ONE STEP IgG antibodies to Canine Parvovirus RAPID TEST

Anigen Rapid CPV Ab Test Kit

■ Explanation of the Test

Canine parvovirus (CPV) is the most important cause of viral gastroenteritits in dogs world-wide. The disease is characterized by severe enteritis and lymphopenia with high mortality especially in non-immune dogs. Antibody titers to CPV are important in the prediction of canine health and preparing vaccination programs. The hemagglutination-inhibition(HI) test has been the most commonly used serological assay for CPV antibody.

[Intended Use] Anigen Rapid CPV Ab Test Kit is a solid phase immunochromatographic assay for the rapid, quantitative detection of IgG antibodies to parvovirus in canine serum, plasma or whole blood. This test is intended for professional use as an aid in presumptive diagnosis, and preparation of vaccination programs. This test provides only a preliminary test result. Therefore, other tests like hemagglutination-inhibition test or serum neutralization test, or more specific alternative diagnosis methods must be used in order to obtain a confirmation of immune status.

[Principle] Anigen Rapid Ab Test Kit is designed to detect IgG antibodies to CPV in serum, plasma or whole blood. Anigen Rapid Ab Test Kit has three pre-coated lines, "**C1**" (Control line 1), "**T**" (CPV IgG Test Line) and "**C2**" (Control line 2) on the surface of the kit. All three lines in the result window are not visible before applying any samples. The "Control Lines" are used for procedural control. Control lines should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple "T" line will be visible in the result window if there are IgG antibodies to CPV in the sample. If IgG antibodies to CPV are not present in the sample, then no color appears in the "**T**" line.

When a specimen is added to the test, anti-CPV IgG in the specimen sample reacts with purified CPV antigen, and then reacts with monoclonal anti-CPV (conjugated gold) and forms a complex of antibodies and colloidal gold conjugates.

As this mixture migrates along the length of the test kit by capillary action, the anti-CPV IgG complex is captured by the relevant anti-canine IgG, immobilized in the test line across the test kit and generates a colored line.

■ Materials Provided

1) Ten test kits individually foil pouched with a desiccant
2) Each test kit contains anti-swine IgG (C1), anti-canine IgG (T) and anti-swine IgG (C2) as capture materials. Also the test kit contains a gold conjugate pad with purified CPV antigens.
3) 1 ul Disposable specimen loops, 10ea
4) Diluent buffer
5) Instruction for use

■ Precautions

1) For best results, strict adherence to these instructions is required.
2) All specimens should be handled as being potentially infectious.
3) Do not open or remove test kits from their individually sealed pouches until immediately before their use
4) Do not reuse test kit.
5) All reagents must be at room temperature before running the assay.
6) Do not use reagents beyond the stated expiration date marked on the package label.
7) The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
8) The assay buffer contains low concentration of sodium azide as a preservative. Sodium azide is toxic and should be handled carefully to avoid ingestion and skin contact.

■ Storage and Stability

The kit can be stored at room temperature (2 ~ 30°C) or refrigerated. 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.

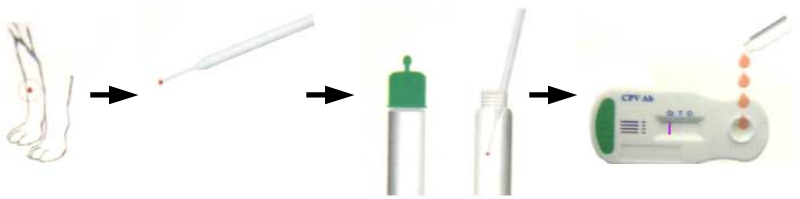
■ Specimen Collection and Preparation

1) Serum, plasma or whole blood samples may be used with this test.
2) Handle all blood products as capable of transmitting infectious diseases.
3) Whole blood samples should be used immediately, if possible or may be stored at 2 ~ 8°C up to three days.
4) If serum or plasma specimens cannot be tested immediately, they should be refrigerated at 2 ~ 8°C. For storage greater than one week, freeze the specimen at –20°C or below.
5) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) The use of hemolytic, lipaemic, icteric or bacterially contaminated specimens should be avoided. Erroneous result may occur.

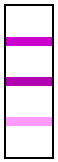
■ Test Procedure

1) Allow all kit components and specimen to reach room temperature prior to testing.
2) Using the loops provided(*), add 1 of specimen to a test tube containing assay buffer. (*Dip the circular end of the specimen loop into the specimen, and then carefully place the circular end of the loop into the test tube. This will add 1 of specimen to assay buffer.)
3) Gently stir the assay buffer with the loop to ensure adequate mixing of the serum in the assay buffer and remove the loop.
4) Remove the test kit from the foil pouch prior to use.
5) Place the kit horizontally, insert all of the specimen-assay buffer mix into the "S" hole.
6) Interpret test results at 20 minutes. Do not interpret after 20 minutes.

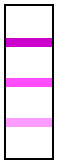
[Figure for test procedures]



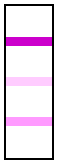
■ Interpretation of the Test



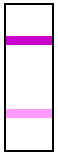
High Titer (Above 1:640 as HI titer)
The strength of T line is higher than that of C2 line. This means high antibody titer to CPV. This is indicative of a good immune status.



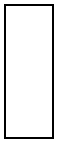
Medium Titer (From 1:80 to 1:320 as HI titer)
The strength of T line is between C1 and C2 lines. This means medium antibody titer to CPV. This is indicative of a good immune status.



Low Titer (Below 1:80 as HI titer)
The strength of T line is lower than that of C1 lines. This means low antibody titer to CPV. This is indicative of a poor immune status and necessary to vaccination within 1 month.



Negative
The control line is only visible on the test kit. No IgG antibodies were detected.



Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat the test using a new test kit.

■ Limitation of the Test

1) This Test is for *in-vitro* diagnostic use only.
2) This test detects the presence of antibodies to CPV in the specimen and should not be used as the sole criterion for the diagnosis of CPV infection.
3) As with all diagnostic tests, all results must be considered with other clinical information available to the veterinarian.
4) For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended

■ Performance Characteristics

1) Comparison of Anigen Rapid CPV Ab Kit with HI Test

Anigen Rapid CPV Ab Kit with HI Test showed good correlation with hemagglutination-inhibition (HI) test

Titer of HI Test	Anigen Rapid CPV Ab Test Kit
<1:10	-
1:10	+/-
1:20	+
1:40	+
1:80	++
1:160	++
1:320	++
1:640	+++
1:1,280	+++

+ : The strength of T line is lower than that of C1 lines.
++ : The strength of T line is between C1 and C2 lines.
+++ : The strength of T line is higher than that of C2 line

□oc. No. : 2101-1
Issued date : Aug. 18, 2004

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