

ONE STEP IgG to Canine Distemper Virus TEST

For veterinary diagnostic use only

Anigen Rapid CDV Ab Test Kit 3.0

Principles

Anigen Rapid CDV Ab Test Kit 3.0 is a chromatographic immunoassay for the semi-quantitative detection of IgG to distemper virus in canine serum, plasma or whole blood. **Anigen Rapid CDV Ab Test Kit 3.0** has two letters which are test ("T") line and control ("C") line on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test has performed. If the target antibodies are present in sample, a purple test line would appear in the result window. The highly selective antigens are used as each capture and detector in the assay. These antigens are capable of detecting IgG antibody to canine distemper virus in sample with high accuracy.

Materials provided

Materials	10 Tests/kit
Anigen Rapid CDV Ab 3.0 Test Device	10
Assay diluent tube	10
Disposable inverted cup (5 µl)	10
Sample sheet	10
Anticoagulant tube	10
Disposable dropper	10
Color scale (1~6) measurement	1
Instructions for use	1

Materials required, but not provided

- 1) Timer
- 2) Micropipette

Precautions

- 1) The test kit is for canine use only. Do not use for other animals.
- 2) The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
- 3) Do not reuse test components.
- 4) Apply the sample using disposable dropper vertically.
- 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) Do not use the test kit if the pouch is damaged or the seal is broken.
- 8) Do not mix components from different lot numbers because the components in this kit have been quality control tested as standard batch unit.
- 9) All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
- 10) Decontaminate and dispose of all samples, reaction kits and potentially contaminated materials safely in accordance with national and local regulations.
- 11) Strictly follow the test procedures to minimize false or invalid test results due to improper administration of the product usage or doses.

Storage and Stability

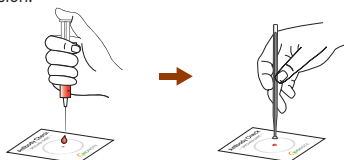
- 1) Store the test kit at 2~30 °C. **DO NOT FREEZE.**
- 2) Do not store the test kit in the direct sunlight.
- 3) The test kit is stable within the expiration date marked on the package label.

Collection and Preparation of Sample

- 1) Canine whole blood, serum, or plasma should be used with this test.
 - [Whole blood]** Collect the whole blood into the anticoagulant tube (Max. vol. 1.5 ml) provided. It is recommended to immediately use the anticoagulant whole blood. If samples are not tested immediately, they can be stored at room temperature for up to four hours from the sample collection, or up to 24 hours if stored at 2-8 °C (35.6-46.4 °F).
 - [Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge to get serum supernatant.
 - [Plasma]** Collect the whole blood into the collection tube(containing anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge to get plasma.
- 2) The collected plasma and serum can be stored at 2-8 °C (35.6-46.4 °F) for up to 2 weeks. For longer storage, they can be stored frozen at -20 °C (-4 °F) or below for up to 1 year. Frozen samples should be brought to room temperature (15-30 °C) prior to use.
- 3) Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.
- 4) As hemolyzed sample can cause non-specific reactions, use the whole blood within 24 hours after collection. For prolonged storage, separate serum from the whole blood and store it frozen.

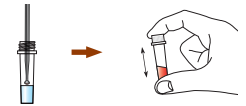
Procedure of the Test

- 1) Allow all kit components and sample to reach room temperature (15~30 °C) prior to testing.
- 2) Remove the test kit from the foil pouch prior to use.
- 3) **[Whole blood]** Drop the whole blood in the sample sheet then collect 5 µl of sample using inverted cup. The whole blood will be automatically collected into the inverted cup by surface tension.

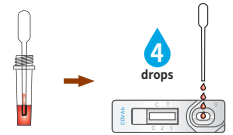


[Serum/Plasma] Collect 5 µl of sample using micropipette (Not provided).

- 4) Add the sample into the assay diluent tube.
- 5) Close the cap and mix the sample thoroughly until the sample has been dissolved into the assay diluent.



- 6) Using the disposable dropper provided, take the samples in the tube.
- 7) Add four (4) drops into the sample hole, drop by drop vertically.

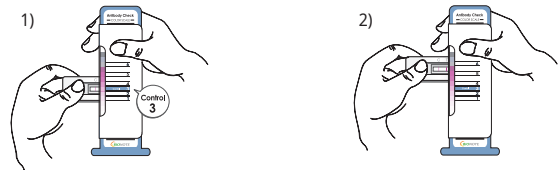


- 8) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of prepared sample to the sample hole.
- 9) Interpret the test results at 10 minutes. Do not interpret after 20 minutes.



Use of color scale

- 1) Compare the color development on the control ("C") line with color scale and fix it to the scale '3'.
- 2) Interpret the color intensity of the Test line.



Interpretation of the Result

1) Negative result

Only Control ("C") line appears in the result window.



2) Positive result

Low titer (Below 1:4 as VN titer)

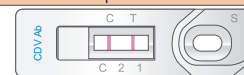
The color development of Test ("T") line is weaker than that of Control ("C") line. (Color scale 1-2)



**Antibody titer is low against CDV.

Medium Titer (1:8 as VN titer)

The Test ("T") line has equal color development with Control ("C") lines. (Color scale 3)



**Antibody titer is medium against CDV. This is indicative of a good immune status.

High Titer (Above 1:16 as VN titer)

The color development of Test ("T") line is higher than that of Control ("C") line. (Color scale 4-6)



**Antibody titer is high against CDV. This is indicative of a good immune status.

3) Invalid Result

If the control ("C") line is does not appear, the result might be considered invalid. The sample should be retested.



Limitations of the Test

- 1) Although the Anigen Rapid CDV Ab Test kit 3.0 is very accurate for detecting IgG to Canine Distemper virus, a low incidence of false results can be occurred. Other clinical and/or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed by the veterinarian after all clinical and laboratory findings have been evaluated.
- 2) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
- 3) BIONOTE Inc. and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

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