VECHEK

CPV+Giardia Lamblia Antigen Combo Rapid Test Cassette (Feces/Vomit) Package Insert

REF VIPG-625	English

INTENDED USE

The CPV+Giardia Lamblia Antigen Combo Rapid Test Cassette (Feces/Vomit) is a combined cassette for the detection of Canine Parvovirus antigen and Giardia Lamblia antigen in dog's feces or vomit.

For veterinary use only.

PRINCIPLE

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

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 the 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 may 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 •ISwabs • Package insert

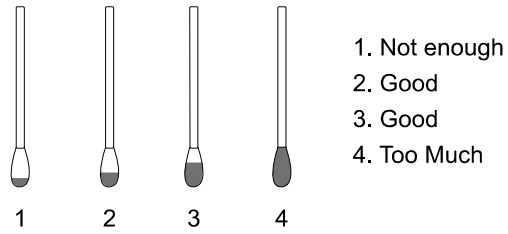
Materials Required but Not Provided

• Timer

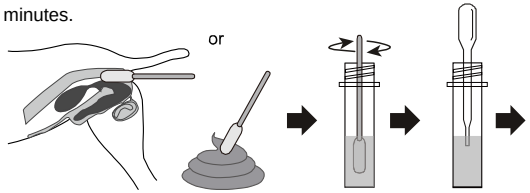
DIRECTIONS FOR USE

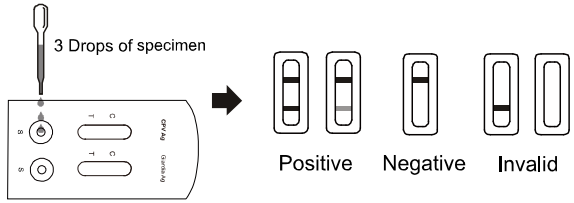
Allow the test cassette, specimen, buffer to equilibrate to room temperature (15-30 °C) prior to testing.

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



2. Insert the swab into the buffer tube provided with the kit. Swirl and shake to ensure sufficient specimen extraction.
3. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
4. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 drops of diluted specimen** (approximately 120 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
5. **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+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+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*: 91.80%-100.00%)

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

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

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

LIMITATION

The CPV+Giardia Lamblia Antigen Combo Rapid Test Cassette is for *in vitro* diagnostic 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	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
	Manufacturer	LOT	Batch code	REF	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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