



# CPV+CCV+Giardia Lamblia Antigen Combo Rapid Test Cassette

**Test Cassette**  
**(Feces/Vomit)**

**Package Insert**

REF VIPCG-635	English
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## INTENDED USE

The CPV + CCV + Giardia Lamblia Antigen Combo Rapid Test Cassette (Feces/Vomit) is a combined cassette to differentially diagnose the presence of Canine Parvovirus antigen and Canine Coronavirus antigen and Giardia lamblia antigen in dog's feces or vomit.

For veterinary use only.

## PRINCIPLE

The CPV + CCV+ Giardia Lamblia Antigen Combo Rapid Test Cassette is based on sandwich lateral flow immunochromatographic assay. The test device has three testing windows. Each testing window has an invisible T (test) zone and C (control) zone. When sample is applied into the sample well on the cassette, the liquid will laterally flow on the surface of the test strip. If there is enough CPV or CCV or Giardia antigen in the sample, a visible T line will appear in the corresponding testing window. The C line should always appear after a sample is applied, indicating a valid result. By this means, the cassette can accurately indicate the presence of CPV or CCV or Giardia antigen in the sample.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

## PRECAUTIONS

- Do not use after expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lot and different products.

## MATERIALS

### Materials Provided

- Test cassettes
- Droppers
- Plastic tubes with buffer
- Swabs
- Package insert

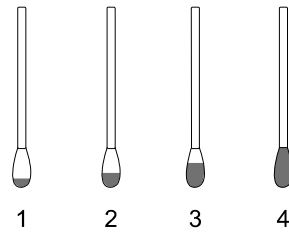
### Materials Required but Not Provided

- Timer

## DIRECTIONS FOR USE

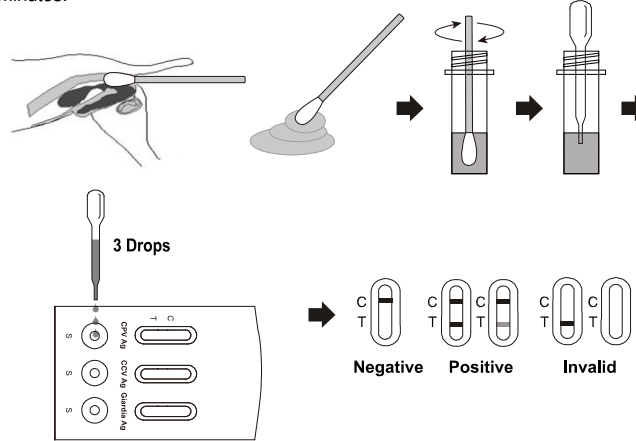
**Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.**

1. Collect dog's feces or vomit with the swab stick from dog's anus or from the ground. The amount of fecal swab as follows:



1. Not enough
2. Good
3. Good
4. Too Much

2. Insert the wet swab into the buffer tube provided with the kit. Swirl and shake to ensure sufficient sample extraction.
3. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 drops of extracted sample** (approximately 120 µL) to each specimen well of the test cassette, then start the timer. See illustration above.
4. **Read the result in 5-10 minutes.** Do not interpret results after 15 minutes.



## INTERPRETATION OF RESULTS

**Positive:** The presence of both C line and T line, regardless of T line being strong or faint.

**Negative:** Only clear C line appears.

**Invalid:** No colored line appears in C zone, regardless of T line's appearance.

## ACCURACY

The CPV + CCV + Giardia Lamblia Antigen Combo Rapid Test Cassette has been evaluated with specimens obtained from veterinary hospital. Commercial control test and microscopy are used as the reference method for the CPV + CCV + Giardia Lamblia Antigen Combo Rapid Test Cassette. Specimens were considered positive if commercial control test or microscopy indicated a positive result.

CPV Antigen Rapid Test Cassette	Commercial control test		Total
	Positive	Negative	
Positive	45	0	45
Negative	2	35	37
Total	47	35	82

Relative Sensitivity: 95.74% (95%CI\*: 85.46%-99.48%)

Relative Specificity: >99.99% (95%CI\*: 90.00%-100.00%)

Accuracy: 97.56% (95%CI\*: 91.47%-99.70%)

## \*Confidence Interval

CCV Antigen Rapid Test Cassette	Commercial control test		Total
	Positive	Negative	
Positive	54	3	57
Negative	4	118	122
Total	58	121	179

Relative Sensitivity: 93.10% (95%CI\*: 83.27%-98.09%)

Relative Specificity: 97.52% (95%CI\*: 92.93%-99.49%)

Accuracy: 96.09% (95%CI\*: 92.11%-98.41%)

## \*Confidence Interval

Giardia Lamblia Antigen Rapid Test Cassette	Commercial control test		Total
	Positive	Negative	
Positive	39	5	44
Negative	2	116	118
Total	41	121	162

Relative Sensitivity: 95.12% (95%CI\*: 83.47%-99.40%)

Relative Specificity: 95.87% (95%CI\*: 90.62%-98.64%)

Accuracy: 95.68% (95%CI\*: 91.30%-98.25%)

## \*Confidence Interval

## CROSS-REACTIVITY

The CPV Antigen Rapid Test Cassette has been tested by Distemper virus, Coronavirus, Adenovirus-I, Rotavirus, Giardia Lamblia positive samples. The results showed no cross-reactivity.

The CCV Antigen Rapid Test Cassette has been tested by Parvovirus, Distemper virus, Adenovirus-I, Rotavirus, Giardia Lamblia positive samples. The results showed no cross-reactivity.

The Giardia Lamblia Antigen Rapid Test Cassette has been tested by Distemper Virus, Coronavirus, Parvovirus, Adenovirus-I, Rotavirus positive samples. The results showed no cross-reactivity.

## LIMITATION

The CPV+CCV+ Giardia Lamblia Antigen Combo Rapid Test Cassette is for veterinary use only for canines. All results should be considered with other clinical information available from veterinarian. For confirming the results, confirmatory methods such as PCR and microscopy are recommended.

## Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Manufacturer		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use



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