

# Canine Coronavirus Antigen Test

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST



## Introduction

Canine coronavirus (CCV), a single-stranded positive-sense RNA virus (family Coronaviridae, genus *Alphacoronavirus*), was first isolated in 1971 from military dogs in Germany suffering from acute gastroenteritis<sup>1</sup>.

CCV infection is characterized by high morbidity and low mortality, as well as by a typical fecal-oral route of transmission<sup>2</sup>. CCV is shed at high titers with the feces of the infected dogs and the infection is restricted to the alimentary tract, leading to typical clinical signs of gastroenteric involvement including loss of appetite, vomiting, fluid diarrhea, dehydration, and sometimes death especially in puppies<sup>2,3</sup>.

Fatal disease commonly occurs as a consequence of mixed infections with CCV together with canine parvovirus, canine adenovirus or canine distemper virus<sup>4</sup>.

## Principle

The **BISAF** CCV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of CCV antigens in canine feces. This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the CCV antigen exists in the sample, it binds to the gold-conjugated CCV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the CCV antibody on the test line, resulting in a red line. The control line indicates that the test is performed correctly and should appear when the test is complete.

The highly selective and sensitive monoclonal antibody to CCV is used as a capture and detector in the kit. The **BISAF** CCV Ag Test Kit can detect CCV antigens in canine feces with high accuracy.

## Performance

### 1. Sensitivity & Specificity

|             |       | RT-PCR |     |       |
|-------------|-------|--------|-----|-------|
|             |       | +      | -   | Total |
| CCV Ag Test | +     | 56     | 3   | 59    |
|             | -     | 3      | 118 | 121   |
|             | Total | 59     | 121 | 180   |

Sensitivity: 94.92% (56/59, 95% CI\*: 86.06% ~ 98.26%)

Specificity: 97.52% (118/121, 95% CI: 92.92% ~ 99.15%)

Diagnostic Agreement: 96.67% (174/180, 95% CI: 92.92% ~ 98.46%)

\* CI: Confidence Interval

### 2. Limit of Detection: $1 \times 10^5$ TCID<sub>50</sub>/mL

### 3. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the **BISAF** CCV Ag Test Kit.

| Pathogen                | Titer                                     | Result   |
|-------------------------|-------------------------------------------|----------|
| Canine distemper virus  | $1.00 \times 10^5$ TCID <sub>50</sub> /mL | Negative |
| Canine influenza virus  | $1.00 \times 10^6$ EID <sub>50</sub> /mL  | Negative |
| Canine parvovirus       | $1.00 \times 10^6$ TCID <sub>50</sub> /mL | Negative |
| <i>Escherichia coli</i> | $3.56 \times 10^8$ CFU/mL                 | Negative |
| <i>Giardia</i> spp.     | $1.42 \times 10^5$ Cysts/μL               | Negative |
| <i>Salmonella</i> spp.  | $1.00 \times 10^6$ CFU/mL                 | Negative |

## Kit Components

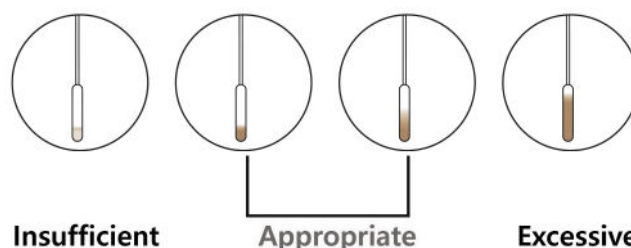
| Component              | Quantity/kit by |
|------------------------|-----------------|
| 1 CCV Ag test device   | 1               |
| 2 Dilution buffer      | 1               |
| 3 Disposable swab      | 1               |
| 4 Instructions for use | 1               |
| 5 Collection bag       | 1               |

## Storage & Stability

- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

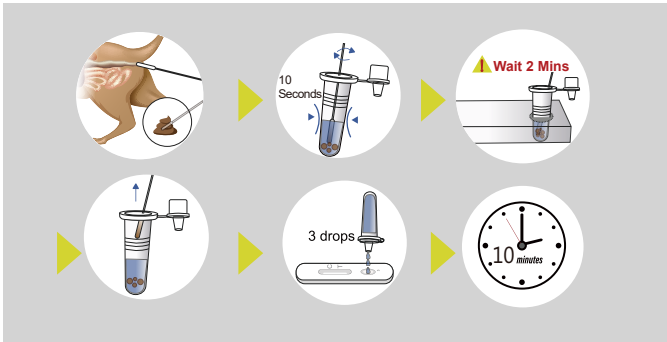
## Sample Preparation

1. Canine fecal swab should be used for this test.
2. The samples should be tested immediately after collection.
3. If samples cannot be tested immediately, they should be stored at 2-8°C (35.6~46.4°F) for up to 24 hours. For longer storage, freeze at -20°C (-4°F) or below. Frozen samples should be brought to room temperature (15~30°C/59~86°F) before use.
4. The amount of fecal sample with swab may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive fecal amount may induce a false positive result and slow migration.



## Test Procedure

1. All reagents and samples must be at room temperature (15~30°C/59~86 °F) before use.
2. Collect fecal sample using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Wait for 2 minutes to settle down the large particles.
5. Remove the swab from the sample dilution buffer.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Apply 3 drops of the mixed sample solution into the sample holes for each, drop by drop vertically.
8. Read test results at 10 minutes.



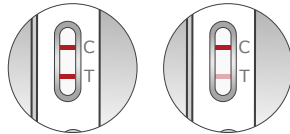
[Summary of Test Procedure]

## Interpretation of Results

### Positive(+)

Presence of two color bands "T" and "C"

Two lines, one next to C and one next to T, even faint lines, shows the test is positive.



### Negative (-)

No presence of color band ("T")

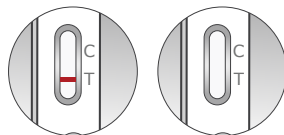
One red-colored line only next to "C" indicates a negative result.



### Invalid

No presence of color band ("C")

If the red-colored line in the control region "C" is not visible, the result is invalid. Run a new test.



## Precautions

1. This test kit is for veterinary *in vitro* diagnostic use only for dogs. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. Do not use the device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the components (device, buffer, dropper, and swab).

7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials in the accordance with national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

## References

1. Binn LN, Lazar EC, Keenan KP, Huxsoll DL, Marchwicki RH, Strano AJ. Recovery and characterization of a coronavirus from military dogs with diarrhea. *Proc Annu Meet U S Anim Health Assoc.* 1974; 78: 359–366.
2. Tennant BJ, Gaskell RM, Kelly DF, Carter SD, Gaskell CJ. Canine coronavirus infection in the dog following oronasal inoculation. *Res Vet Sci.* 1991; 51(1): 11–18.
3. Evermann JF, Abbott JR, Han S. Canine coronavirus-associated puppy mortality without evidence of concurrent canine parvovirus infection. *J Vet Diagn Invest.* 2005; 17(6): 610–614.
4. Decaro N, Buonavoglia C. An update on canine coronaviruses: viral evolution and pathobiology. *Vet Microbiol.* 2008; 132: 221–234.

## Symbol Descriptions



License number



Catalogue number



Batch code, Lot number



Consult instructions for use



Contains sufficient for <n> tests



Do not reuse



*In vitro* diagnostic medical device



Temperature limitation



Do not use, if the package is damaged



Upper side



Manufacturer



Manufacturer: Feng Chun Yuan Medical Equipment(Shenzhen)Co.,Ltd  
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