Rapid CCV Antigen & CPV Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ CCV/CPV Ag Combo Test Kit

[CAT No. CGM-CCG-21]

Introduction

Canine coronavirus (CCV), a single-stranded positive-sense RNA virus (family Coronaviridae, genus *Alphacoronavirus*), and canine parvovirus (CPV), a single-stranded DNA virus (family Parvoviridae, genus *Protoparvovirus*), are contagious pathogens responsible for acute gastroenteritis in dogs.

Despite structural, genetic, and molecular biological differences, clinical signs, including diarrhea and vomiting, are very similar when infected with dogs. Whereas CPV can cause a severe, often fatal, disease, CCV is generally recognized as an etiological agent of mild, self-limiting enteritis followed by rapid recovery[1]. Lymphopenia was the only parameter related to CCV infection that was statistically significant; vomiting, anorexia, lethargy, hemorrhagic fluid diarrhea, leukopenia, lymphopenia, thrombocytopenia, hypoglycemia, and hypoproteinemia were correlated with CPV infection[2].

Dogs infected with CCV have mild symptoms, but CCV is a mixed infection with CPV to make their symptoms worse[3]. The simultaneous infection rate of CCV and CPV was reported 25% of CPV infections[4]. The mixed infection of CCV and CPV was 17.9% in the epidemiological survey in five Western European countries and up to 49.1% in the Albanian research[5, 6].

Principle

The RIDX™ CCV/CPV Ag Combo Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of CCV and CPV antigens in canine feces. This kit shows two letters which are the test (T) line and the control (C) line for each test on the surface of the device. If viral (CCV or CPV) antigens exist in the sample, that bind to the gold-conjugated virus (CCV or CPV) specific antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the virus (CCV or CPV) specific antibody on the test line, resulting in a red line. The control line indicates that the test is performed correctly and should appear when the test is complete.

The highly selective and sensitive monoclonal antibody to CCV (or CPV) is used as capture and detector in the kit. The RIDX™ CCV/CPV Ag Combo Test Kit can detect CCV antigens and CPV antigens in canine feces with high accuracy.

Performance

[CCV]

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™	+	56	3	59
CCV Ag	-	3	118	121
Test	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%)
Diagnostic Agreement: 96.67% (174/180, 95% CI: 92.92% ~ 98.46%)

* CI: Confidence Interval

2. Limit of Detection: $1x10^5$ $TCID_{50}$/mL
3. No cross-reactivity with infectious pathogens in canine.

[CPV]

1. Sensitivity & Specificity

		PCR		
		+	-	Total
RIDX™	+	101	0	101
CPV Ag	-	2	214	216
Test	Total	103	214	317

Sensitivity: 98.06% (101/103, 95% CI*: 93.19% ~ 99.47%)
Specificity: 100% (214/214, 95% CI: 98.24% ~ 100%)
Diagnostic Agreement: 99.37% (315/317, 95% CI: 97.73% ~ 99.83%)

* CI: Confidence Interval

2. Limit of Detection: $5 x 10^3$ $TCID_{50}$/mL
3. CPV-2, CPV-2a, CPV-2b diagnosis are also available.
4. No cross-reactivity with other diarrheal pathogens in dogs.

Kit Components

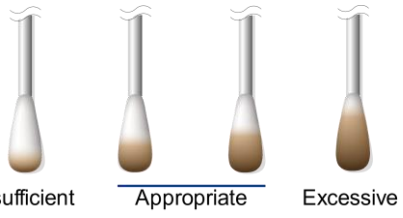
	Component	Number/Kit
1	CCV/CPV Ag Combo Test device	10
2	Sample dilution buffer (1mL)	10
3	Disposable swab	10
4	Disposable dropper	10
5	Instructions for use	1

Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86℉). Do NOT freeze.
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

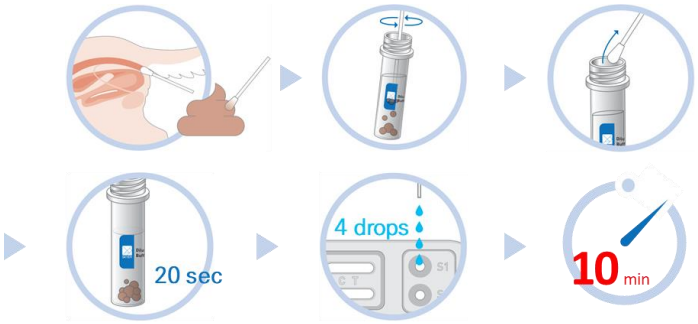
1. Canine feces swab should be used for this test.
2. The samples should be tested immediately after collection.
3. If samples cannot be tested immediately, they should be stored at 2~8°C (35.6~46°F) for up to 24 hours. For longer storage, freeze at −20°C (−4°F) or below. Frozen samples should be brought 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℃ /59~86℉) before use.
2. Collect feces samples 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. Remove the swab from the sample dilution buffer.
5. Wait for 20 seconds to settle down the large particles.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Take the supernatant sample in the tube by using a disposable dropper.
8. Add 4 drops of the mixed sample into each sample holes (S), drop by drop vertically.
9. Read test results at 10 minutes.



[Summary of Test Procedure]

Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of viral antigens.

[CCV positive]

[CPV positive]

2. Negative result
Only control (C) line appears in the result window.

3. Invalid results
If the control (C) line does not appear, the result might be considered invalid. The sample should be retested.

Precautions

1. This test kit is for veterinary *in vitro* diagnosis only especially canine. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (device, buffer, dropper, swab).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials in the accordance with national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. Decaro, N., Buonavoglia, C. An update on canine coronaviruses: viral evolution and pathobiology. *Vet Microbiol*. 2008; 132: 221–234.
2. Castro TX, Garcia RCNC, Goncalves LPS, Costa EM, Marcello GCG, Labarthe NV, Mendes-de-Almeida F. Clinical, hematological, and biochemical findings in puppies with coronavirus and parvovirus enteritis. *Can Vet J*. 2013; 54: 885–888.
3. Pratelli A, Tempesta M, Roperto FP, Sagazio P, Carmichael L, Bounavoglia C. Fatal coronavirus infection in puppies following canine parvovirus 2b infection. *J Vet Diagn Invest*. 1999; 11: 550–553.
4. Evermann JF, McKeirnan AJ, Eugster AK, Solozano RF, Collins JK, Black JW and Kim JS. Update on canine coronavirus infections and interactions with other enteric pathogens of the dog. *Comp Anita Pract.* 1989; I9(2): 6–12.
5. Cavalli A, Desario C, Kusi I, Mari V, Lorusso E, Cirone F, Kumbe I, Colaianni ML, 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. 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.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

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