BISAF VET

For Veterinary Use Only

Canine Coronavirus / Parvovirus Antigen Combo Rapid Test Kit

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

Contents

	1 test/kit	5 tests/kit	25 tests/kit
Test cassette	1	5	25
Specimen collection swab	1	5	25
Buffer Tube	1	5	25
Instruction of use	1	1	1
Collection bag	1	5	25

INTENDED USE

The Canine Coronavirus/Parvovirus Antigen Combo Rapid Test Kit is intended for the qualitative detection of canine coronavirus (CCV) and canine parvovirus (CPV) antigens in canine feces. It is designed for use in home settings or veterinary clinics to facilitate rapid preliminary diagnosis.

Summary

Canine coronavirus (CCV) and canine parvovirus (CPV) are highly contagious pathogens that cause acute gastroenteritis in dogs. Although their genetic structures differ, clinical symptoms such as vomiting, diarrhea, and lethargy are often similar. CPV infection can lead to severe and frequently fatal illness, while CCV typically results in milder, self-limiting enteritis. However, co-infections are common and may exacerbate clinical outcomes. This test kit allows for rapid and simultaneous detection of both viruses, supporting timely intervention.

Test Principle

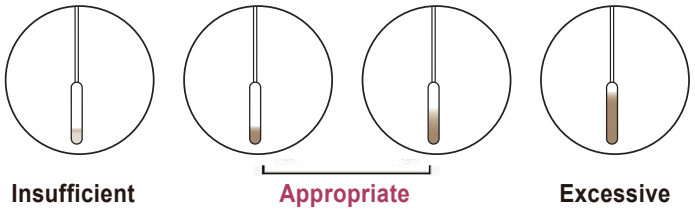
This test is based on a lateral flow chromatographic immunoassay. Gold-conjugated monoclonal antibodies specific to CCV and CPV are used as detection agents. If CCV or CPV antigens are present in the fecal sample, they bind to the conjugated antibodies and migrate along the membrane. The complex then interacts with immobilized antibodies at the respective test lines (T lines), producing visible red lines. A control line (C line) is included to confirm proper test procedure and validity of the result. The kit demonstrates high sensitivity and specificity for both antigens.

Storage & Stability

- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

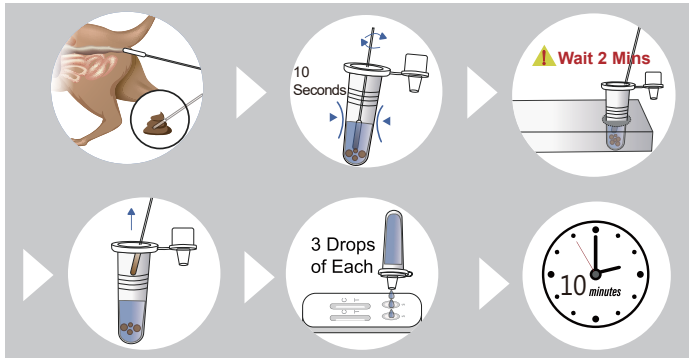
Sample Preparation

1. Canine fecal swab should be used for this test.
2. The samples should be tested immediately after collection.
3.If samples cannot be tested immediately, they should be stored at 2~8°C(35.6~46.4°F) for up to 24 hours. For longer storage, freeze at -20°C (-4°F) or below.Frozen samples should be brought to room temperature (15~30°C/59~86°F) before use.
4.The amount of fecal sample with swab may affect the results. It is required to follow the swab amount of feces as shown in the picture below.The excessive fecal amount may induce a false positive result and slow migration.



Test Procedure

1.All reagents and samples must be at room temperature (15~30°C/59~86℉) before use.
2. Collect fecal sample using a swab.
3.Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4.Wait for 2 minutes to settle down the large particles
5.Remove the swab from the sample dilution buffer.
6. Remove the test device from the pouch and place it on a flat and drysurface.
7.Apply 3 drops of the mixed sample solution into the sample holes foreach , drop by drop vertically.
8.Read test results at 10 minutes.



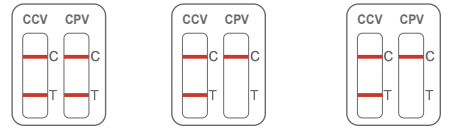
[Summary of Test Procedure]

Interpretation of Results

Positive(+)

Presence of two color bands "T"and "C"

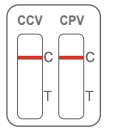
Two lines, one nextto C and one next to T, even faint lines, shows the test is positive.



Negative (-)

No presence of color band ("T")

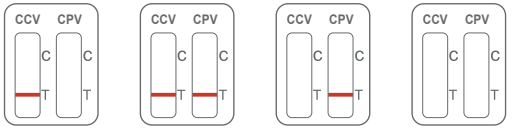
One red-coloredline only next to "C" indicates a negative result.



Invalid

No presence of color band ("C")

If the red-colored line in the control region "C" is not visible, the result is invalid. Run a new test.



Precautions & Warnings

1. Intended Use & Validity
- For veterinary in vitro diagnostic use only. Not for human or other animal use.
- Do not use beyond the expiration date printed on the package label.
- Do not use if the foil pouch is damaged or already open.

2. Handling & Storage
- Store at 2–30°C. Do not freeze or expose to direct sunlight.
- Once opened, use the test device within 10 minutes.
- Avoid touching the membrane area of the test device.

3. Operational Guidelines
- Use only components provided in the kit. Do not reuse any items.
- Do not mix components from different lot numbers.
- Ensure all reagents and samples are at room temperature (15–30°C) before use.

4. Safety & Disposal
- Treat all samples as potentially infectious.
- Wear protective gloves during handling and wash hands thoroughly
- afterward.
- Dispose of used kits and samples in accordance with local biohazard regulations.

Test Limitations

1.A negative result does not preclude the possibility of infection. Negative results may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.

2.The test is designed to detect specific antigens of Canine Coronavirus (CCV) and Canine Parvovirus (CPV). Positive results do not rule out co-infections with other pathogens

3.The accuracy of the test depends on the quality of the sample collected. Samples containing excessive mucus or bloody fluids may interfere with test performance and could yield invalid or inaccurate results.

4.Results should be interpreted at the designated time (10 minutes). Reading results too early or too late may lead to erroneous interpretation.

5.This test is a rapid qualitative immunoassay and provides a preliminary result. For a definitive diagnosis, all results should be confirmed by additional clinical findings, histopathology, and/or other testing methods (e.g., PCR, virus isolation), especially in cases where the clinical presentation is inconsistent with the test result.

6.The test is validated for use with canine fecal samples only. Performance in other sample types has not been established.

7.As with any diagnostic test, all results must be interpreted in conjunction with the animal's clinical history and symptoms by a qualified veterinarian.

Clinical Evaluation:

The Canine Coronavirus/Parvovirus Antigen Combo Test demonstrates high diagnostic accuracy for simultaneous detection of CCV and FPV antigens in canine fecal samples. Validation studies comparing against RT-PCR show excellent sensitivity and specificity for both targets, providing reliable results for clinical use.The following data summarize the clinical performance characteristics:

CCV Antigen Test	Contrast Reagent (PCR)		
	Positive	Negative	Total
Positive	56	3	59
Negative	3	118	121
Total	59	121	180
Sensitivity	94.92% (56/59 , 95% CI: 86.06% ~ 98.26%)		
Specificity	97.52% (118/121 , 95% CI: 92.92% ~ 99.15%)		
Total coincidence rate	96.67% (174/180 , 95% CI: 92.92% ~ 98.46%)		

Limit of Detection (Analytical Sensitivity)

1. Canine Coronavirus (CCV):
The minimum detectable concentration of the CCV/CPV Ag Combo Test Kit for Canine Coronavirus is 1.0×10^5 $TCID_{50}$/mL

2. Canine Parvovirus (CPV):
The minimum detectable concentration for Canine Parvovirus is 5.0×10^3 $TCID_{50}$/mL

Cross Reactivity

The CCV/CPV Ag Combo Test Kit utilizes highly specific monoclonal antibodies to ensure accurate detection of CCV and CPV antigens. To validate assay specificity, cross-reactivity studies were performed with a panel of common canine enteric pathogens and potential interfering substances.

Category	Tested Substance	Concentration tested	Cross Reactivity
Viruses	Canine Distemper Virus (CDV)	10^5 $TCID_{50}$/mL	None
	Canine Adenovirus (CAV)	10^5 $TCID_{50}$/mL	None
	Canine Rotavirus	10^5 $TCID_{50}$/mL	None
Bacteria	Solmonella spp	10^8 CFU/mL	None
	Campylobacter jejunus	10^8 CFU/mL	None
	Escherichia coli (K99+)	10^8 CFU/mL	None
Parasites	Giardia lamblia (cysts)	10^5 cysts/mL	None
	Cryptosporidium parvum (oocysts)	10^5 oocysts/mL	None
Substances	Hemoglobin	10 mg/mL	None
	Bilirubin	0.2 mg/mL	None
	Fat Emulsion	10 mg/mL	None
	Mucus	5% (v/v)	None

Interfering Substances

The following substances have been evaluated for potential interference with the CCV/CPV Ag ComboTest Kit at the indicated concentrations. No significant interference was observed under the tested conditions.The following substances were evaluated for potential interference:

Substance Category	Specific Substance	Concentration tested	Effect on Assay
Endogenous Substances	Hemoglobin (Whole Blood)	4%(v/v)	No Interference
	Mucin	5 mg/mL	No Interference
	Bilirubin	0.4 mg/mL	No Interference
	Intestinal fats	5 mg/mL	No Interference
Medications	Antibiotics	1 mg/mL	No Interference
	Antiparastics	1 mg/mL	No Interference
	Anti-diarrheal agents	1 mg/mL	No Interference
Dietary Components	Plant fibers	5%(w/v)	No Interference
	Digested matter	5%(w/v)	No Interference
	Food particles	5%(w/v)	No Interference

References

1. Decaro, N., Buonavoglia, C. An update on canine coronaviruses: viral evolution and pathobiology. Vet Microbiol. 2008; 132: 221–234.

2.Decaro, N., Desario, C., Billi, M., Mari, V., Elia, G., Cavalli, A., Martella, V., Buonavoglia, C. Western European epidemiological survey for parvovirus and coronavirus infections in dogs. Vet J. 2011; 187(2): 195–199.

3.Pratelli, A., Tempesta, M., Roperto, F.P., Sagazio, P., Carmichael, L., Buonavoglia, C. Fatal coronavirus infection in puppies following canine parvovirus 2b infection. J Vet Diagn Invest. 1999; 11: 550–553.

4. Castro, T.X., Garcia, R.C.N.C., Goncalves, L.P.S., Costa, E.M., Marcello, G.C.G., Labarthe, N.V., Mendes-de-Almeida, F. Clinical, hematological, and biochemical findings in puppies with coronavirus and parvovirus enteritis. Can Vet J. 2013; 54: 885–888.

5. Cavalli, A., Desario, C., Kusi, I., Mari, V., Lorusso, E., Cirone, F., Kumbe, I., Colaianni, M.L., Buonavoglia, D., Decaro, N. Detection and genetic characterization of Canine parvovirus and Canine coronavirus strains circulating in district of Tirana in Albania. J Vet Diagn Invest. 2014 Jul; 26(4): 563–566.

6. Evermann, J.F., McKelman, A.J., Eugster, A.K., Solozano, R.F., Collins, J.K., Black, J.W., Kim, J.S. Update on canine coronavirus infections and interactions with other enteric pathogens of the dog. Comp Anita Pract. 1989; 19(2): 6–12.

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Do not desterilize		

Manufacturer: Feng Chun Yuan Medical Equipment(Shenzhen)Co.,Ltd
Address: Room.1304 & Room.1306 , No.48, Xinyu Road, Xiangshan Community Xinqiao Street, Baoan District, Shenzhen, Guangdong, China. 518 000

EC REP Riomavix S.L.
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
Tel.: +34 658 396 230
E-mail: leis@riomavix.com

Importer & Distributor: BISAF Sp. z o.o.
Add: ul. Rdestowa 5, 54-530 Wrocław, Poland
Website: www.bisaf.pl