



Canine Distemper-Adenovirus Combo Rapid Test

(Secretions)

Intended Use

The Canine Distemper-Adenovirus Combo Test is a lateral flow immunochromatographic assay for the qualitative distinguish diagnosis of canine Distemper virus antigen (CDV Ag), and canine Adenovirus antigen (CAV Ag) in secretions from dog's eyes, nasal cavities or ocular secretions.

Principle

The Canine Distemper-Adenovirus Combo Test is based on sandwich lateral flow immunochromatographic assay. The test card has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample hole on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated monoclonal antibodies. If there is targeted antigen in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of CDV, CAV 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 device 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 device from its pouch until immediately before use.
- Do not reuse the test kit.

- Do not mix components from different lot and different products.

Additional Special Equipment

Materials Provided

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

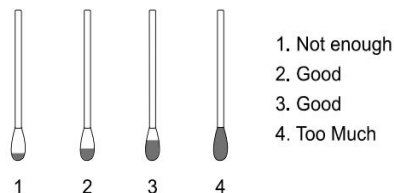
Materials Required But Not Provided

- Timer

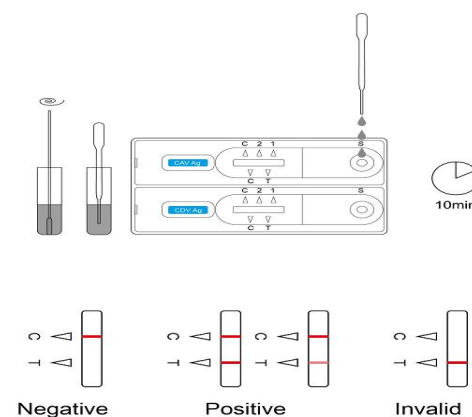
Direction For Use

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

1. Collect dog's ocular, nasal or eyes secretions with the cotton swab and make the swab wet sufficiently. The amount of fecal swab as follows:



1. Insert the wet swab into the provided plastic tubes with buffer. Agitate it to assure good sample extraction.
2. 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.
3. Read the result at **5-10 minutes**. Do not interpret results after 15 minutes.



Interpretation of Results

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: 95.74% (95%CI*: 85.46% - 99.48%)

Relative Specificity: 100.00% (95%CI*: 91.80% - 100.00%)

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

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

Limitations

The Canine Distemper-Adenovirus Combo Test 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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