INTENDED USE

The RA.ECUN Ab Test is a lateral flow immunochromatographic assay for the qualitative detection of Encephalitozoon Cuniculi antibody (RA.ECUN Ab) in rabbit's serum or plasma specimen.
Assay Time: 5-10 minutes
Specimen: serum or plasma

PRINCIPLE

The RA.ECUN Ab Test is based on sandwich method lateral flow immunochromatographic assay. The test card has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated RA.ECUN recombinant antigens. If there are RA.ECUN antibodies in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of RA.ECUN antibodies in the specimen.

REAGENTS AND MATERIALS

- 5 test pouches, with cards and desiccants
- 5 capillary droppers
- 1 bottle of assay buffer
- 1 package insert

STORAGE AND STABILITY

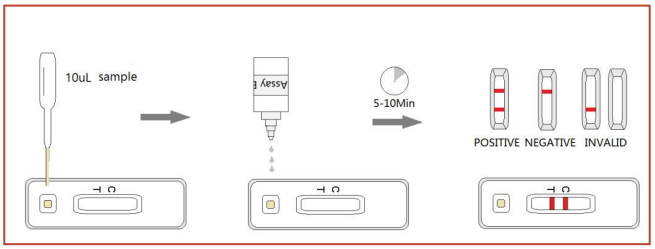
The kit can be stored at room temperature (2-30°C). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

SPECIMEN PREPARATION AND STORAGE

1. Specimen should be obtained and treated as below.
   - Serum or plasma: collect the whole blood for the patient cat, centrifuge it to get the serum, or place the whole blood into a tube which contains anticoagulants to get plasma.
2. All specimen should be tested immediately. If not for testing right now, they should be stored at 2-8°C.

TEST PROCEDURE

- Allow all materials, including specimen and test device, recover to 15-25°C before running the assay.
- Take out the test card from the foil pouch and place it horizontally.
- Use the capillary dropper to place 1 drop (approx.10μL) of the prepared specimen into sample well "S" of the test card. Then drop 3 drops (approx. 90μL) of the assay buffer into sample well. Start the timer.
- Interpret the result in 5-10 minutes. Result after 10 minutes is considered as invalid.



INTERPRETATION OF RESULTS

- Positive (+): The presence of both "C" line and zone "T" line, no matter T line is clear or vague.
- Negative (-): Only clear C line appear. No T line.
- Invalid: No colored line appears in C zone. No matter if T line appears.

PRECAUTIONS

- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

LIMITATION

RA.ECUN Ab Test is designed for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further methods when positive result was observed.

Manufacturer:
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