

AG-CANINE DISTEMPER Ag RAPID TEST KIT

INTENDED USE

AstraGene's Canine Distemper Ag Rapid Test Kit is a lateral flow immunochromatographic assay for the qualitative detection of Canine Distemper Virus (CDV Ag) in intraocular secretions (on the conjunctiva), nasal fluid, and saliva of dogs.

PRINCIPLE

AstraGene's Canine Distemper Ag Rapid Test Kit is a qualitative lateral flow immunochromatographic assay for detection of antigens of Canine Distemper Virus (CDV). The test cassette 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 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.

PACKAGE CONTENTS

| Description | 10 tests | 1 test |
|---------------------------------------|-------------|------------|
| Test Cassette with Desiccant | 10 Cassette | 1 Cassette |
| Extraction Tubes with Buffer and Tips | 10 No's | 1 No's |
| Sterile Swabs | 10 No's | 1 No's |
| Instruction for Use | 1 No's | 1 No's |

| Catalogue Number | 10 tests | 1 test |
|------------------|--------------------|--------------------|
| Cassette Model | AG/RTK/CDTAg/23/01 | AG/RTK/CDTAg/23/02 |

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Personal protective equipment in accordance with local recommendations (i.e. lab coat, face mask, face shield/goggles and gloves)
- biohazard waste bin
- Pipette
- Clock or timer.

STORAGE & STABILITY

• Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.

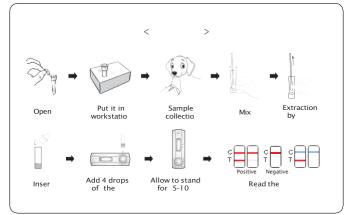
• The test device should be kept away from direct sunlight, moisture and heat.

SAMPLE COLLECTION & PROCEDURE

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 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.
- **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 4 drops of extracted sample** (approximately 120 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



RESULT INTERPRETATIONS

Positive

A clear colored control band (C) and a detectable test band (T) appear, indicating a positive result. Band T: Positive for Canine Distemper Virus antigen



Negative:

A single-colored band appears only at the control region (C), indicating a negative result

Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number. If blue color is shown in the control line (C), it indicates that the operation process is incorrect or the test cassette has been disabled and a retest is required.

Note: The shade of the purple line at the test line (T) is directly related to the CDV antigen content of the test sample. When the antigen content in the test sample is very high, the purple-red line at the test line (T) may appear and then slowly fade or even disappear, in which case it is recommended to dilute the sample for 10 times before test.



LIMITATION OF THE PROCEDURE:

- AstraGene's Canine Distemper Ag Rapid Test Kit is for veterinary 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.

WARNING & PRECAUTIONS:

- For in vitro diagnostic use only. Do not reuse. Do not use the pouch seal or its packaging is compromised.
- Do not use it after the expiration date shown on the pouch. Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay. Wash your hands thoroughly after finishing the tests.
- Do not eat, drink, or smoke in the area where the specimens or kits are being handled. Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing
 procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of hazardous materials should follow local, national, or regional regulations. Keep out of children's reach





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