Canine Coronavirus / Parvovirus / Giardia Antigen Combo Rapid Test Kit

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

Principles

The BISAF CCV/CPV/Giardia Ag Kit is a lateral flow chromatographic immunoassay for the qualitative detection of CPV (Canine parvovirus), CCV (Canine coronavirus) and *Giardia* 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 the pathogenic antigens (CCV, CPV or *Giardia*) exist in the sample, that bind to the gold - conjugated pathogens (CCV, CPV or *Giardia*) specific antibod ies. The antigen- antibody complex moves through the membrane by capillary force and responds to the pathogen (CCV, CPV or *Giardia*) specific antibodies on the test line, resulting in a red line. The control line indicates that the test is performed correctly a nd should appear when the test is complete.

The highly selective and sensitive monoclonal antibod ies to CPV (CCV or *Giardia*) is used as capture and detector in the kit. The BISAF CCV/CPV/Giardia Ag Kit can detect CPV antigens, CCV antigens and *Giardia* antigens in canine feces with high accuracy.

Performances

[CPV Ag Test]

1. Sensitivity & Specificity

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

Sensitivity: 98.06% (101/1 03, 95% CI*: 9 3.19% ~ 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 $TCID_{50}$/m L

3. CPV- 2, CPV- 2a, CPV- 2b diagnosis are also available.

4. Cross- Reactivity

Potential y cross- reactive substances listed below have no effect on the performance of the BISAF CPV Ag Test

Pathogen	Titer	Result
Canine coronavirus	1.00 x 10^6 $TCID_{50}$/ mL	Negative
Canine distemper virus	1.00 x 10^5 $TCID_{50}$/ mL	Negative
Canine influenza virus	1.00 x 10^6 EID_{50}/ mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/ µL	Negative
Salmonella spp.	1.00 x 10^6 CFU/mL	Negative

[CCV Ag Test]

1. Sensitivity & Specificity

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

* CI: Confidence Interval

2. Limit of Detection: 1 x 10^5 $TCID_{50}$/m L

3. Cross- Reactivity

Potentially cross- reactive substances listed below have no effect on the performance of the BISAF CCV Ag Test Kit.

Pathogen	Titer	Result
Canine distemper virus	1.00 x 10^5 $TCID_{50}$/ mL	Negative
Canine influenza virus	1.00 x 10^6 EID_{50}/ mL	Negative
Canine parvovirus	1.00 x 10^6 $TCID_{50}$/ mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/ µL	Negative
Salmonella spp.	1.00 x 10^6 CFU/mL	Negative

[Giardia Ag Test]

1. Clinical Sensitivity & Clinical Specificity

		PCR		
		+	-	Total
Giardia Ag Test	+	34	4	38
	-	1	109	110
	Total	35	113	148

Clinical Sensitivity: 97.14% (34/35 , 95% CI*: 95.47% ~ 99.49%)
Clinical Specificity: 96.46% (109/113 , 95% CI: 91.25% ~ 98.61%)
Diagnostic Accuracy: 96.62% (143/148 , 95% CI: 92.34% ~ 98.55%)

* CI: Confidence Interval

2. Limit of Detection: 1 .25 Cysts/ µL

3. Cross- Reactivity

Potentially cross- reactive substances listed below have no effect on the performance of the BISAF Giardia Ag Test.

Pathogen	Titer	Result
Canine coronavirus	1.00 x 10^6 $TCID_{50}$/m L	Negative
Canine distemper virus	1.00 x 10^5 $TCID_{50}$/m L	Negative
Canine influenza virus	1.00 x 10^6 EID_{50}/m L	Negative
Feline calici virus	1.00 x 10^5 $TCID_{50}$/m L	Negative
Feline coronavirus	1.97 x 10^4 $TCID_{50}$/m L	Negative
Feline parvovirus	1.00 x $10^{5.5}$ $TCID_{50}$/m L	Negative

Kit Components

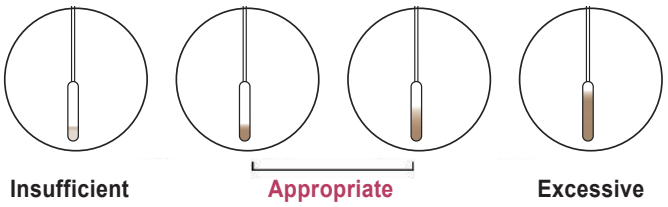
	Component	Quantity/kit by
1	CCV/CPV/Giardia Ag combo test device	1
2	Dilution buffer	1
3	Disposable swab	1
4	Instructions for use	1
5	Collecrion bag	1

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, th ey should be stored at 2~8°C (35.6~46.4℉) for up to 24 hours. For longer storage, freeze at -20°C (-4℉) or below. Frozen samples should be brought to room temperature (15~30°C/59~86℉) 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).

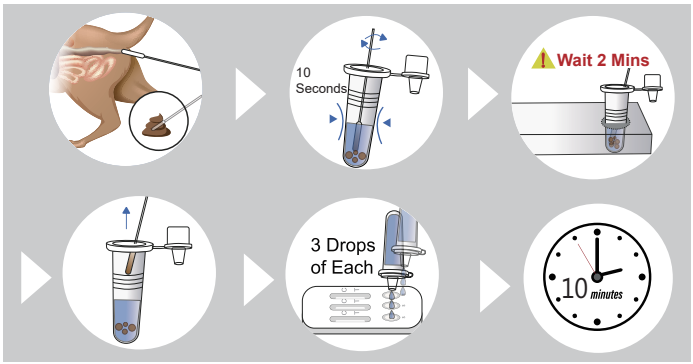
4.Wait for 2 minutes to settle down the large particles

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.



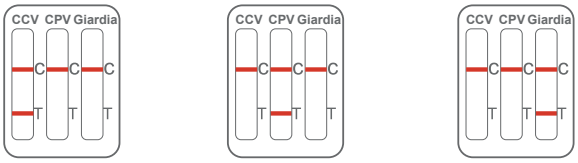
[Summary of Test Procedure]

Interpretation of Results

1. Positive Results

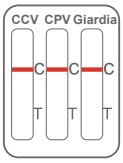
Test (T) line and control (C) line within the result window indicate the presence of pathogenic antigens.

[CCV positive] [CPV positive] [*Giardia* positive]



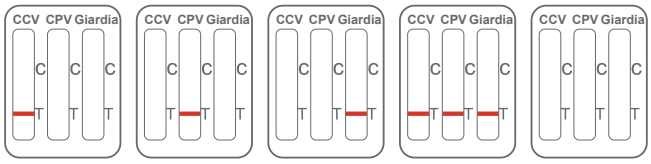
2. Negative Result

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* diagnostic use only for dogs. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the t est device within 10 minutes after removing the foil pouch .
3. Do not touch t he 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, and 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.

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