPV 2a, CPV 2b) vs. Hemagglutination test (HA)
- Specificity : 98.8% vs. Hemagglutination test
- No cross reaction against CCV, CDV, ICH, PI2, causative agents of other diarrhea
- Detection limit : 1.0 x 10^3 $TCID_{50}$/ml or 0.5 HAU
- Shelf life : 24 months
- Storage temperature : 2~30˚C
- Packing size : 10 Tests/Kit
- CAT. No. : RG11-01

Comparison Study

The Anigen Rapid Parvovirus Ag was evaluated with positive and negative clinical samples, confirmed by clinical signs and leading commercial Parvovirus antigen Rapid test kits

1. Comparison test kit: 2 commercially available CPV Ag Immunochromatographic assays
2. No. of Positive specimens by PCR: 51 feces
3. No. of Negative specimens by PCR: 104 feces

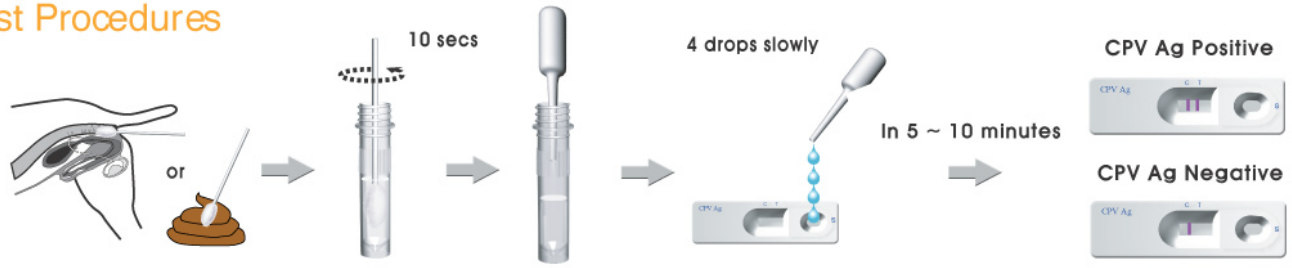
	51 positive feces		104 negative feces	
	Positive	Negative	Positive	Negative
Anigen CPV Ag Test	51	0	0	104
Commercial product A	51	0	0	104
Commercial product B	51	0	1	103

The results of this comparison of the Anigen Rapid Parvovirus Ag versus confirmed feces specimens, show a sensitivity of 51/51 x 100%= 100%, a specificity of 104/104 x 100%= 100% and a total agreement of 100% (155/155).

Special Features

- Detection of pathogenic CPV subtypes (CPV2, CPV2a & CPV2b)
- Detection of CPV within 3 days of the infection in feces
- No detection of CPV originating from vaccinations
- Rapid test result: 10 minutes
- One-step testing procedure: Easy to use, saving time and labor
- No additional equipment is required
- Good indicator for the prognosis of CPV infected dog during treatment
  (A weak Test line intensity indicates a reduction in the viral load)

Test Procedures



Rapid Test Kit

Heartworm Ag 2.0

Anigen Rapid Dirofilaria immitis (Heartworm) Ag Test Kit is a solid phase chromatographic immunoassay for the qualitative detection of Canine Dirofilaria immitis antigen in canine serum, plasma, or whole blood

Background

Heartworm (Dirofilaria immitis) is a relatively large parasite that, in adulthood, lives in the heart and pulmonary arteries of an infected dog. Dogs acquire this infection when larval heartworms are transferred between infected and healthy dogs via mosquito bites. Some geographic areas with high mosquito populations have severe heartworm problems. Commercial HW antigen tests detect specific antigens from adult female heartworms, and are used with varying success to detect canine heartworm infection.

Currently, most commercial tests will accurately detect infections with 3~5 (or more) mature female heartworms that are at least 7 or 8 months old, but generally do not detect infections of less than 5 months duration. All heartworm infections do not result in microfilaria circulating in the blood, especially in cases of occult heartworm infection, single sex heartworm infection, periodic appearance, host immune responses and most significantly the administration of heartworm preventives.

Specifications

- Principle : Immunochromatographic assay using Direct Sandwich Method
  - Antibodies against Dirofilaria immitis (Capture) - Dirofilaria immitis Ag
  - Antibodies against Dirofilaria immitis (Detector)
- Purpose : Detection of Canine Dirofilaria immitis antigen
- Specimen : Canine serum, plasma, or whole blood
- Reading time : 5 -10 minutes
- Sensitivity : 94.4% vs. Necropsy
- Specificity : 100% vs. Necropsy
- No cross reaction with Dipetalonema reconditum, parasites caused by flea, lice
- Shelf life : 24 months
- Storage temperature : 2~30˚C
- Packing size : 10 Tests/Kit
- CAT. No. : RG11-02

Special Features

- Unique antibody system in the Anigen Canine Heartworm Ag test kit
- Detection of heartworms that are at least 7~8 months old
- High sensitivity : Accurately detects infections with a burden of 2 heartworms of any type including
  (1) Male (2) Adult female (3) Immature female (4) Non-propagated female worms
- Rapid test result : 10 minutes
- One step testing procedure : Easy to use, saving time and labor
- No additional equipment is required

Sensitivty and Specificity Study

Table 1. Sensitivity and specificity of Anigen Rapid Heartworm Ag

Infection Status		No. of specimen	No. of worm/dog	No. of Positive results by Anigen Rapid Heartworm Ag
Negative (102)		102	0	0
Positive (72)	Only adolescent worms	7	1-6	4
	Only male adult worms	4	1-3	4
	Only female adult worms	8	1-2	7
	Adult and adolescent male worms	6	1-2 adult worms	6
	Adult and adolescent male worms	11	>2 adult worms	11
	Adult and adolescent female worms	8	1-2 adult worms	8
	Adult and adolescent female worms	6	>2 adult worms	6
	Adult and adolescent worms of both sexes	12	1-2 adult worms	12
	Adult and adolescent worms of both sexes	10	>2 adult worms	10
Total(Negative/Positive)		102/72		102/68

• Sensitivity: 94.4%(68/72) **• Specificity: 100%(100/100)**

Table 2. Comparative Sensitivity and Specificity of Commercial Kits Vs. Necropsy (Published in AAVP, American Association of Veterinary Paratologists)

	Sensitivity (%)			Specificity (n=54)
	1 adult female worm (n=13)	2 adult female worms (n=12)	>3 adult female worms (n=30)	
Anigen Heartworm Ag	85 %	100 %	100 %	100 %
Company A	76.2 %	85 %	100 %	
Company B	76.2 %	95 %	96.5 %	
Company C	71.4 %	90 %	94.7 %	

Test Procedures

Rapid Test Kit

CDV Ag

Anigen Rapid CDV Ag Test Kit is a solid phase chromatographic immunoassay for the qualitative detection of Canine Distemper virus antigen in canine secretion - conjuntiva, serum, plasma or urine.

Background

Canine Distemper virus, Paramyxoviridae Morbillivirus, is a leading cause of death in dogs. The virus is similar to the one that causes measles in human, and has H and F envelope glycoproteins. The virus is shed in saliva, blood, urine and other body secretions, with the more virulent strains having a strong tropism for epithelial tissues. Unvaccinated dogs are highly susceptible especially between 3-6 months of age, with clinical signs including fever, cough, depression, vomiting, diarrhea, head tremors, and convulsions. With the Anigen Rapid CDV Ag test kit, CDV can be easily and accurately diagnosed in canine conjunctiva, blood, etc. within 10 minutes.

Specifications

- Principle : Immunochromatographic assay using Direct Sandwich Method
  • Monoclonal anti-CDV (Capture) - CDV - Monoclonal anti-CDV (Detector)
- Purpose : Detection of canine distemper virus
- Specimens : Conjunctiva (recommendable), serum, plasma, urine
- Reading time : 5-10 minutes
- Sensitivity : 100% vs. RT-PCR
- Specificity : 98.5% vs. RT-PCR
- No cross reaction against CPV, CCV, ICH, PI2
- Detection limit : $10^{1.8}TCID_{50}$/0.1ml
- Shelf life : 24 months
- Storage temperature: 2~30°C
- Packing size : 10 Tests/Kit
- CAT. No. : RG11-03

Clinical field trial data

1. Comparison test : Peroxidase Linked Assay (PLA, Cell ELISA), RT-PCR
2. Positive specimens:
   A. 66 specimens confirmed by Peroxidase Linked Assay (PLA, Cell-ELISA)
   B. 20 specimens confirmed by RT-PCR combined with nested PCR
3. Negative specimens
   Healthy canine specimens from dogs at least in 14 days after vaccination confirmed by RT-PCR

Table 1) Sensitivity comparison result with PLA

No of Specimen	Anigen Rapid CDV Ag	PLA
66	65/66(98.5%)	66

Table 2) Sensitivity comparison result with RT-PCR

No of Specimen	Anigen Rapid CDV Ag	RT-PCR
20	20/20(100%)	20

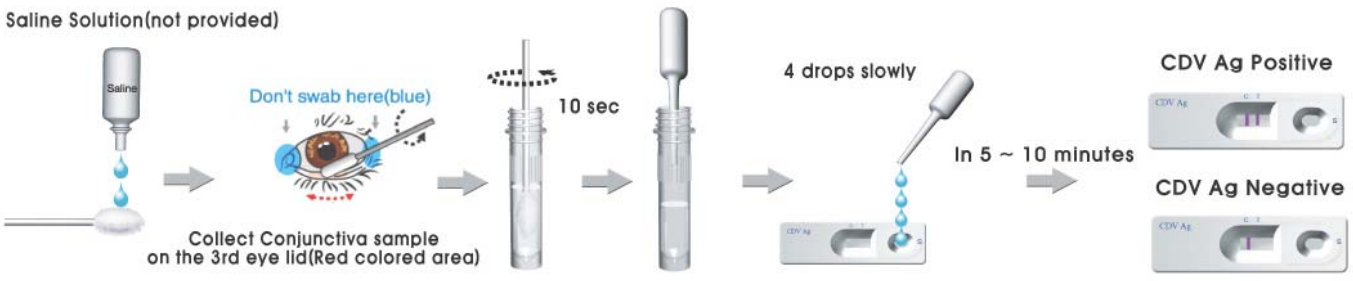
Table 3) Specificity comparison result with RT-PCR

No of Specimen	Anigen Rapid CDV Ag	RT-PCR
132	129/132(98.5%)	132

Special Features

- High sensitivity : 99.9%
- Excellent tool to predict the prognosis of a CDV infected dog during treatment (weak Test line intensity indicates a decrease in viral load)
- Rapid test result : 10 minutes
- No detection of CDV from vaccinations
- Detects all strains of CDV
- Detection of CDV in serum 3 days post infection
- One step testing procedure: Easy to use, saving time and labor
- No additional equipment is required

Test Procedures



Rapid Test Kit

CDV/CAV Ag

How do you differenciate CAV from CDV?

Background

Canine distemper is a highly contagious and often fatal disease in dogs, and is transmitted through contact with mucous and watery secretions discharged from the eyes and noses of infected dogs.

The canine adenovirus has two types of virus that can be and harmful to dogs, Type 1 is highly contagious and the cause of ICH(Infectious Canine Hepatitis) that results in damage to the liver, kidney and eyes, type 2 causes kennel cough that affects respiratory organs.

The Anigen CDV/CAV Ag Rapid Test Kit can discriminate between this two diseases when they are both suspected in a dog showing

[Differentiation between CDV and CAV]

Disease / Symptoms	CDV	CAV
Fever	Transient fever	High fever, Severe cough
Tonsils	Showing clinical sign at terminal stage	Acute tonsilitis
Clinical sign	Encephalitis, Pneumonia	Leukoma, Pneumonia
Neurologic	Yes	No
Inclusion body	Form within the cytoplasm of nerve cell	Form within the nucleus of liver , cell and endothelium
The Route of infection	Droplet infection, airborne infection	Respiratory infection
Mortality	50%	Less than 10%, Death at the beginning of disease

Specifications

- Principle : Chromatographic immunoassay
  Monoclonal anti - CDV (Capture) – **CDV**
  – Monoclonal anti - CDV (Detector)
  Monoclonal anti - CAV (Capture) – **CAV**
  – Monoclonal anti - CAV (Detector)
- Purpose : Simultaneous detection and differentiation of Canine Distemper virus antigen and Adenovirus antigen
- Specimen : Conjunctiva and Nasal fluid
- Reading time : 10 minutes
- Sensitivity : CDV-97%, CAV-96.3%
- Specificity : CDV-97%, CAV-97.8%
- Shelf life : 24 months
- Storage temperature : 2~30°C
- Packing size : 10 Tests/Kit
- CAT. No.: RG11-08

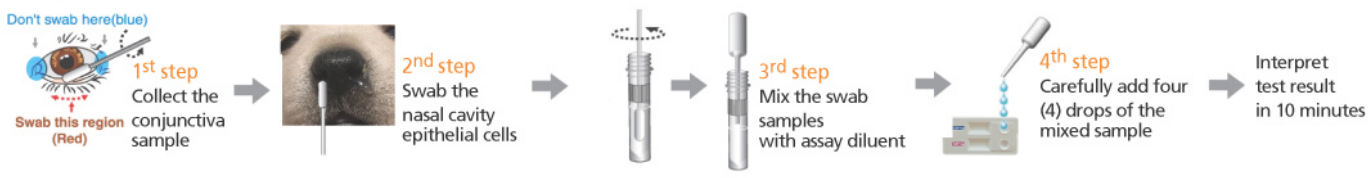
Clinical study of CAV Ag Test

1. Specimen: Canine adenovirus suspected 61 samples (Secretion of eye and nasal discharge) from the local animal hospital.
2. Gold standard : RT-PCR for Adenovirus

Sensitivity: 94% Specificity: 97%

		Anigen Adenovirus Ag test kit		Total
		Positive	Negatve	
RT-PCR	Positive	11	7	18
	Negatve	6	37	43
	Total	17	44	61

Test procedures



Rapid Test Kit

CCV Ag

Anigen Rapid CCV Ag Test Kit is a solid phase chromatographic immunoassay for the qualitative detection of canine coronavirus antigen in canine feces.

Background

Canine Coronavirus causes sporadic outbreaks of vomiting and diarrhea in dogs, very similar symptoms to a Canine Parvovirus infection. CCV is widely distributed throughout the world, with a sero-prevalence of 25 ~ 54% in family dogs and 80~100% in kennel dogs. The virus is excreted in a dogs feces from the first sign of clinical symptoms. Infections in 1~3 month old puppies have a poor prognosis and if simultaneous infections with CPV occur, the disease is more severe and often fatal, making the detection of a Canine Coronavirus infection very important.

Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - Monoclonal anti-CCV (Capture) - CCV - Monoclonal anti-CCV (Detector)
- Purpose: Detection of canine coronavirus antigen
- Specimen: Canine feces
- Reading time: 5 -10 minutes
- Sensitivity: 93.1% vs. Nested PCR
- Specificity: 97.5% vs. Nested PCR
- No cross reaction with CPV, CDV, Parainfluenza virus, ICH, PI2, other parasites
- Detection limit: $10^{5.0}TCID_{50}$/ml
- Shelf life: 24 months
- Storage temperature: 2 ~ 30°C
- Packing size: 10 Tests/Kit
- CAT. No.: RG11-04

Sensitivity and Specificity Study

		Nested PCR			
		Positive	Negative	Total	Sensitivity: 93.1%(54/58)
Anigen CCV Ag	Positive	54	3	57	Specificity: 97.5%(118/121)
	Negative	4	118	122	
	Total	58	121	179	

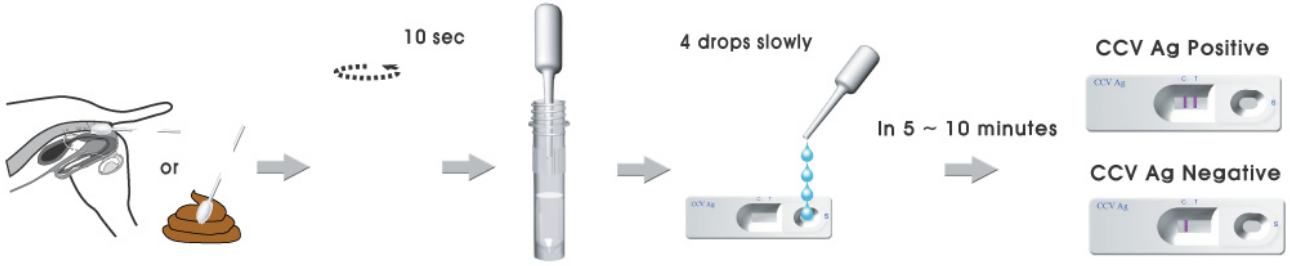
Cross Reaction Study

Pathogen	Titer	Results
Canine distemper virus	$10^{4.5}$ EID50/ml	Negative
Canine parvovirus	10^{7}TCID50/ml	Negative
Canine parainfluenza virus	$10^{5.5}$TCID50/ml	Negative
Canine hepatitis virus	10^{5}TCID50/ml	Negative
Transmissible Gastroenteritis virus	10^{6}TCID50/ml	Negative
Leptospira canicola	OD8.0 at 560nm	Negative
20% Ascaris homogenates	-	Negative
Giardia cyst suspension	-	Negative
E. coli spp.	$10^{8.0}$CFU/ml	Negative
Canine coronavirus D2	$10^{6.1}$TCID50/ml	Strong Positive

Special Features

- World's first CCV Ag rapid test
- Excellent tool for prognosis:
  (1) CPV/CCV dual infections are often fatal
  (2) CCV only infection has a good prognosis
  (3) CPV only infection has a poor prognosis
- Increased customer's satisfaction aids diagnosis and clinical decisions
- No detection of CCV from vaccinations
- Rapid test result: 10 minutes
- One step testing procedure: Easy to use, saving time and labor
- No additional equipment is required

Test Procedures



Rapid Test Kit

CPV/CCV Ag

Anigen Rapid CPV/CCV Ag Test Kit is a solid phase chromatographic immunoassay for the simultaneous qualitative detection and differentiation of Canine Parvovirus antigen and Coronavirus antigen in canine feces.

Background

Canine Parvovirus and Coronavirus cause sporadic outbreaks of vomiting and diarrhea in dogs, and are widely distributed throughout the world. The rate of simultaneous infection of CPV and CCV is up to 25% of CPV infections (Evermann 1989). If a simultaneous infection with CPV occurs, it would be more severe than a single virus infection and often fatal. The clinical signs of CCV are usually mild to severe enteritis and a dog will usually recover, however deaths have been reported in young pups. The clinical signs of CPV and CCV are very similar (diarrhea and vomiting) making it difficult to differentiate which virus is the causative agent by clinical signs alone.

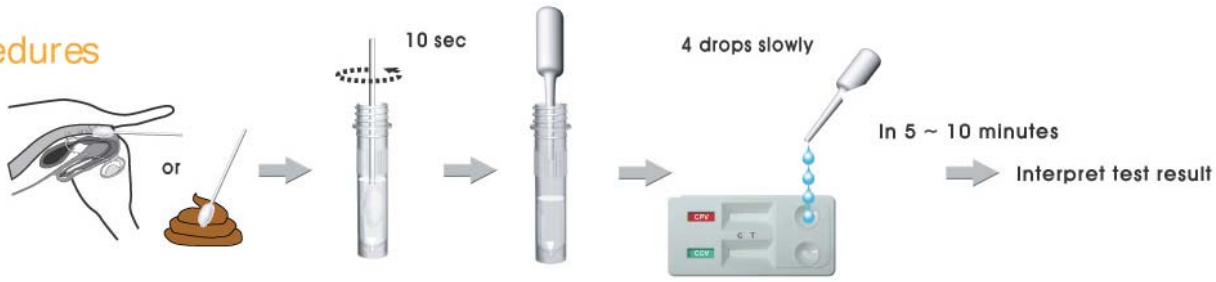
Specifications

- Principle: Immunochromatographic assay using Direct Sandwich Method
  - Monoclonal anti-CPV (Capture) - CPV - Monoclonal anti-CPV (Detector)
  - Monoclonal anti-CCV (Capture) - CCV - Monoclonal anti-CCV (Detector)
- Purpose: Simultaneous detection and differentiation of Canine parvovirus antigen and Coronavirus antigen
- Specimen: Canine feces
- Reading time: 5 - 10 minutes
- Sensitivity: (1) CPV Ag - 100% (CPV 2, CPV 2a, CPV 2b) vs. HA Test
  (2) CCV Ag - 93.1% vs. nested PCR
- Specificity: (1) CPV Ag - 98.8% vs. HA Test
  (2) CCV Ag - 97.5% vs. nested PCR
- No cross reaction with CDV, ICH, PI2, other parasite
- Detection limit: (1) CPV Ag - $10^{3.0}$ $TCID_{50}$/ml (2) CCV Ag- $10^{5.0}$ $TCID_{50}$/ml
- Shelf life: 24 months
- Storage temperature: 2 ~ 30°C
- Packing size: 10 Tests/Kit
- CAT. No.: RG11-05

Special Features

- Simultaneous detection of CPV Ag and CCV Ag with one specimen preparation ⇒ aids a veterinarian in the choice of treatment
- Excellent tool for prognosis:
  (1) CPV/CCV dual infections are often fatal
  (2) CCV only infection has a good prognosis
  (3) CPV only infection has a poor prognosis
- Cost effective
- World's first CPV Ag and CCV Ag combo test
- No detection of CPV and CCV from vaccinations
- Rapid test result: 10 minutes
- One step testing procedure: Easy to use, saving time and labor
- No additional equipment is required

Test Procedures



Interpretation of the result

1) Negative result

2) Simultaneous CPV and CCV Positive result

3) CPV Positive result

4) CCV Positive result

Rapid Test Kit

CPV Ab, CDV Ab

Anigen Rapid CPV Ab and CDV Ab Test Kit are solid phase chromatographic immunoassays for the rapid, semi qualitative detection of IgG antibodies to parvovirus and distemper virus in canine serum, plasma or whole blood.

Background

Vaccination at less than 6 weeks of age is often not effective due to interference of vaccinal immunity because maternally derived antibodies are at a high enough concentration to interfere with vaccination and a small percentage of pups (<5%) fails to develop enough immunity to certain CDV vaccines and a higher percentage of pups (<17%) fails to develop enough immunity to certain CPV vaccines. Routine measurement of CPV and CDV-specific antibodies is based on hemagglutination-inhibition (HI) test for CPV Ab and serum neutralization assays (SN) for CDV Ab, which are costly as well as time-consuming (at least 4 days) and require specialized laboratories. Anigen succeeded to develop more convenient and accurate rapid test kit for the detection of CPV (CDV) - specific antibody (IgG)

During treatment for CPV or CDV infection, the antibody titer is increased and virus titer is decreased. It means that IgG titer is the probe of the prognosis of the virus infected dog.

Specifications of CPV Ab Test Kit

- Principle: Immunochromatographic assay using In Direct Sandwich Method
  - (Anti-canine IgG capture) - (CPV IgG) - (CPV) - (CPV Monoclonal Ab detector)
- Purpose: Canine parvovirus antibody (IgG) titration in Canine blood
- Specimen: Canine serum, plasma, or whole blood
- Reading time: 20 minutes
- Sensitivity: 98% vs. Hemagglutination-Inhibition (HI)
- Specificity: 100% vs. Hemagglutination-Inhibition (HI)
- Detection limit: <1:10 HI
- Shelf life: 24 months
- Storage temperature: 2~30˚C
- Packing size: 10 Tests/Kit
- CAT. No.: RB21-01 (CPV Ab)
- CAT. No.: RB21-02 (CDV Ab)

Specifications of CDV Ab Test Kit

- Principle: Immunochromatographic assay using In Direct Sandwich Method
  - (Anti-canine IgG capture) - (CDV IgG) - (CDV) - (CDV Monoclonal Ab detector)
- Purpose: Canine distemper virus antibody (IgG) titration in canine blood
- Specimen: Canine serum, plasma, or whole blood
- Reading time: 20 minutes
- Sensitivity: 85% vs. Serum Neutralization (SN)
- Specificity: 100% vs. Serum Neutralization (SN)
- Detection limit: <1: 2 SN
- Shelf life: 24 months
- Storage temperature: 2~30˚C
- Packing size: 10 Tests/Kit

Special Features

- For serological diagnosis of CPV and CDV infection
- For prediction of the prognosis of CPV and CDV patient
- For evaluation of immune status of puppies after vaccination
- For determination of the proper time of vaccination by measuring a maternal antibody titer
- For determination of the proper time of revaccination
- World's first CPV Ab and CDV Ab titration rapid immunochromatographic test kit
- One step testing procedure: Easy to use, Saving time and labor
- No additional equipment is required

Comparison data of Anigen Rapid CPV Ab Kit with HI Test

Anigen Rapid CPV Ab Test Kit showed good correlation with hemagglutination-inhibition (HI) test.

Titer of HI Test	Anigen Rapid CPV Ab Test Kit
<1:10	-
1:10	+/-
1:20	+
1:40	+
1:80	++
1:160	++
1:320	++
1:640	+++

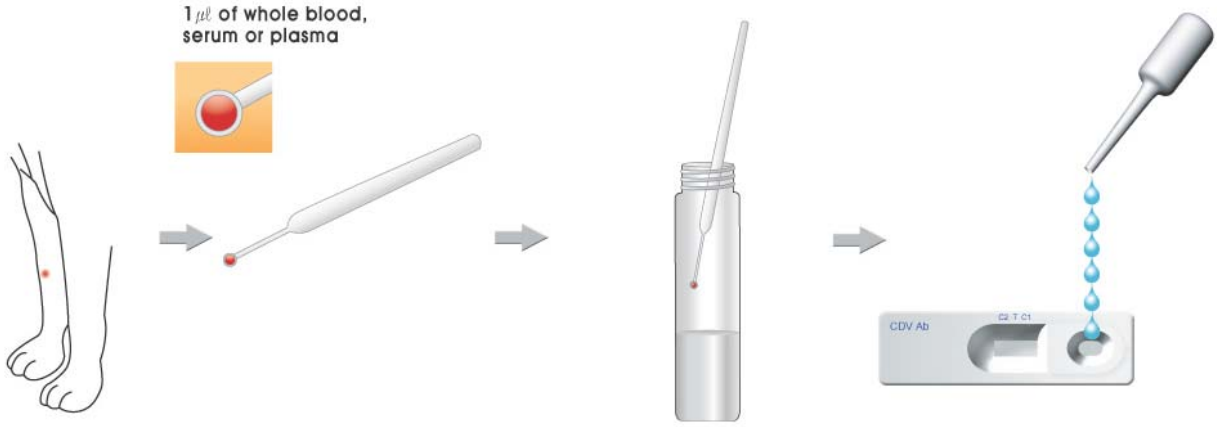
+: The strength of T line is lower than that of C1 line.
++: The strength of T line is between C1 and C2 line
+++: The strength of T line is higher than that of C2 line

Comparison data of Anigen Rapid CDV Ab Kit with SN Test

Anigen Rapid CDV Ab Test Kit showed good correlation with serum neutralization (SN) test.

Titer of SN Test	Anigen Rapid CPV Ab Test Kit
<1:2	-
1:2	+/-
1:4	+
1:8	+
1:16	++
1:32	++
1:64	++
1:128	+++
1:256	+++

Test Procedures



1. Collect 1ul of the sample by a circular end of the loop. 2. Carefully place the circular end of the loop into the test tube. This will add 1㎕.
3. Add six(6) drops of specimen - assay diluent mix into the "S" hole using disposable dropper.

Result Interpretation Table of Anigen Rapid CPV Ab and CDV Ab Titer Test Kit

	Titer	Line Color Intensity	What to do ? Pre-vaccination	What to do ? Post-vaccination	Prognosis ? In early infection phase	Prognosis ? In later infection phase
1	CPV HI Below 20 CDV SN Below 4	C2 T C1 — No or Faint T line	Immediate vaccination	Additional vaccination	Highly critical (Retest 2~3 days later)	Highly critical (Retest 2~3 days later)
2	CPV HI 40 CDV SN 8	C2 T C1 — The strength of T line is lower than C1 line.	Immediate vaccination	Additional vaccination	Highly critical (Retest 2~3 days later)	Highly critical (Retest 2~3 days later)
3	CPV HI 80 CDV SN 16	C2 T C1 — The strength of T line is same with C1 line.	Immediate vaccination	Additional vaccination	Highly critical (Retest 2~3 days later)	Highly critical (Retest 2~3 days later)
4	CPV HI 160 CDV SN 32	C2 T C1 — The strength of T line is between C1 and C2 line.	Vaccination 10 days later	Vaccinated (Additional vaccination or retest 6 months later)	50% chance of recovery	50% chance of survival
5	CPV HI 320 CDV SN 64	C2 T C1 — The strength of T line is between C1 and C2 line.	Vaccination 20 days later	Vaccinated (Retest 1 year later)	80% chance of recovery	80% chance of survival
6	CPV HI Over 640 CDV SN Over 128	C2 T C1 — The strength of T line is higher than C2 line.	Vaccination 30 days later	Vaccinated (Retest 1 year later)	90% chance of recovery	90% chance of survival

Rapid Test Kit

C.Brucella Ab

Anigen Rapid C. Brucella Ab Test Kit is a solid phase chromatographic immunoassay for the qualitative detection of *Brucella canins* antibody in canine blood.

Background

The causative agent of canine brucellosis is Brucella canis. Any bodily fluids can infect another dog and human. The most common sign of brucellosis infection in a healthy-appearing bitch is abortion between days 45 to 59 of gestation. When an infected bitch aborts, spread throughout a kennel can be very rapid. Kennels with active stud dogs should never breed a male to an untested female. Unfortunately, there is no vaccine available for the prevention or treatment of brucellosis. If a dog or bitch in the main kennel area shows positive test result for brucellosis, the entire kennel must be tested. Several tests should be done on each dog, each one a month apart, to make sure that all positive animals are identified, and then immediately destroyed and properly disposed of.

Specifications

- Principle: Immunochromatographic assay
  - (LPS capture)-(blood)-(Monoclonal anti-canine IgG detector)
  ⇒ LPS (Lipopolysaccharide) antigen originated from Brucella canis
- Purpose: Detection of Brucella canins antibody
- Specimen: Canine whole blood, plasma, or serum.
- Reading time: 20 minutes
- Sensitivity: 93% vs. blood culture
- Specificity: 100% vs. blood culture
- Shelf life: 24 months
- Storage temperature: 2~30˚C
- Packing size: 10 Tests/Kit
- CAT. No.: RB21-03

Study I. Comparison Test of Anigen C. Brucella Ab test kit and 2-ME RSAT, Blood culture in the 742 specimens from kennels where C. Brucellosis

No. of positive result		
2-ME RSAT	Anigen Rapid Test	Blood Culture
254/742(34.2%)	248/711(34.9%)	118/483(24.4%)

Special Features

- Earlier detection of C. Brucella Ab than blood culture and 2-ME RSAT
- World's first & sole C.brucella Ab Rapid Test Kit
- One step testing procedure: Easy to use, Saving time and labor
- No additional equipment is required

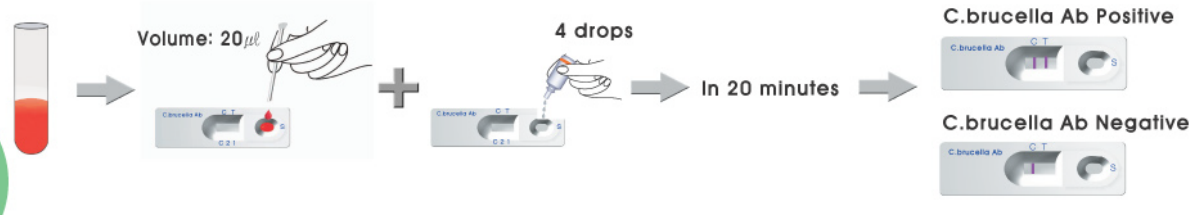
<Comparison Table of Anigen Rapid Test VS. 2-ME RSAT>

	Anigen C.Brucella Ab Rapid Test	2-ME RSAT	Anigen's benefit
Principle	Chromatographic Immunoassay	Slide Agglutination Test	Advanced
Specimen	Whole blood, serum, plasma, available	Serum	All specimen are available
Reading Method	Positive : 2 lines Negative : 1 line	Eye observation may make difficulty to interpret the agglutination	Simple
Required testing time	20 Minutes	Minimum one day due to acquiring of serum specime	Time saving

Study II. Comparison Test of Anigen C. brucella Ab test kit and 2-ME RSAT, Blood culture in challenge-infected dogs.

Post challenge /weeks	Blood Culture			2-ME RSAT			Anigen in whole blood			Anigen in serum		
	Patient's No.			Patient's No.			Patient's No.			Patient's No.		
	1	2	3	1	2	3	1	2	3	1	2	3
4th day	-	-	-	-	-	-	-	-	-	-	-	-
1st week	+	-	-	-	-	-	-	-	-	-	-	-
2nd week	+	-	-	-	-	-	+	-	-	+	-	+
3rd week	+	-	-	+++	-	-	+++	-	++	+++	+	+
4th week	+	-	+	+++	-	-	+++	-	+	+++	+	+
5th week	+	+	+	+++	-	+	+++	-	++	+++	+	+++
6th week	+	+	+	+++	+	+	+++	-	++	+++	+	+++
7th week	+	+	+	+++	++	+	+++	+	+++	+++	+	+++
8th week	+	+	-	+++	+++	+	+++	+	+++	+++	++	++

Test Procedures



Rapid Test Kit

Rabies Ag

Anigen Rapid Rabies Ag Test Kit is a solid phase chromatographic immunoassay for the qualitative detection of Rabies virus antigen in canine, bovine, raccoon dog s secretions of saliva, and brain homogenates.

Background

Rabies is an acute viral disease that can be transmitted from wild animals to unvaccinated pets and livestock, as well as to humans. It is caused by the rabies virus, which is present in the saliva of infected animals, and is transmitted through infected secretions. The virus cannot live outside its host's body for more than a couple of seconds, but live virus has been found in animals that have been dead as long as 48 hours. Once infection occurs, the virus spreads to the central nervous system and causes inflammation in the brain (acute encephalitis). It is transmitted by viral contamination of a fresh wound, through a scratch, or through contamination of a mucous membrane (i.e., eyes, nose, mouth). Rabies kills more than 35,000 people every year, mostly in Asia, Africa, and Latin America. The current diagnosis of Rabies is not easy because the specialized technique, equipment, time & cost are required.

Specifications

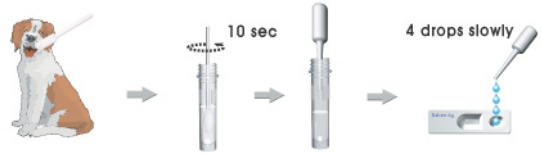
- Principle: Immunochromatographic assay using Direct Sandwich Method
  - Monoclonal anti - Rabies virus (capture) - Rabies Virus - Monoclonal anti-Rabies virus (detector)
- Purpose: Detection of rabies virus antigen
- Specimen: Canine, bovine, raccoon dog's secretions of saliva, and 10% brain homogenates.
- Reading time: 5 -10 minutes
- Sensitivity: 94.4% vs. RT-PCR, 100% vs. FAT
- Specificity: 100% vs. RT-PCR, 100% vs. FAT
- No cross reaction with CDV, Pseudorabies virus, Porcine Encephalo myocarditis virus, Infectious Bovine Rhinotracheitis virus, and Japanese Encephalitis virus.
- Detection limit: $10^{1.7}$ LD_{50}/0.03ml
- Shelf life: 24 months
- Storage temperature: 2~30°C
- Packing size: 10 Tests/Kit
- CAT. No.: RG18-01

Special Features

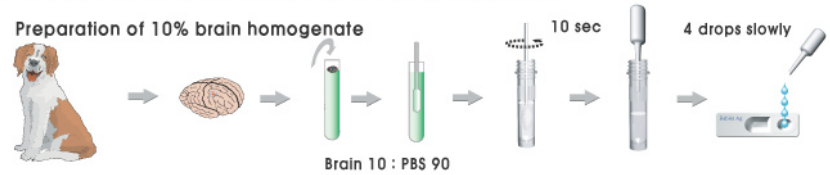
- Good detection limit:
  - Anigen Rabies Ag Test: $10^{1.7}$ LD_{50}/0.03ml - RT- PCR: $10^{0.5}$ LD_{50}/0.03ml
- Good specificity (100%) and no cross reaction against other viruses
- Rapid test result : 10 minutes ➡ It is suitable for emergency testing.
- One step testing procedure: Easy to use, Saving time and labor
- No additional equipment is required

Test Procedures

1) Test procedures with a saliva specimen



2) Test procedures with a 10% Brain homogenate specimen



Sensitivity and Specificity Study

1. The positive samples were 10% brain homogenates, which had been originated from 7 dogs, 5 cows and 6 raccoon dogs.
2. The negative samples were saliva, which had been swabbed from 12 cows, 29 pigs and 17 dogs

		RT-PCR			
		Positive	Negative	Total	Sensitivity: 94.4%
Anigen Rabies Ag	Positive	17	0	17	Specificity: 100%
	Negative	1	58	59	
	Total	18	58	76	

		FAT(Fluorescent Antibody Test)			
		Positive	Negative	Total	Sensitivity: 100%
Anigen Rabies Ag	Positive	21	0	21	Specificity: 100%
	Negative	0	3	3	
	Total	21	3	24	

Cross Reaction Study

Pathogens	Titer	Results
Canine distemper virus	$10^{4.5}$ $TCID_{50}$/ml	Negative
Porcine Encephalo- myocarditis virus	$10^{4.5}$ $TCID_{50}$/ml	Negative
Infectious Bovine Rhinotracheitis virus	$10^{5.5}$ $TCID_{50}$/ml	Negative
Pseudorabies virus	$10^{6.1}$ $TCID_{50}$/ml	Negative
Japanese Encephalitis virus	$10^{7.1}$ $TCID_{50}$/ml	Negative
Leptospira canicola	OD 8.0 at 560nm	Negative
E. coli spp.	$10^{8.0}$ CFU/ml	Negative
Canine coronavirus D2	$10^{6.1}$ $TCID_{50}$/ml	Negative

In 10 minutes

Rabies Ag Positive

Rabies Ag Negative

Rapid Test Kit

CIV Ag

Anigen Rapid Canine Influenza Virus Antigen Test Kit is a chromatographic immunoassay for the qualitative detection of Canine influenza virus H3 strain antigen in a canine nasal swab.

Background

It is new emerging disease for dogs. Canine Influenza is caused by a type A influenza virus. It is spreaded via aerosolized respiratory secretion and contaminated objects and people moving between infected and uninfected dogs. Clinical sign is similar to other respiratory diseases (CDV or Kennel cough) such as fever, cough, and nasal discharge. Some dogs are more severely affected with clinical signs of pneumonia, a high-grade fever and increased respiratory rate and effort. The morbidity rate associated with canine influenza is 100% and the mortality rate has ranged from 5%~8%.

[Canine Influenza Q&A]

- **When did outbreak of canine Influenza virus (CIV) recognize?**
  It is believed to have occurred in racing greyhound in January 2004 in Florida, U.S. Molecular studies indicated that canine influenza represents a mutation from Equine influenza Virus (H3N8). However, CIV was confirmed as H3N2 similar to Avian influenza virus of Asia in May 2007, Korea by the Anigen laboratory.
- **Can people be infected by canine influenza?**
  It is not an evidence of people being infected by this virus, but there may still be possible to infect human.
- **When is detected CIV Ag by Rapid kit?**
  Anigen Rapid CIV Ag test kit can detect CIV for 2 to 6 days after clinical signs. After 6 days, we recommend Anigen Rapid CIV Ab test kit for CIV diagnosis.
  • We provide also Anigen Rapid CIV Ab test kit in late phase of CIV infection.

Specifications

- Principal : Chromatographic immunoassay
  Monoclonal anti-influenza type A antibody (Capture) - CIV - Monoclonal anti-influenza type A antibody (detector)
- Purpose : Detection of CIV Ag
- Specimen : Nasal fluid
- Shelf life : 24 months
- Storage Temperature : 2~30°C
- Sensitivity : 90% Vs. PCR
- Specificity : 100% Vs. PCR
- Recommendation : Use after 2-4days of infection.
  Anigen Rapid CIV Ab test kit is useful to detect antibody after that period.
- CAT. No.: RG11-07

Sensitivity and Specificity Study

		Nested PCR		
		Positive	Negative	Total
Anigen CIV Ag	Positive	9	0	9
	Negative	1	303	104
	Total	10	303	313

Sensitivity : 90% Vs. PCR
Specificity : 100% Vs. PCR

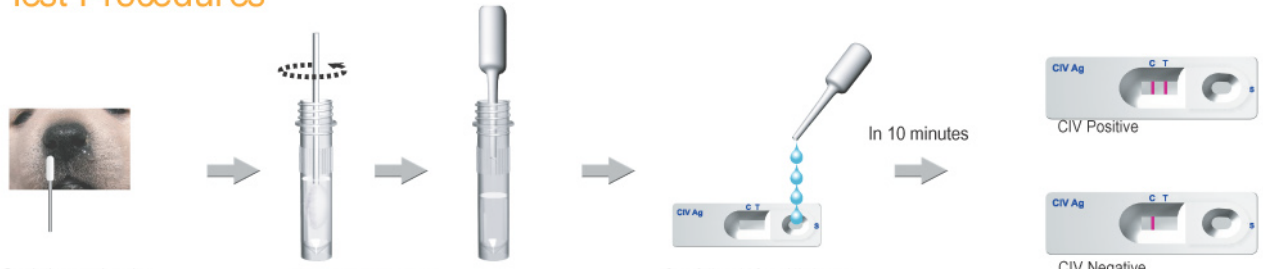
Cross Reaction Study

Pathogen	Titer	Results
Canine distemper	$10^{4.5}$ EID_{50}/ml	Negative
Canine parvovirus	10^{7} EID_{50}/ml	Negative
Canine hepatitis virus	10^{6} EID_{50}/ml	Negative
Canine parainfluenza	$10^{6.5}$ EID_{50}/ml	Negative
Boedetella bronchiseptica	$10^{10}$$EID_{50}$/ml	Negative

Special features

- Early diagnosis of CIV using rapid detection kit.
- Confirm the pathogen causing generalized respiratory symptoms.
- World's first Rapid CIV Ag test kit

Test Procedures



Swab the nasal cavity.

Mix the swab samples with assay diluent.

Carefully add four (4) drops of the mixed samples.

Rapid Test Kit

Giardia Ag

Anigen Rapid Giardia Ag Test Kit is an immunochromatographic test for the qualitative determination of Giardia lamblia in feces samples from dogs and cats.

Background

Giardia is a diarrhea causative protozoa infecting the small intestine of dogs and cats, and one of the most important pathogenic intestinal protozoa found in these animals.
Young puppies tend to be highly infected especially in group breeding situations. No specific signs are seen in adult dogs and cats, but puppies and kittens show watery or foamy diarrhea with a bad smell due to malabsorption in the intestine. Usually, Giardiosis is diagnosed by finding cysts or trophozoites by fecal microscopy, but it has very low sensitivity.
The Anigen Rapid Giardia Ag Test Kit enables detection of vegetative stages and cysts of giardia lamblia that are not detectable by microscopy.


Cyst Trophozoite

Specification

- Principle: Immunochromatographic assay
- Reading time: 5~10 minutes
- Storage temperature: Room temperature (2~30℃)
- Specimens: Diarrhea feces
- Shelf life: 24 months
- Packing size: 10Tests/Kit
- Detection limit : 125 cysts / 100㎕ of feces
- CAT. No: RG18-04

[Sensitivity and Specificity Study]

		Other commercial rapid kit		
		Positive	Negative	Total
Anigen	Positive	50	0	50
	Negative	0	150	150
	Total	50	150	200

- Sensitivity : 100% Vs. Other commercial rapid kit
- Specificity : 100% Vs. Other commercial rapid kit

Special Features

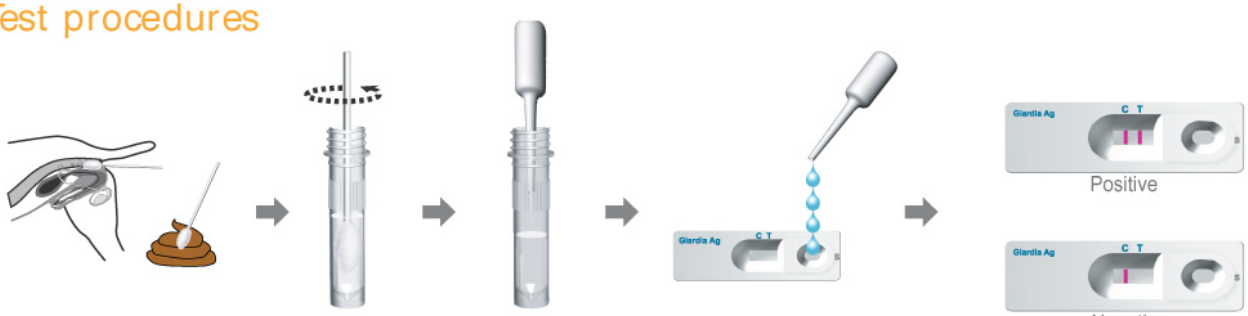
- High sensitivity and specificity
- No cross reaction with other pathogens of enteric disease
- Good differential diagnostic method for diarrhea causative agents
  - Excellent tool for prognosis
- Good detection limit
- Able to detect the pathogen in both dogs and cats
- Rapid test result within 10 minutes
- One step testing procedure : Easy to use, saving time and labor

[Cross Reaction Study]

Pathogen	Titer	Results
Canine Parvovirus	10^{7} EID_{50}/ml	Negative
Canine Distemper virus	$10^{4.5}$ EID_{50}/ml	Negative
Canine Corona virus	10^{6} EID_{50}/ml	Negative
Canine Hepatitis virus	10^{5} EID_{50}/ml	Negative

- No cross reaction with other pathogens

Test procedures



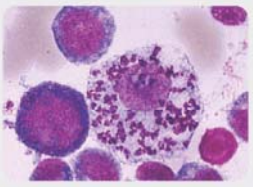
Rapid Test Kit

Leishmania Ab

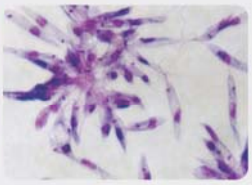
Anigen Rapid Leishmania Ab test Kit is an immunohromatographic test for the qualitative determination of Leishmania infantum antibody in blood sample.

Background

Leishmaniasis is caused by diphase protozoa of the genus Leishmania. The disease is endemic in many parts of the world including Central and South America, Africa, India, and the Mediterranean basin. The infection is transmitted by sandflies of the genus Phlebotomus in Europe, Asia, Africa and sandflies of the genus Lutzomyia in the America. Reservoirs hosts vary within different geographic areas and can include domestic or wild animals. Dogs are reservoirs for Leishmania infantum infection. Visceral leishmaniasis, the most severe disease form, is a frequent cause of clinical illness in dogs in some regions. Canine Visceral leishmaniasis is a chronic system disease. The sign of the disease are highly variable and often begin with slight but progressive dullness and insidious exercise intolerance.



Amastigotes within the cytoplasm of a macrophage



Promastigotes

Specifications

- Principle: Chromatographic Immunoassay
- Purpose: Detection of Leishmania infantum antibody
- Sensitivity: 95.6% vs IFA
- Specificity: 98% vs IFA
- Testing time: 20 minutes
- Shelf life: 24 months
- Cat. No.: RB21-04
- Specimen: Whole blood, Serum or Plasma

Performance data

• Sensitivity : 95.6% VS. IFA • Specificity : 98.0% VS. IFA

		Anigen Rapid Leishmania Ab Test kit		
		Positive	Negative	Total
IFA (Immunofluorescent antibody test)	Positive	22	1	23
	Negative	2	98	100
	Total	24	99	123

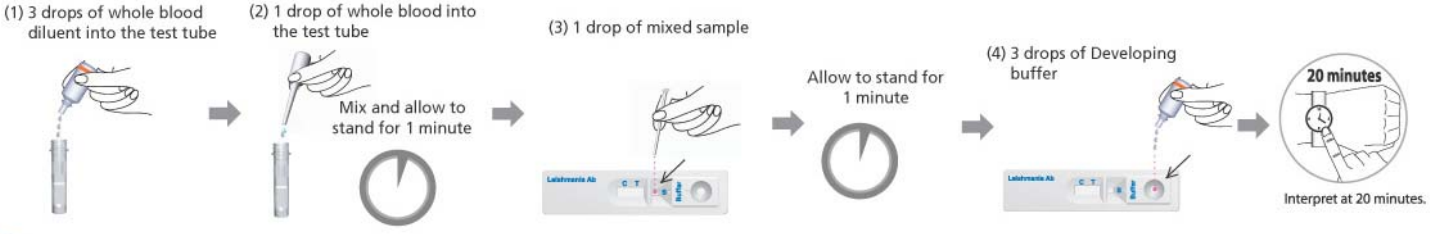
Special Features

- No special equipment or training required
- High sensitivity and specificity in whole blood, serum or plasma
- No cross reaction with another protozoan orgamism
- Rapid test result within 20minutes

Test Procedures

[Serum or Plasma]

[Whole blood]



Rapid Test Kit

E.canis Ab

Anigen Rapid E.canis Ab Test Kit is an immunochromatographic test for the qualitative determination of Ehrlichia canis antibody in blood sample.

Background

Ehrlichiosis, also known as "Tropical Canine Pancytopenia" or "Canine Rickettsiosis" is a tick-borne disease caused by obligate intracellular bacteria of the genus Ehrlichia of the family rickettsiaceae. Clinical findings in dogs with Ehrlichiosis vary with the phase of the infection. During the acute phase, nonspecific signs such as fever, oculonasal, anorexia, weight loss, dyspnea, and lymphadenopathy may occur. Clinical signs commonly seen during the chronic phase include depression, weight loss, pale mucous membranes, abdominal pain, hemorrhage, lymphadenopath, spleno-megaly, dyspnea, increased lung sounds, hepatomegaly, arrhythmias, pulse deficits, polyuria, polydypsia, and stiff, swollen, painful joints.

Specifications

- Principle : Immunochromatographic assay
  <specific E.canis Ag (Capture) - E.canis Ab in sample - Protein A - Gold conjugate (Detector)>
- Purpose : Detection of antibodies against Ehrlichia canis in serum, plasma or whole blood
- Cat. No. : RB21- 05
- Specimen : Whole blood, serum or plasma
- Reading time : 20 minutes
- Shelf life : 24 months
- Storage : 2~30℃
- Packing size : 10 Tests/kit
- Sensitivity : 97.6% vs. IFA / Specificity : 99.0% vs. IFA

Special Features

- Good correlation with IFA
- Rapid test result within 20 minutes
- Easy application for Erhlichiosis detection

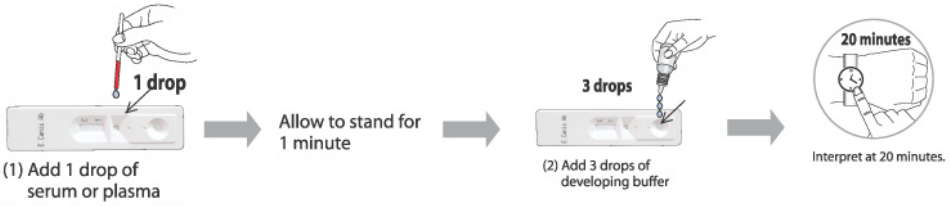
Evaluation result of Anigen E. canis Ab Test Kit compared with IFA

Reference method(IFA)	Results of Anigen E.canis Ab Test		Total No. of result
	No. of positive result	No. of negative result	
Positive	41	1	42
Negaive	2	202	204

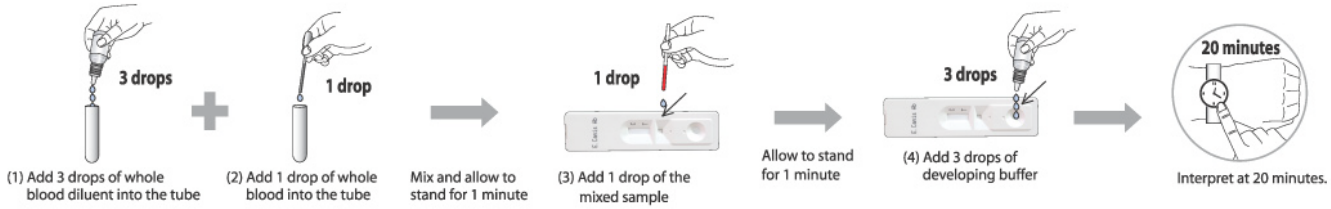
• **Sensitivity :** 97.6% • **Specificity :** 99.0% ***IFA :** Indirect immunofluorescence assay

Test procedures

[Serum or Plasma]



[Whole blood]



Rapid Test Kit

FPV Ag

Anigen Rapid FPV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Feline Panleukopenia virus antigen in feline feces.

Background

Feline Panleukopenia is caused by a non-enveloped parvovirus, which has the potential to lead to significant disease in unprotected cats of all ages. The disease is most prevalent in cats less than 1 year of age, fatalities may reach 50~90%. The queen usually remains clinically unaffected but the kittens infected in the uterus may be aborted, if they survive they may demonstrate non-progressive cerebellar dysfunction.

Specifications

- Principle: Chromatographic Immunoassay
  - Monoclonal Feline Panleukopaenia virus Ab (Capture) - FPV - Monoclonal Feline Panleukopaenia virus Ab (Detector)
- Purpose: Detection of Feline Panleukopenia Virus Ag
- Specimen: Feces
- Testing time: 10 minutes
- Sensitivity: 97% vs. RT-PCR
- Specificity: 98.5% vs. RT-PCR
- Shelf life: 24 months
- Storage temperature: 2~30℃
- Packing size: 10 Tests/Kit
- Cat. No: RG12-03

Sensitivity and Specificity Study

		Nested PCR		Total	
		Positive	Negative		
Anigen FPV Ag Rapid Kit	Positive	54	3	57	Sensitivity : 93.1%
	Negative	4	118	122	Specificity : 97.5%
	Total	58	121	179	

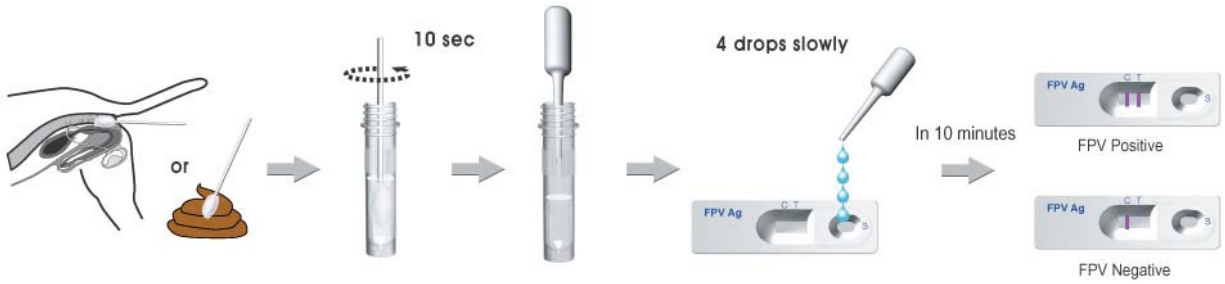
Cross Reaction Study

Pathogens	Titer	Results
Feline Infectious Peritonitis	$5x10^{3}EID_{50}$/ml	Negative
Feline Leukemia Virus	$10^{6.0}TCID_{50}$/ml	Negative
Feline Calicivirus	$10^{5.5}TCID_{50}$/ml	Negative
Feline Immunodeficiency virus	$10^{5.0}TCID_{50}$/ml	Negative

Special Features

- Simple and quick
- No need for any special equipments
- Suitable to be adopted in a clinical laboratory for screening of Feline Panleukopaenia Virus infection
- World first FPV Ag detection kit

Test Procedures



Rapid Test Kit

FIV Ab/FeLV Ag

Anigen Rapid FIV Ab/FeLV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Feline Immunodeficiency virus antibody and Feline Leukemia virus antigen in feline serum, plasma or whole blood.

Background

The Feline Leukemia Virus (FeLV) and Feline Immunodeficiency Virus (FIV) are both members of the retroviridae family of RNA viruses. Both cause severe, often fatal diseases in domestic cats and occur worldwide with prevalence varying by location. The clinical signs are mainly caused by the cats immunodeficiency and the resulting secondary infections, tumours, and haematological abnormalities. All cats should be tested for FIV and FeLV, especially those that are sick with signs that might be related to FeLV and/or FIV infection or before being introduced into a multiple-cat household.

Specifications

- Principle : Chromatographic Immunoassay
- Purpose : Simultaneous detection of Feline Immunodeficiency Virus Ab and Feline Leukemia Virus Ag
- Specimen : Whole blood, Serum or Plasma
- Testing time : 10 minutes
- Shelf life : 24 months
- Sensitivity: 96%(FIV Ab) vs. Western blot, 94%(FeLV Ag) vs. Virus isolation
- Specificity: 98%(FIV Ab) vs. Western blot, 99%(FeLV Ag) vs. Virus isolation
- Storage temperature: 2~30℃
- Packing size: 10 Tests/Kit
- CAT. No.: RC12-04

[Recommended FIV/FeLV diagnosis period]

- **FIV Ab Test :** A cat in the acute phase of infection may be antibody negative, and retesting within 6~8 weeks is warranted to establish a diagnosis in cats with a recent history that puts them at risk of exposure.
- **FeLV Ag Test :** To completely eliminate any risk to established household when bringing in a new cat. A follow-up test should be performed at least 90 days after the initial test or possible exposure to FeLV, because cats may be in the early stage of infection at the time of the first test.
- **Kitten :** FIV Ab tests have to be interpreted carefully in kittens less than 6 months of age. Kittens up to 12 weeks of age can have passively acquired anti-FIV antibody from mothers that are infected or have been vaccinated. If the kittens have a FIV positive result, the kitten should be retested after 8~12weeks. If FIV negative, the kitten is unlikely to be infected, if still positive it is probably infected.
  FeLV Ag can be tested at any age, If the mother is FeLV positive, the kitten may test positive at birth.
- **Vaccine :** Commercial FIV Ab tests can not distinguish between vaccinated cats and infected cats. However, FeLV vaccines do not influence FeLV Ag tests.

Comparison with other commercial kits

	Anigen	
Principle	Immunochromatographic Assay	A company ELISA
Storage	Room Temperature	2~8°C
Test procedure	2 steps	4 steps
Interpretation	Clear	Confused

Sensitivity and Specificity Study

[Anigen Rapid FIV Ab Test]

	Western Blot	Anigen	A company	B company
Positive	31	30	29	30
Negative	262	263	264	263

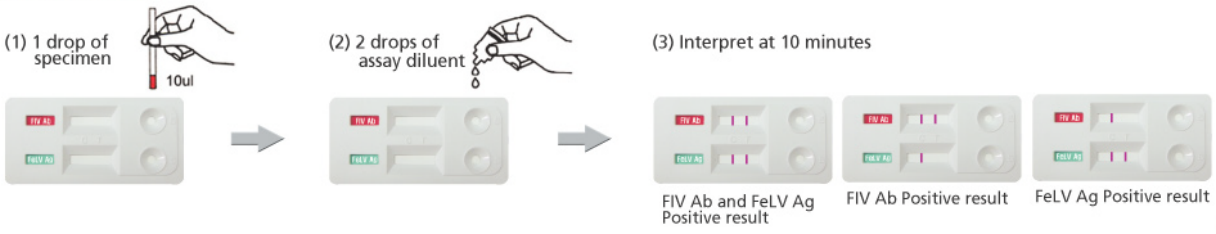
- Anigen Rapid FIV Ab Test Sensitivity : 96.8% Vs Western Blot
- Anigen Rapid FIV Ab Test Specificity : 99.6% Vs Western Blot

[Anigen Rapid FeLV Ag Test]

	Virus isolation	Anigen	A company	B company
Positive	19	18	17	17
Negative	301	302	303	303

- Anigen Rapid FeLV Ag Test Sensitivity : 94.7% Vs Virus isolation
- Anigen Rapid FeLV Ag Test Specificity : 99.7% Vs Virus isolation

Test Procedures



Rapid Test Kit

FCoV Ag

Anigen Rapid FCoV Ag Rapid Test Kit is an immunochromatographic assay for the qualitative detection of feline corona virus antigen in feline feces.

Background

The Feline Coronavirus is in group I of Coronaviridae, the same group as Transmissible Gastroenteritis Virus (TGEV), porcine respiratory coronavirus and Canine Coronavirus (CCV). Cats become infected with FCoV by ingestion and possibly by inhalation, and transmission is done through indirect contact with virus containing feces or fomites. The virus remains in the cat population by chronic carrier and through re-infection of transiently infected cats. In the early stage of infection, it may be found in saliva for hours or days and possibly in the respiratory secretions and urine.

[The Clinical signs of FCoV infection]

- Feline Coronaviral Enteritis (FECV)
  - Transient and clinically mild diarrhea, vomiting, or both
- Feline Infectious Peritonitis (FIPV)
  - Effusive(Wet) : ascites, thoracic effusion, or both
  - Non effusive(Dry) : mild pyrexia, weight loss, dullness, and depressed appetite

Specifications

- Principle : Chromatographic Immunoassay
- Purpose : Detection of Feline Coronavirus Ag
- Specimen : Feces
- Testing time : 10 minutes
- Shelf life : 24 months
- Packing size : 10 Tests/Kit
- Storage temperature : 2~ 30℃
- CAT. No. : RG12-02

Sensitivity and Specificity of Anigen Rapid FCoV Ag test kit compared with PCR Kit

	Anigen Rapid FCoV Ag	PCR	No. of Specimen
Positive	42	44	42
	2	0	2
Sensitivity	42/44(95.5%)	44/44	44
Negative	89	90	89
	1	0	1
Specificity	89/90(98.8%)	90/90	90

Total Results compared with a commercial PCR Kit

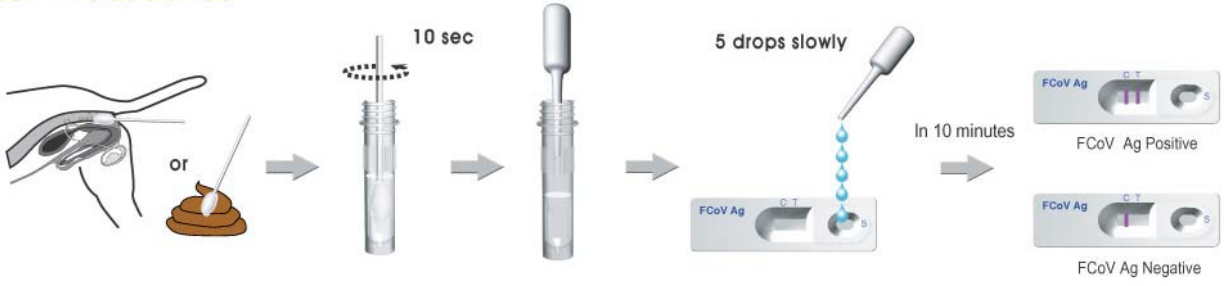
	Sensitivity	Specificity89
Anigen Rapid FCoV Ag Test Kit	95.5%(42/44)	98.8%(89/90)

Use of Feline corona virus antigen Tests
FCoV antigen test is just confirming the presence of FCoV in cats.The presence of FCoV anitigen in cats means risk of exposure to FIP, not FIP infection

Special Features

- Simple, quick
- No need for any special equipments
- Suitable to be adopted in a clinical laboratory of basic hospital for screening of Feline Coronavirus infection

Test Procedures



Rapid Test Kit

FCoV Ab

Anigen Rapid FCoV Ab Test Kit is an immunochromatographic test for the qualitative determination of Feline Coronavirus antibody in blood.

Background

It is now believed that all natural FCoV infections have the potential to cause FIP, although they do so in only approximately 10% of infected cats. Most of initial feline coronavirus infections are subclinical showing upper respiratory tract signs or diarrhea, meanwhile enteritic FCoV can cause transient and clinically mild diarrhea and vomiting in cats.

[Feline infectious peritonitis; FIP]

There are two basic forms of FIP-effusive(wet) and FIP-noneffusive(dry) have been characterized. Cats with effusive FIP usually only survive a few days-weeks at best. Cats with noneffusive FIP can survive for weeks or months, although after neurologic signs begin death usually occurs rapidly.

Specifications

- Principle: Immunochromatographic assay
- Reading time: 10 minutes.
- Storage: At room temperature (2~30℃)
- Specimen: Whole blood, serum or plasma.
- Shelf life: 24 months
- Packing size: 10 Tests/kit
- CAT.No. : RB22-03

Sensitivity & Specificity

		Anigen Rapid FCoV Ab Test kit		
		Positive	Negative	Total
IFA (Immunofluorescent antibody test)	Positive	49	2	51
	Negative	2	96	98
	Total	51	98	149

- Sensitivity : 96.0% VS. IFA
- Specificity : 97.9% VS. IFA

Special Features

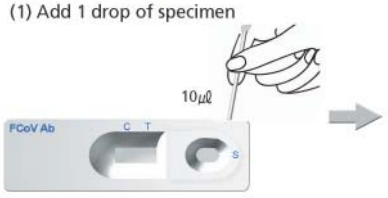
- Easy application tool for diagnosis of feline infectious peritonitis (FIP)
  * FCoV Ab test is only one parameter for the diagnosis of FIP.
- Good correlation with IFA

[How to do FIP diagnosis with Rapid FCoV Ab test]

- Many healthy cats and the cats with conditions other than FIP are FCoV Ab positive.
- Some cats with effusive FIP appear to have low titers or are FCoV Ab negative.
- FCoV Ab testing should only be performed to diagnose FIP in conjunction with a compatible history, clinical signs, and examination of effusions or blood for high globulins and a low A:G ratio.

Test Procedures

(1) Add 1 drop of specimen



(2) Add 3 drops of assay diluent

(3) Interpret at 10 minutes.

Comming soon

Canine Blood Glucose Monitoring System

Anigen Check

Description

Testing dog's blood glucose regularly helps him or her better manage diabetes. Medical studies show that, with veterinarian's care, they may be able to be managed the glucose to near normal levels. This can prevent or slow the development of diabetes complications.
Anigen-CHECK test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electic current. The amount of current that is created depends on how much glucose is in the blood.
Anigen-CHECK meter measures the current that is created and converts the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on the system's monitor display. By touching a drop of blood to the tip of the Anigen-CHECK test strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the Anigen-CHECK meter start to measure the blood glucose level. It is a simple and practical system for the regularly monitoring of dog's blood glucose level.

The reasons why dog needs "Anigen - Check"

- The Anigen check have adapted to accurate measure blood glucose level in dogs. Several problems exist when trying to use human glucose strips to measure whole blood glucose levels in dog.
- The difference in the meter value and the actual value is dependent on the meter manufacture's membrane selection and time setting.
- We will continue to support the system with validated glucostrips.
- The difference of biochemical index between human and dog.
  - Hematocrit(PCV) level of the blood - Human : 35~50%(men), 36~45%(women)/ Dog: 43~59%(male), 39~55%(female)
  - Partial blood pressure of the oxygen(pO2) level - Blood collection from capillary vessel in human : pO2 70~80mmHg
    - Blood collection from vein in dog : pO2 40mmHg

Advantages

Glucometer only for dog

- Use a small blood sample(0.9㎕)
- Fast (approximately 5 seconds)
- Accurate at low levels
- An audible beep signals when strip is full

Characteristics of Glucometer

- Broad system measurement range: 20 ~ 600 mg/dL
- Minimal deviation among meters
- Less electricity consuming
- Minimize the result difference by temperature
- Soft test strip slot
- Code chip calibration
- 400 tests memory and indexing

Characteristics of Test Strip

- Whole gold electrode strip (broad reaction region)
- Rapid blood inhalation
- Small blood sample(0.9㎕) size
- Blood drawn on the head of test strip (convenient for Right-handed and Left-handed user both)
- Less effect of oxygen saturation

Common indication of glucose level changes

- Polyuria, Polydipsia, Polyphagia
- Weakenss
- Coma
- Behavioral change
- Seizure (partial or complete)

Clinical Evaluation Data

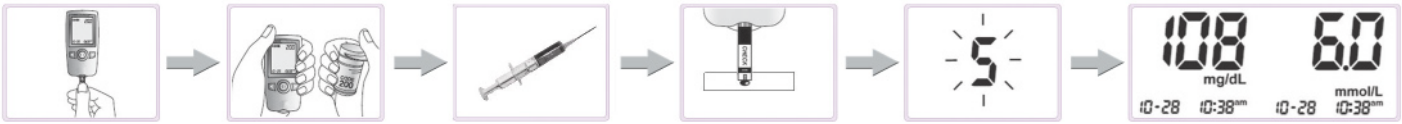
[Regression analysis]

BGMS	Intercept	Slop	r	n
Anigen Check	-1.5	1.03	0.98	175
Product A	-20.7	0.75	0.95	175
Product S	-19.3	0.87	0.98	175

Regression analysis were calculated for each potable blood glucose meter vs. the IDEXX® vetest 8008.

- BGMS = Blood Glucose Monitoring System
- r = Correlation coefficient
- n = Sample numbers (175 venous whole blood samples for PBGM and 175 Plasma samples for the IDEXX® vetest 8008 from 102 dogs)

Test Procedures



Insert strip
Meter turns on automatically

Check the code number displayed on the meter matches the code number on the test strip container

Collect blood using a syringe

Drop the blood on clean paper.
Apply blood drop to the edge of the test strip and the blood is drawn into the test strip

The display counts down from 5 seconds to 1 second and the result appears on the display in just 5 seconds

The blood glucose result is displayed in mg/dl or mmol/L and stored in the meter's memory

CURRENT AVAILABLE PRODUCT LIST

ISO 9001&ISO 13485 certified

BIONOTE

← 접는선 안쪽부분

Rapid Test	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 CAV Ag Test Kit	RG11-06	Device	1Test x 10/Kit	Detection of Canine adenovirus antigen	conjunctiva or urine
		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 Rabies Ag Test Kit	RG18-01	Device	1Test x 10/Kit	Detection of Rabies virus antigen	Saliva & brain homogenates
		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 E.canis Ab Test Kit	RB21-05	Device	1Test x 10/Kit	Detection of E.canis antibody	Whole blood, plasma or serum
		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 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 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	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 AIV Ag Test Kit	RG15-01	Multidevice	1Test x 30/Kit	Detection of Avian influenza type A virus 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
		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 Ag/NDV Ag combo 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 type A/H5 AIV Ag combo 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 NDV Ag Test Kit	RG15-03	Device	1Test x 10/Kit	Detection of Newcastle Disease virus antigen	Cloaca Feces, Trachea 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

ELISA Kit	Species	Product	Cat. No.	Type	Packing Size	Description	Sample
Industrial Animal		Bovine Brucella Ab ELISA	EB43-02	Microplate	960 wells/Kit	Detection of Brucella abortus antibody	Serum, Plasma, Raw milk
		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
			EB48-51		96 wells/Kit		
		BTB Ab ELISA	EB43-03	Microplate	480 wells/Kit	Detection of Mycobacterium bovis antibody	Serum
		AIV Ag ELISA	EG35-02	Microplate	480 wells/Kit	Detection of avian influenza type A virus antigen	Diarrhoea faeces, Cloaca Feces, Trachea swab
			EG35-52		96 wells/Kit		
		H5 AIV Ag ELISA	EG35-03	Microplate	480 wells/Kit	Detection of avian influenza type A subtype H5 virus antigen	Diarrhoea faeces, Cloaca Feces, Trachea swab
			EG35-53		96 wells/Kit		
		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		
		Velo NDV Ab ELISA	EB45-01	Microplate	480 wells/Kit	Detection of high pathogenic NDV virus antibody	Serum, Plasma
			EB45-51		96 wells/Kit		
		CSFV Ab ELISA	EB44-13	Microplate	480 wells/Kit	Detection of Classical swine fever virus antibody for routine screening	Serum, Plasma
			EB44-63		96 wells/Kit		
		PRRS Ab ELISA	EB44-04	Microplate	480 wells/Kit	Detection of Porcine Reproductive and Respiratory Syndrome (PRRS) antibody	Serum, Plasma
			EB44-54		96 wells/Kit		

Conventional PCR	Species	Product	Cat. No.	Type	Packing Size	Description	Sample
Industrial Animal		AIV PCR Kit	PD55-01	Conventional PCR	96Tests/kit	Detection of AIV type A	sercetion, organ, blood, feces, fluid etc.
		AIV H5 PCR Kit	PD55-02	Conventional PCR	96Tests/kit	Detection of AIV subtype H5	sercetion, organ, blood, feces, fluid etc.
		AIV H7 PCR Kit	PD55-03	Conventional PCR	96Tests/kit	Detection of AIV subtype H7	sercetion, organ, blood, feces, fluid etc.
		AIV H9 PCR Kit	PD55-04	Conventional PCR	96Tests/kit	Detection of AIV subtype H9	sercetion, organ, blood, feces, fluid etc.
		Lento NDV PCR Kit	PD55-07	Conventional PCR	96Tests/kit	Detection of low pathogenci NDV virus (Lentogenic)	sercetion, organ, blood, feces, fluid etc.
		Velo NDV PCR Kit	PD55-08	Conventional PCR	96Tests/kit	Detection of high pathogenic NDV virus (Velogenic)	sercetion, organ, blood, feces, fluid etc
		IBDV PCR Kit	PD55-11	Conventional PCR	96Tests/kit	Detection of Infectious Bursal Disease Virus	sercetion, organ, blood, feces, fluid etc.

Real-Time PCR	Species	Product	Cat. No.	Test Type	Packing Size	Description	Sample
Industrial Animal		AIV A Real-Time PCR Kit	PD65-01	Real Time-PCR	96Tests/kit	Detection of AIV type A	sercetion, organ, blood, feces, fluid etc.
		AIV H5 Real-Time PCR Kit	PD65-02	Real Time-PCR	96Tests/kit	Detection of AIV subtype H5	sercetion, organ, blood, feces, fluid etc.
		AIV H7 Real-Time PCR Kit	PD65-03	Real Time-PCR	96Tests/kit	Detection of AIV subtype H7	sercetion, organ, blood, feces, fluid etc.
		AIV H9 Real-Time PCR Kit	PD65-04	Real Time-PCR	96Tests/kit	Detection of AIV subtype H9	sercetion, organ, blood, feces, fluid etc.
		AIV H5/N1 Duplex Real-Time PCR Kit	PD65-51	Real Time-PCR	96 tests/kit	Detection of AIV H5 and N1	sercetion, organ, blood, feces, fluid etc.
		REV Real-TIme PCR Kit	PD65-05	Real Time-PCR	96 tests/kit	Detection of Reticuloendotheliosis Virus	sercetion, organ, blood, feces, fluid etc.
		MDV Real-TIme PCR Kit	PD65-06	Real Time-PCR	96 tests/kit	Detection of Marek's disease virus	sercetion, organ, blood, feces, fluid etc.
		Lento NDV Real-Time PCR Kit	PD65-07	Real Time-PCR	96 tests/kit	Detection of low pathogenci NDV virus (Lentogenic)	sercetion, organ, blood, feces, fluid etc.
		Velo NDV Real-Time PCR Kit	PD65-08	Real Time-PCR	96 tests/kit	Detection of high pathogenic NDV virus (Velogenic)	sercetion, organ, blood, feces, fluid etc.
		IBV Real-Time PCR Kit	PD65-09	Real Time-PCR	96 tests/kit	Detection of Infectious Bronnchitis Virus	sercetion, organ, blood, feces, fluid etc.
		TRT Real-Time PCR Kit	PD65-10	Real Time-PCR	96 tests/kit	Detection of Infectious Turkey Rhinotracheitis	sercetion, organ, blood, feces, fluid etc.
		IBDV Real-Time PCR Kit	PD65-11	Real Time-PCR	96 tests/kit	Detection of Infectious Bursal Disease Virus	sercetion, organ, blood, feces, fluid etc.
		REO Real-Time PCR Kit	PD65-12	Real Time-PCR	96 tests/kit	Detection of Avian Reovirus	sercetion, organ, blood, feces, fluid etc.
		MYCO G/S Real-Time PCR Kit	PD65-14	Real Time-PCR	96 tests/kit	Detection of Avian Mycoplasma gallisepticum, and M. iowae, M. meleagridis , M. synoviae	sercetion, organ, blood, feces, fluid etc.
		ALV Real-Time PCR Kit	PD65-15	Real Time-PCR	96 tests/kit	Detection of Avian Leukosis Virus	sercetion, organ, blood, feces, fluid etc.

⟷ 접는선 바깥쪽부분

Global expertise in In Vitro Diagnostics

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