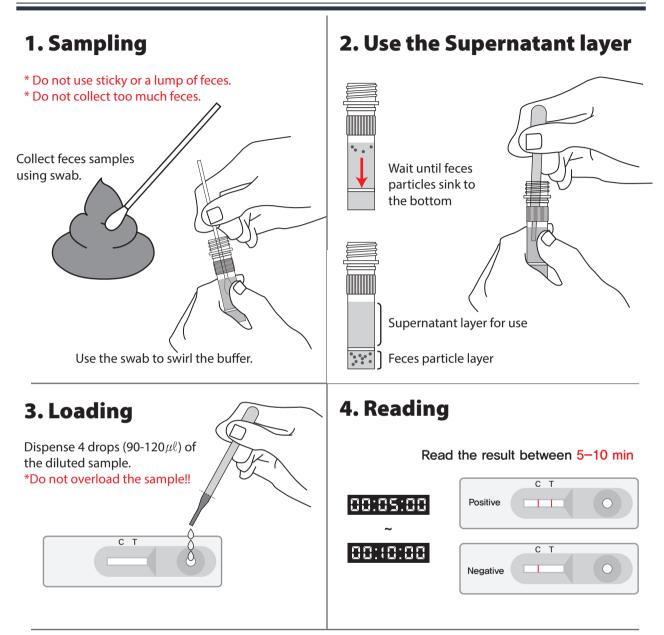


# **Instruction for CCV Ag test**

For veterinary use only

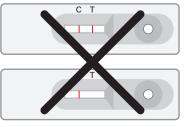


# 5. Discard



Discard the used device Invalid result after 10min

\*Do not read the test result after 10 minutes.





# Imedicom Diagnostics CCV Ag Test Kit

#### - Principles

The Imedicom Diagnostics CCV Ag Test Kit is a chromatographic immunoassay kit for rapid and qualitative detection of canine coronavirus(CCV) infection from stool specimen of dog. A nitrocellulose membrane is immobilized with a monoclonal antibody against the CCV antigen. Another anti-CCV Ag-monoclonal antibody is conjugated to colloidal gold particles. This conjugate is placed on a polyester pad as a conjugate pad. This test is aimed to the detection of CCV antigen either in stool (feces) or in virus-cultured supernatant. When the device is loaded with assay buffer containing specimens, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the anti-CCV Ag antibody that it absorbed onto the nitrocellulose. The result is visible within 10 minutes in the form of a red line on the test line (T) region of the device. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line on the control line (C) area.

# - Materials provided (10 tests/kit)

- 10 X Imedicom diagnostics CCV Ag test devices
- 10 X Assay diluent tubes
- 10 X Disposable swabs
- 10 X Disposable droppers
- 1 X Instructions for use

# - Storage & Stability

- 1. Store the test kit at 2-30  $^\circ C$  (36-86  $^\circ F$ ), Do not freeze.
- 2. Do not store the test kit in the direct sunlight and heat.
- 3. The test kit is stable within the expiration date that marked on the package label.

### - Warnings & Precautions

- 1. The test kit is for canine use only. Do not use for other animals.
- 2. The test kit is intended for in vitro diagnostic use only.
- 3. Do not use the test kit if the pouch is damaged or the seal is broken.
- 4. Perform the test immediately after removing the test device from the foil pouch.
- 5. Do not touch the membrane in the result window of test device.
- 6. Do not use the test kit beyond the stated expiration date marked on the package label.
- 7. Avoid cross-contamination between samples by using a new dropper for each test.
- 8. Do not reuse test components.
- 9 Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
- 10. Decontaminate and dispose of all samples, test devices, and potentially contaminated materials safely in accordance with national and local regulations.

# - Sample collection & Preparations

- 1. The sample of the test is canine feces. collect the sample using a swab.
- 2. The samples should be tested immediately after collection. 3. If samples are not tested immediately, they should be stored at 2-8  $^{\circ}{\rm C}$
- for 24 hours. For longer storage, freeze at -20  $^\circ$ C or below. Frozen samples should be brought to room temperature (15-30  $^\circ$ C) prior to use.

#### Test procedure

- 1. Place all samples, test devices and allow them to room temperature prior to testing (15-30min).
- Remove the test device from the sealed pouch and place it on a clean and plain place.
- Collect the feces samples at 4 different points or directly take the samples from the canine colon.
  \*Do not use sticky feces or a lump of feces.
- Insert and mix the swab with assay solution in a tube until the specimens has been dissolved. Then, discard the swab and repeat the procedure for each sample.
- Add 4 drops (approx. 120µl) of the solution taken by the disposable dropper into the sample well.
- 6. Within 5-10 minutes, interpret the test result (s). Do not read after 10 minutes.

### - Interpretation of the Result

A color band will appear in the control line (C) of the result window to show that the test is working properly. The other color band in the test line (T) of the result window indicates the test results.

### 1. Negative

1) One band is appeared in the control line (C).



## 2. Positive

1) Two bands are appeared in the test line (T) and control line (C).



### 3. Invalid

 If at 10 minutes, the red color band does not appear in the control line (C), even if any shade of a pink-to-red test Line (T) appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new sample and a new test device.



## - Limitations of the test

Imedicom Diagnostics CCV Ag Test Kit is designed for primary screening test of canine coronavirus antigen. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and veterinarian's view, collectively.

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