VECHEK™

CDV Antigen Rapid Test Cassette (Secretions) Package Insert

REF VIDV-502	English

INTENDED USE

The CDV Antigen Rapid Test Cassette (Secretions) is a lateral flow immunochromatographic assay for the qualitative detection of antigen of Canine Distemper Virus (CDV Ag) in dog's nasal/ocular secretions.

For veterinary use only.

PRINCIPLE

The CDV Antigen Rapid Test Cassette is a qualitative lateral flow immunochromatographic assay for detection of antigens of Canine Distemper Virus (CDV). The test cassette has a testing window with a T (test) region and C (control) region. During testing, sample is applied into the sample well on the test cassette. CDV antigens, if present in specimen, react with the pre-coated anti-CDV antibodies in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-CDV antibodies on the membrane in the test line region. If the specimen contains Canine Distemper Virus, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain CDV 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 lots and different products.

MATERIALS

Materials Provided

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

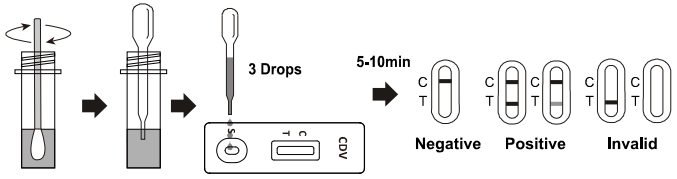
Materials Required but Not Provided

- 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. 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.
2. Collect dog's ocular/nasal secretions with the 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.
3. Insert the wet swab into the provided plastic tubes with buffer. Agitate it to assure good sample extraction.
4. 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 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 region, regardless of T line's appearance.

ACCURACY

The CDV Antigen Rapid Test Cassette (Secretions) has been evaluated with specimens obtained from veterinary hospital. Commercial control test is used as the reference method for the CDV Antigen Rapid Test Cassette. Specimens were considered positive if commercial control test indicated a positive result.

CDV Antigen Rapid Test Cassette	Commercial control test		Total
	Positive	Negative	
Test Positive	48	1	49
Test 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 Cassette has been tested by Parvovirus, Parainfluenza virus, Adenovirus-I, II and Coronavirus positive specimens. The results showed no cross-reactivity.

LIMITATION

The CDV Antigen Rapid Test Cassette is for 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

	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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Number: V145002400
Revision date: 2025-04-28