

# Canine Coronavirus Antigen Rapid Test Device (Feces/Vomit)

## Package Insert

VR-CCV-AG-10

English

### INTENDED USE

The Canine Coronavirus (CCV) Antigen Rapid Test Device is a lateral flow immunochromatographic assay for the qualitative detection of Canine Coronavirus (CCV Ag) in dog's feces or vomit.

### PRINCIPLE

The CCV Antigen Rapid Test Device is a lateral flow immunochromatographic assay based on sandwich format. 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. 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.

### 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

- The test kit is for canine use only.
- 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.

### MATERIALS

#### Materials Provided

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

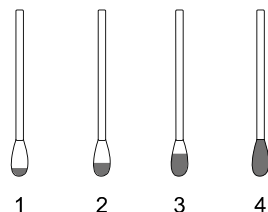
#### Materials Required but Not Provided

- Timer

### DIRECTIONS FOR USE

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

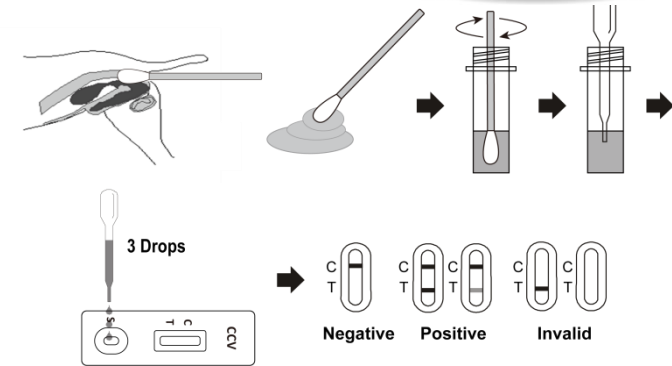
1. Collect dog's feces or vomit with the swab stick from dog's anus or from the ground. The amount of faecal swab as follows:



1. Not enough
2. Good
3. Good
4. Too Much

2. Insert the wet swab into the buffer tube provided with the kit. Swirl and shake to ensure sufficient 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 120µL) 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.

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### 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 zone, regardless of T line's appearance.

### INTERPRETATION OF RESULTS

Relative Sensitivity: 93.10% (95%CI\*: 83.27% - 98.09%)

Relative Specificity: 97.52% (95%CI\*: 92.93% - 99.49%)

Accuracy: 96.09% (95%CI\*: 92.11% - 98.41%)

### LIMITATION

CCV 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.

Index of Symbols			
	Attention, see instructions for use		Tests per kit
	For in vitro diagnostic use only		Use by
	Store between 2-30°C		Lot Number
	Do not use if package is damaged		Manufacturer
	Do not reuse		Catalog #
	Consult Instructions For Use		



Manufactured by Rapid Labs Ltd.

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