

* Anigen Rapid Total IgE Ab Test Kit

■ Principles

The **Anigen Rapid Total IgE Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of canine total IgE antibody in canine serum.

The Rapid Total IgE Ab Test Kit has the letter "T" and "C" as 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 samples. 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 are enough canine IgE antibodies in the specimen.

The specially selected anti-canine IgE antibody is used in the test band as both capture and detector materials. These enable the Anigen Rapid Total IgE Ab Test Kit to identify canine IgE antibody in canine serum with a high degree of accuracy.

■ Materials provided (10 tests/kit)

- 1) Ten(10) Anigen Rapid Total IgE Ab Test Devices.
 - 2) One(10) Assay diluents (0.5ml)
 - 3) Ten(10) Disposable capillary tubes
 - 4) Ten(10) Disposable droppers
 - 5) One(1) Package insert
- ♣ A dark color score line on the capillary tube is the indicator line for 10 μ l.



■ Precautions

- 1) For veterinary diagnostic use only.
- 2) The Rapid Test Kit is only dog for use. Do not apply to other animals.
- 3) For the best results, strict adherence to the instructions is required.
- 3) Do not open or remove test kit from their individually sealed pouches until immediately before use.
- 4) Do not use the test kit if the pouch is damaged or the seal is broken.
- 5) Do not reuse test kit.
- 6) All reagents must be at room temperature before running assay.
- 7) Do not use reagents beyond the stated expiration date marked on the label.
- 8) 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

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

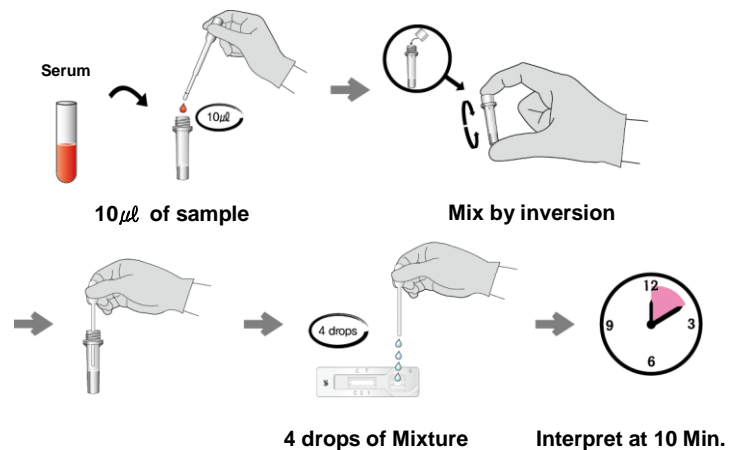
■ Specimen Collection and Preparation

- 1) The test should be used to canine serum.
 - (1) Collected blood should be left at room temperature for 30minutes for coagulation and then separate serum by centrifugation.
 - (2) Serum may be stored at 2~8°C for up to 1 weeks, for longer storage (1 year), freeze at or below -20°C.
- 2) Specimen should be brought to room temperature(18~25°C) prior to use.

■ Procedure of the test

- 1) Using a disposable capillary tube provided, add **10 μ l of canine serum** into assay diluents bottle.
- 2) Cap the assay diluents bottle and mix thoroughly by inverting bottle for a few seconds.
- 3) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 4) Using a disposable dropper provided, add **4 drops of mixed sample** into sample well.
- 5) As the test begins to work, you will see purple color move across the result window in the center of the test device. If the migration has not appeared after 1minute, add one more drop of the mixed sample to the sample well.
- 6) Interpret test results at **10 minutes**. Do not interpret after 10 minutes.

[Figure for Test Procedure]



■ Interpretation of the test

A color band will appear in the left section of the result window to show that the test is working properly, this is the Control band. The right section of the result window indicates the Test band, and it indicates a positive test result.

1) Negative result

The only one band ("C") in the result window indicates a negative result against canine total IgE antibody.



2) Positive result

The two color bands ("T" and "C") within the result window indicate the presence of total IgE antibody. The minimum indicative level and warning level of total IgE for allergic disease is generally agreed to be 10 μ g/ml.



3) Invalid Result

If the control 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.



■ Limitations of the test

- 1) Negative result means that total IgE concentration is below 10 μ g/ml in canine serum, not necessarily means that the dog has free of allergy. 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.
- 2) The Anigen Rapid Total IgE Test is qualitative test kit. Test line density may not proportional to IgE concentration in canine blood.
- 3) Steroids or antihistamine medications may affect test result. 2 weeks of withdrawal period is required for the test.
- 4) Parasite infection should be cleared before the test.

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