

Rapide - Parvovirus Ag Test Kit

■ Principles

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

The **Rapide - Parvovirus Ag Test Kit** has a letter “T” as test line and “C” as control line on the surface of the device. Both the test line and the control line in the result window are not visible before applying any sample. The control line is used for procedural control. The control line 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 Parvovirus antigens are present in the specimen.

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

■ Materials provided (10 tests/kit)

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

■ Precautions

- 1) For veterinary diagnostic use only.
- 2) For best results, strict adherence to these 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 – 30°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 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.

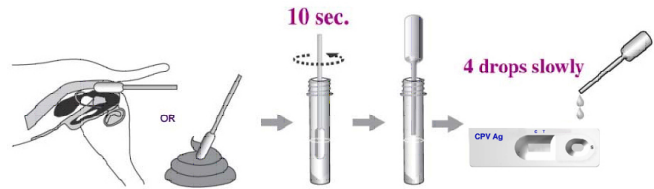
■ Specimen Collection and Preparation

- 1) The canine fecal samples should be used for this test.
- 2) For best results specimens should be tested immediately as soon as the sample is collected.

■ Procedure of the test

- 1) Collect the samples from canine feces using the swab.
- 2) Insert the swab into the specimen tube containing 1ml of assay diluent.
- 3) Mix the swab samples with the assay diluent to extract well.
- 4) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 5) Using the disposable dropper, take the mixed assay diluent from the tube.
- 6) Add four (4) drops into the sample hole using the disposable dropper. **The mixed assay diluent should be added exactly, slowly drop by drop.**
- 7) 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 mixed assay diluent to the sample well.
- 8) Interpret test results at 5 ~ 10 minutes. Do not decide after 20 minutes.

[Figure for test procedures]

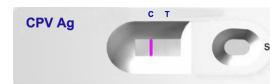


■ Interpretation of the test

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 result.

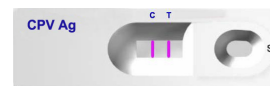
1) Negative result

The presence of only one band (“C” band) within the result window indicates a negative result.



2) Positive result

The presence of two colored bands (“T” and “C”) within the result window, no matter which band appears first indicates a positive result.



3) Invalid Result

If the purple colored band “C” 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 a study using 155 fecal samples, **Rapide - Parvovirus Ag Test kit** was compared to Hemagglutination assay (HA), a reference standard technique in laboratory diagnostics; both the sensitivity and specificity were 100%.

In another field trial study taking place at multiple veterinary clinics in the United States, the sensitivity and the specificity were 100% compared to PCR.

■ Limitations of the test

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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Modern Veterinary Therapeutics SAS
5, Chemin du Champ Boissel
35800 Saint-Lunaire - FRANCE
Tel. +33 (0)2 99 46 30 77
Fax +33 (0)2 22 44 19 26
info@modernveterinarytherapeutics.com
www.modernveterinarytherapeutics.com