FLASHTEST

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Canine Total IgE Rapid Test (C.IgE)

Intended Use

Canine Total IgE Rapid Test is a chromatographic immunoassay kit for rapid detection of IgE in canine serum or plasma.

Principle

The Canine Total IgE Test Kit is a qualitative test card. This test aimed to the detection of canine IgE in serum/ plasma based on the principle of immunochromatography. When the sample to be tested is added to the sample well, it moves along the nitrocellulose membrane with the gold-labeled reagent. If the sample contains canine allergen-specific IgE antibodies, they will bind with the gold-labeled reagent and the antibodies on the test line, showing a purplish-red color. The control line will also show a red band as the gold-labeled reagent binds to the antibodies on the control line. If the sample does not contain canine allergen-specific IgE antibodies or the level is too low, no color reaction occurs or the color band is weaker.

Reagent and Materials Provided

· Test devices · Sampling pipe
· Buffer tube · Package insert
· Timer (Materials Required but not Provided)

Storage and Stability

The test device is sealed and should be stored away from light at a room temperature (4-30℃). Do not freeze.
The test device should be used before the expiration date marked on the package label.

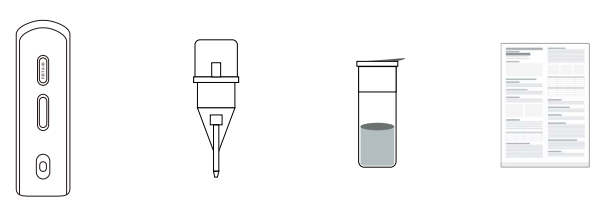
Warnings, Precautions and Safety Information

1. The test device is used for feline only.
2. The results may be influenced by humidity and temperature.
3. Make sure that the foil pouch containing the test is not damaged before open. Perform the test immediately when the pouch package is opened.
4. Do not reuse the test components.
5. Do not use after the expiry date.
6. Do not mix product components in different lot numbers.
7. As all samples are potentially infectious. Operators should wear protective gloves while handling samples and wash hands thoroughly afterwards.
8. Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.

Specimen Collection, Handling, and Transport

1. Serum or plasma should be used with this test.Serum: Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), and then stand or centrifuge whole blood to get serum.
Plasma: Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) and then stand or centrifuge whole blood to get plasma.
2. Samples should be stored at 2~8°C. Please freeze the samples at ﹣20°C or below for longer storage and avoid repeated freezing and thawing.
3. Samples containing precipitate may yield inconsistent test results. They must be clarified prior to assaying.
4. Hemolyzed or contaminated samples may lead to erroneous results.

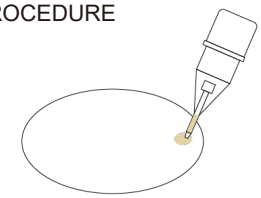
STEP 1 CHECK THE KIT CONTENTS BEFORE USE



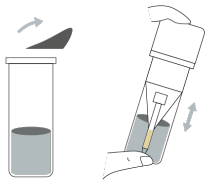
Test device | Sampling pipe | Buffer tube | Package insert

Check the product components and ensure that the operation is carried out at room temperature (15-30°C).

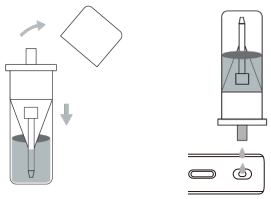
STEP 2 TEST PROCEDURE



Use a sampling pipe to draw some serum or plasma specimens (approximately 10 μL) through the capillary effect.



Peel off aluminum foil seal from the top of the extraction tube containing the extraction buffer, insert sampling end into pipe and cover tightly， mixed completely.



Holding the sampling pipe upright, carefully take off the cap of sampling pipe, transfer 3 drops (approximately 90 μL) to the specimen well (S) of the test device.

STEP 3 INTERPRETATION OF TEST RESULT

After 5 minutes, interpret the results.
Results after 10 minutes are invalid.

Positive (+): The presence of both C line and T line, regardless of T line being strong or faint.

Negative (-): Only clear C line appears.

Invalid: No colored line appears in C region, regardless of T line's appearance.

Limitations

Although The Canine Total IgE Test is very accurate in detecting Canine IgE, a low incidence of false results may be occurred. Other clinically 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.

LOT	batch code		use by
	manufacturer	Σ	contains sufficient for <n> tests
IVD	in vitro diagnotic medical device		temperature limitation
	do not reuse		consult instructions for use