

## Rapide - Parvovirus - Coronavirus Ag Test Kit

### Principles

The **Rapide - Parvovirus - Coronavirus Ag Test Kit** is a chromatographic immunoassay for the qualitative detection of Canine Parvovirus antigen and Coronavirus antigen in canine feces.

The **Rapide - Parvovirus - Coronavirus Ag Test Kit** has the letters "T" and "C" as the Test line and Control line on the surface of the device. Both the test line and control line in the result window are not visible before applying any sample. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple test line will be visible in the result window if there is Canine Parvovirus antigen and/or Canine Coronavirus antigen in the specimen.

The specially selected Canine Parvovirus antibodies and Canine Coronavirus antibodies are used in the test bands as both capture and detector materials. These enable the **Rapide - Parvovirus - Coronavirus Ag Test Kit** to identify Canine Parvovirus antigen and Canine Coronavirus antigen in canine feces with a high degree of accuracy.

### Materials provided (10 tests/kit)

- 1) Ten(10) **Rapide - Parvovirus - Coronavirus Ag Test Devices**
- 2) Ten(10) Specimen tubes containing assay diluent buffer
- 3) Ten(10) Sample collection swabs
- 4) Ten(10) Disposable droppers
- 5) One(1) Instructions for use

### Precautions

- 1) For veterinary diagnostic use only.
- 2) For best results, strict adherence to the instructions is required.
- 3) All specimens should be handled as being potentially infectious.
- 4) Do not open or remove test kits from their individually sealed pouches until immediately before their use.
- 5) Do not use the test kit if the pouch is damaged or the seal is broken.
- 6) Do not reuse test kits.
- 7) All reagents must be at room temperature (15°C~25°C) before running the assay.
- 8) Do not use reagents beyond the stated expiration date marked on the label.
- 9) The components in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

### Storage and Stability

The kit can be stored at room temperature or refrigerated (2~30°C). The test kit is stable through the expiration date marked on the package label. **DO NOT FREEZE.** Do not store the test kit in direct sunlight.

### Specimen Collection and Preparation

- 1) Canine fecal samples should be used for this test.
- 2) The specimens should be tested immediately after collection.

### Procedure of the test

- 1) Collect a sample from canine feces using a swab.
- 2) Insert the swab into a specimen tube containing 1ml of assay diluent.
- 3) Mix the swab sample with the assay diluent vigorously to extract the viruses.
- 4) Remove a test device from an aluminum foil pouch, and place it on a flat and dry surface.
- 5) If the fecal particles are large, wait for 1 minute until the large particles are settled, and then take the supernatant of the sample in the tube.
- 6) Using a disposable dropper provided, take an aliquot from the extracted sample.
- 7) Add four (4) drops into the sample hole using the disposable dropper. The assay diluent should be added exactly, slowly drop by drop.
- 8) As the test begins to work, you will see a purple color move across the result window in the center of the test device. If the migration has not appeared after 1 minute, add one more drop of the sample to the sample well.
- 9) Interpret test results at 5 ~ 10 minutes.

[Figure for test procedures]

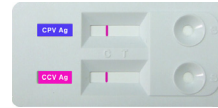


### Interpretation of the test

A colored band will appear in the left section of the result window ("C" band) to show that the test is working properly. This band is the control band. The right section of the result window indicates the test results.

#### 1) Negative result

The presence of only one band within the result window ("C" band) on both of the CPV Ag and CCV Ag test areas indicates a negative result.



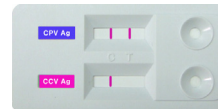
#### 2) Simultaneous CPV and CCV Positive result

The presence of two color bands ("T" and "C") within the result window on both of the CPV Ag and CCV Ag test areas respectively, no matter which band appears first, indicates a positive result of Canine Parvovirus and Canine Coronavirus simultaneously.



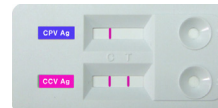
#### 3) CPV Positive result

The presence of two color bands ("T" and "C") within the result window on the CPV Ag test area, and the presence of only one band ("C") within the result window on the CCV Ag test area, no matter which band appears first, indicates a positive result of Canine Parvovirus.



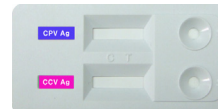
#### 4) CCV Positive result

The presence of two color bands ("T" and "C") within the result window on the CCV Ag test area, and the presence of only one band ("C") within the result window on the CPV Ag test area, no matter which band appears first, indicates a positive result of Canine Coronavirus.



#### 5) Invalid Result

If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



### Performance

In large scale studies using several hundreds clinical samples, **Rapide - Parvovirus - Coronavirus Ag Test Kit** was compared to PCR, a reference standard technique used by diagnostic labs, for detection of CPV and CCV antigens; the sensitivity and specificity were 100% for CPV antigen detection compared to PCR; the sensitivity was 93.1% and the specificity was 97.5% for CCV antigen detection compared to PCR

In a field trial study taking place at multiple veterinary clinics in the United-States, the sensitivity and specificity were 100% compared to PCR for CPV antigen detection.

### Limitations of the test

Although the **Rapide - Parvovirus - Coronavirus Ag test kit** is very accurate in detecting Canine Parvovirus antigen and Canine Coronavirus antigen, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the veterinarian after all clinical and laboratory findings have been evaluated.

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