

CDV +CPV Antigen Combo Rapid Test Cassette

(Secretions+Feces/Vomit)

Package Insert

REF VIDP-525 English

INTENDED USE

The CDV+CPV Antigen Combo Rapid Test Cassette (Secretions+ Feces/Vomit) is a lateral flow immunochromatographic assay for the qualitative detection of Canine Distemper Virus (CDV Ag) in dog's nasal/ocular secretions and Canine Parvovirus (CPV Ag) in dog's feces or vomit.

For veterinary use only.

PRINCIPLE

The CDV+CPV Antigen Combo Rapid Test Cassette is a qualitative lateral flow immunochromatographic assay for detection of antigens of Canine Distemper Virus (CDV) and Canine Parvovirus (CPV). The test cassette has two testing windows. Each testing window has T (test) region and C (control) region. During testing, sample is applied into the sample wells on the cassette. CDV or CPV antigens, if present in specimen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain CDV or CPV antigens, a colored line will not appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test cassette 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
- Plastic tubes with buffer
- Package insert
- Droppers
- Swabs

Materials Required but Not Provided

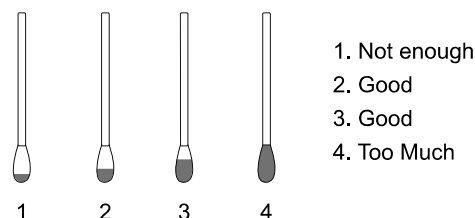
- Timer

DIRECTIONS FOR USE

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

- 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.
- Sample collection:
 - For feces/vomit:

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



Insert the wet swab into the provided plastic tube with buffer. Agitate it to assure good sample extraction.

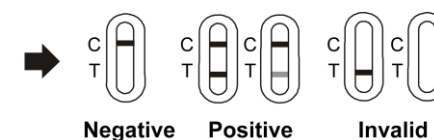
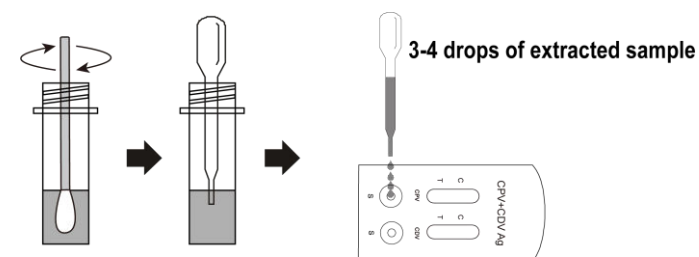
- For secretions:

Collect dog's ocular and nasal secretions with **another swab** provided. Make the swab wet sufficiently.

Note: Collect ocular secretion from upper and lower eyelids, please avoid secretions at the corner of the eye. Insert the wet swab into **the same plastic tube with buffer**. Agitate it to assure good sample extraction.

- Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3-4 drops of extracted sample** (approximately 120-160 µl) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
- 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+CDV Antigen Combo Test Cassette has been evaluated with specimens obtained from veterinary hospital. Commercial control test is used as the reference method for the CPV+CDV Antigen Combo Test. Specimens were considered positive if commercial control test indicated a positive result.

CPV Antigen tests	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

CDV Antigen tests	Commercial control test		Total
	Positive	Negative	

Positive	48	1	49
Negative	1	39	40
Total	49	40	89

Relative Sensitivity: 97.96% (95%CI*: 89.15%-99.95%)

Relative Specificity: 97.50% (95%CI*: 86.84%-99.94%)

Accuracy: 97.75% (95%CI*: 92.12%-99.73%)

*Confidence Interval

CROSS-REACTIVITY

The CDV Antigen Rapid Test has been tested by Coronavirus, Adenovirus-I, Rotavirus positive samples. The results showed no cross-reactivity.

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

LIMITATION

The CDV+CPV 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 are recommended.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse
	Store between 2-30 °C		Use by		Catalog #
	Do not use if package is damaged		Lot Number		Consult Instructions For Use


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