Canine Distemper Virus Antigen Rapid Test

(Secretions)

Intended Use

The CDV Antigen Rapid Test Device (Secretions) is a lateral flow immunochromatographic assay for the qualitative detection of antigen of Canine Distemper Virus (CDV Ag) in secretions from dog's eyes, nasal cavities, and ocular or in serum, plasma specimen.

Principle

CDV Antigen Rapid Test Device is a qualitative lateral flow immunochromatographic assay for detection of antigens of Canine Distemper Virus (CDV). The test device has a testing window. The testing window has T (test) region and C (control) region. During testing, sample is applied into the sample well on the Device. CDV antigens, if present in specimen, react with the pre-coated antiCDV 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 is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use**. DO NOT FREEZE.** Do not use beyond the expiration date.

Additional Special Equipment

Materials Provided

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

Materials Required But Not Provided

- Timer

Direction For Use

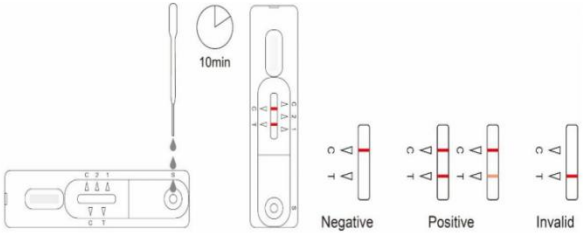
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1.Remove the test device 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 and 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. Insert the wet swab into the provided plastic tubes with buffer. Agitate it to assure good sample extraction. If using serum or plasma specimen, use the dropper to collect the specimen. Place 3 drops of serum or plasma into the assay buffer tube for dilution. The diluted sample is used as sample extraction.

3.Place the test device 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 device, then start the timer. See illustration above.

4. Read the result in **5-10 minutes**. Do not interpret results after 10 minutes.



Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Performance Characteristics

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%)
*CI = confidence interval compared to RT-PCR method.

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 device from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lot and different products.

Limitations

The CDV Antigen Rapid Test Device 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.

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