

Anigen Rapid Total IgE Test Kit

Principles

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

The **Anigen Rapid Total IgE Test Kit** 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 Total IgE are present in sample, a purple test line would appear in the result window.

The highly selective anti canine IgE are used as a capture and detector in the assay. These are capable of detecting canine Total IgE in canine sample with high accuracy.

Materials provided (10 Tests/Kit)

- 1) Ten(10) Anigen Rapid Total IgE Test devices
- 2) Ten(10) Assay diluents tubes
- 3) Ten(10) Disposable capillary tubes
- 4) Ten(10) Disposable droppers
- 5) One(1) Instructions for use

♣ A black line on the capillary tube is the indicator line for 10 μ l.



Materials required, but not provided

Timer

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 the disposable dropper.
- 4) Apply the sample 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, used kits and potentially contaminated materials safely in accordance with national and local regulations.

Storage and Stability

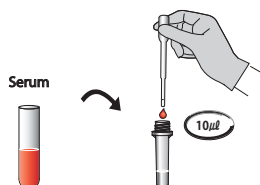
- 1) Store the test kit at 2~30°C. **DO NOT FREEZE.**
- 2) Do not store the test kit in the direct sunlight.
- 3) The test kit is stable within the expiration date that marked on the package label.

Collection and Preparation of Sample

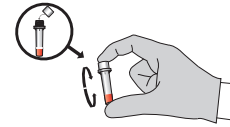
- 1) Canine serum should be used for this test. Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get supernatant.
- 2) If serum samples are not tested immediately, they should be refrigerated at 2~8°C. For longer storage, freeze at -20°C or below. 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) The use of hemolytic or bacterially contaminated specimens should be avoided. Erroneous result may occur.

Procedure of the Test

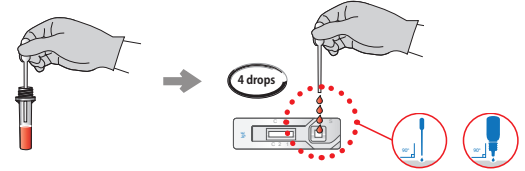
- 1) All reagents and samples must be at room temperature (15~30°C) before use.
- 2) Using a disposable capillary tube, add 10 μ l of sample into assay diluents tube.



- 3) Recap the assay diluents tube and mix thoroughly by inverting tube for a few seconds.



- 4) Using a disposable dropper, add 4 drops of mixed sample into sample hole ("S"), drop by drop vertically.



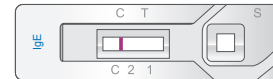
- 5) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of mixed sample to the sample hole.
- 6) Interpret test results at 10 minutes. Do not interpret after 20 minutes.



Interpretation of the Result

1) Negative

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



2) Positive

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



3) Invalid

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



Limitations of the Test

- 1) Although the Anigen Rapid Total IgE test kit is very accurate in detecting Canine Total IgE, 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.
- 2) Steroids or antihistamine medications may affect test result. 2 weeks of withdrawal period is required for the test.
- 3) Parasite infection should be cleared before the test.
- 4) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
- 5) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.