CCV Antigen Rapid Test Strip Package Insert

【PRODUCT NAME】

CANINE CORONAVIRUS (CCV) ANTIGEN RAPID TEST CASSETTE (*For professional in vitro diagnostic use only*)

【PACKING】

10 Pcs/Box

【MATERIALS】

Test devices; Disposable specimen droppers; Swab; Dilution Buffer; Package Insert

【INTENDED USE】

The CCV Antigen Test Device is a rapid chromatographic immunoassay for qualitative detection of CCV antigen in nasal swab specimens. It is intended to aid in the rapid differential diagnosis of CCV infections.

【PRINCIPLE】

The CCV Rapid Test Device (Swab) is a qualitative, lateral flow immunoassay for the detection of CCV antigen in nasal swab specimens. In this test, antibody specific to the CCV is separately coated on the test line regions of the test strip. During testing, the extracted specimen reacts with the CCV antibodies that are coated onto particles. The mixture migrates up the membrane to react with the antibody to CCV on the membrane and generate one or two colored lines in the test zones. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control zone if the test has performed properly.

【STORAGE AND STABILITY】

The test kit can be stored at room temperature or refrigerated (2-30°C) for the duration of the shelf life. The test must remain in the sealed pouch until use. DO NOT FREEZE. Does not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

1.Use the sterile swab supplied in the kit.

2.Insert this swab into the excrement that presents the most secretion under visual inspection.

3.Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch in the nostril).

4.Rotate the swab three times against the nasal wall.

5.It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately they should be placed into a dry, sterile, and tightly sealed plastic tube for storage. Swabs can be stored dry at room temperature for up to 24 hours.

【DIRECTIONS FOR USE】

Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

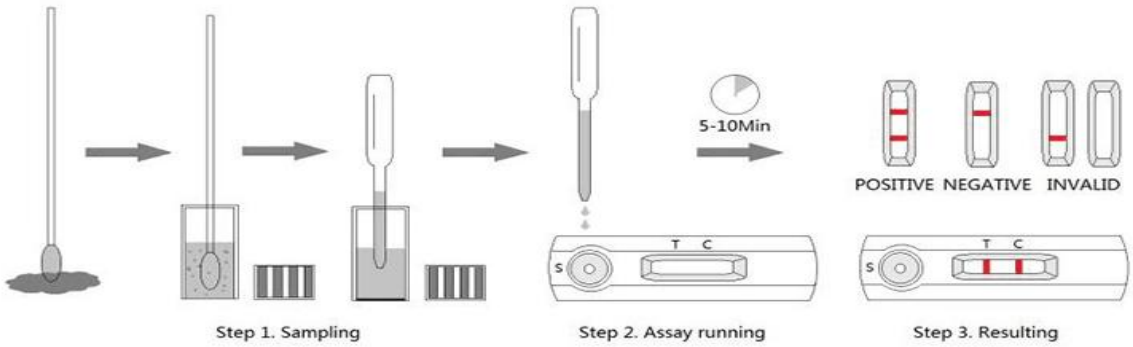
Step of the testing：

1. Remove the test strip from the foil pouch and collect the specimen with swab.

2. Place the swab specimen in the dilution buffer tube and fully mixed.

3. Place the test device on a clean and level surface.

4. Hold the dropper vertically and transfer 3 full drops of buffer specimen (approx. 120 μl) to the specimen well (S) of the test device, and then start the timer. Read the result in 10 minutes. Avoid trapping air bubbles.



【INTERPRETATION OF RESULTS】

1、**NEGATIVE：One red line appears in the control region (C)**. No apparent red or pink line appears in the test region (T).

2、**POSITIVE: Two distinct red lines appear.** One line should be in the control region (C) and another line should be in the test region (T).

3、**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATION】

The CCV Test Device (Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of CCV virus in nasal swab specimens only. Neither the quantitative value nor the rate of increase in CCV virus concentration can be determined by this qualitative test.

【NOTES】

1. No for second use.
2. DO NOT FREEZE.
3. Humidity sensitive，use the device within one hour after open the pouch .
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.