

AG- CANINE CORONAVIRUS Ag RAPID TEST KIT

INTENDED USE

AstraGene's Canine Coronavirus Ag Rapid Test Kit is a lateral flow immunochromatographic assay for the qualitative detection of Canine Coronavirus (CCV Ag) in dog's feces.

PRINCIPLE

AstraGene's Canine Coronavirus Ag Rapid Test Kit is a lateral flow immunochromatographic assay based on sandwich format. 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. CCV antigens, if present in fecal specimen, react with the pre-coated anti-CCV antibodies in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-CCV antibodies on the membrane in the test line region. If the specimen contains Canine Coronavirus, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain CCV 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/CCVAg/23/01	AG/RTK/CCVAg/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.

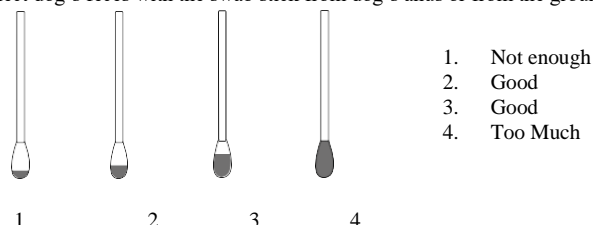
STORAGE & STABILITY

- 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.

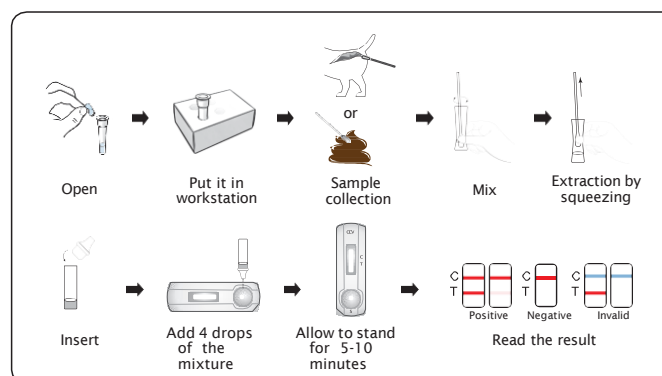
SAMPLE COLLECTION & PROCEDURE

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

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



- Insert the wet swab into the buffer tube provided with the kit. Swirl and shake to ensure sufficient sample extraction.
- Cover the dropper tip and invert it to add 4 drops of the mixture slowly to the sample hole.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 4 drops of extracted sample (approximately 120µL) to the specimen well (S) of the test cassette, then start the timer. See illustration above.
- Read the result in 5-10 minutes. Do not interpret results after 10 minutes.

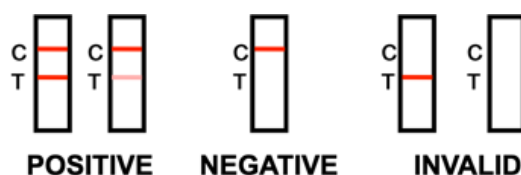


RESULT INTERPRETATIONS

Positive

A clear colored control band (C) and a detectable test band (T) appear, indicating a positive result.

Band T: Positive for Canine Coronavirus 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.

LIMITATION OF THE PROCEDURE:

- Canine Coronavirus 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

SYMBOLS



Do not use if package is damaged



Batch Code



CE mark of Conformity



ISO



GMP



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