



CCV Ag Instructions For Use

Fast result in 10 minutes

For use with Canine Coronavirus Antigen Test

Veterinary in-vitro diagnostic use only

Store between 4~30°C (40~86 °F) **DO NOT FREEZE**

INTENDED USE

Canine Coronavirus Antigen Test is a lateral flow immunochromatographic assay for the qualitative detection of canine coronavirus in canine feces.

PRECAUTIONS AND WARNINGS

- **Important:** Do not remove device from the pouch until ready for use.
- Do not use the components after expiration date.
- Humidity and temperature can influence the results.
- Do not mix components from kits with different lot numbers.
- All wastes should be properly decontaminated prior to disposal.
- Use a separate transfer pipette for each patient.
- Decontaminate and dispose of all samples, used kits and potentially contamination materials safely in accordance with national and local regulations.

KIT COMPONENTS

1. Test devices
2. Swab
3. Buffer
4. Package Insert
5. Workstation

STORAGE AND STABILITY

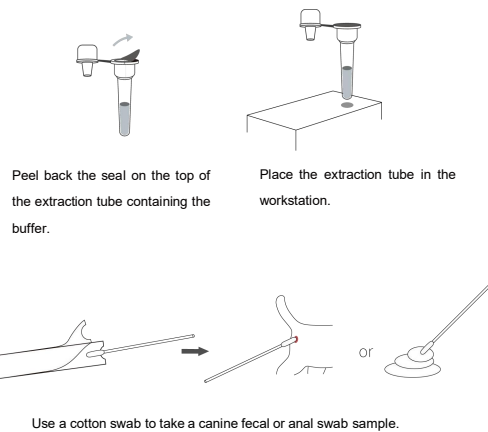
- The test device is sealed and stored away from light at room temperature or refrigerated 4~30 °C (40~86°F). Do not freeze.
- The test kit should be used before the expiration date marked on the package insert.

DIRECTION FOR USE

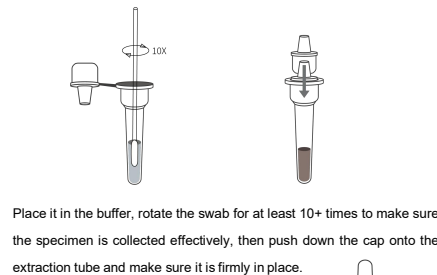
STEP 1 CHECK THE KIT CONTENTS BEFORE USE



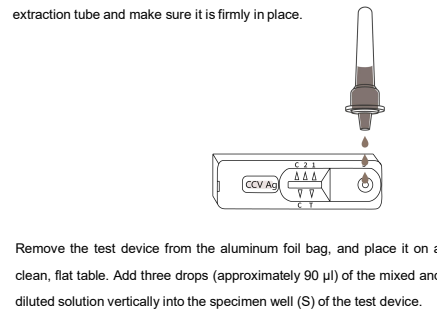
STEP 2 TEST PROCEDURE



Use a cotton swab to take a canine fecal or anal swab sample.

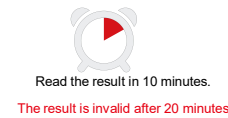


Place it in the buffer, rotate the swab for at least 10+ times to make sure the specimen is collected effectively, then push down the cap onto the extraction tube and make sure it is firmly in place.



Remove the test device from the aluminum foil bag, and place it on a clean, flat table. Add three drops (approximately 90 µl) of the mixed and diluted solution vertically into the specimen well (S) of the test device.

STEP 3 INTERPRETATION OF TEST RESULT



Positive:

Two colored 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(T).



Negative:

Only one colored line appears in the control line region (C), and no colored line appears in the test line region (T).



Invalid:

No colored line appears in the control line region (C), indicating that the test result is ineffective. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

In this case, read the package insert carefully and test again with a new test device.



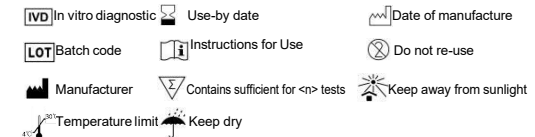
LIMITATIONS

Although the Canine Coronavirus Antigen Test is very accurate in detecting canine coronavirus a low incidence of false results may be occurred. Other clinically or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed by the veterinarian after all clinical and laboratory findings have been evaluated.

INTERFERING SUBSTANCE

Analytes	Conc.	Analytes	Conc.
Whole Blood	20ul/ml	Oxymetazoline	0.6mg/ml
Mucin	50ug/ml	Phenylephrine	12mg/ml
Budesonide	200ul/ml	Rebetol	4.5ug/ml
Dexamethasone	0.8mg/ml	Relenza	282ng/ml
Flunisolide	6.8ng/ml	Tamiflu	1.1ug/ml
Mupirocin	12mg/ml		

SYMBOL



CLINICAL PERFORMANCE

The clinical performance was evaluated using different samples.

Clinical Result For CCV				
	Antigen	PCR	Sensitivity	Specificity
Positive	197	200	98.5%	/
Negative	146	150	/	97.33%
95% Confidence interval			95.48%-99.69%	93.11%-99.19%

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