## INTENDED USE

The Canivet EHR-ANA-BC-BG Combo Test is a lateral flow immunochromatographic assay for the qualitative detection of Ehrlichia canis (EHR) antibodies, Anaplasma (ANA) antibodies and Babesia canis (BC) antibodies and Babesia gibsoni (BG) antibody in dog's serum, plasma and whole blood specimen.

Assay Time: 5-10 minutes

Specimen: dog's serum, plasma or whole blood

## PRINCIPLE

The Canivet EHR-ANA-BC-BG Combo Testis based on sandwich 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 each sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated Ehrlichia canis, Anaplasma, Babesia canis, Babesia gibsoni recombinant antigens. If there are Ehrlichia canis, Anaplasma, Babesia canis or Babesia gibsoni 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 Ehrlichia canis, Anaplasma, Babesia canis and Babesia gibsoni antibodies in the specimen.

## REAGENTS AND MATERIALS

- 10 test pouches, with cards and desiccants
- 2 bottles of assay buffer
- 10 capillary droppers
- 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

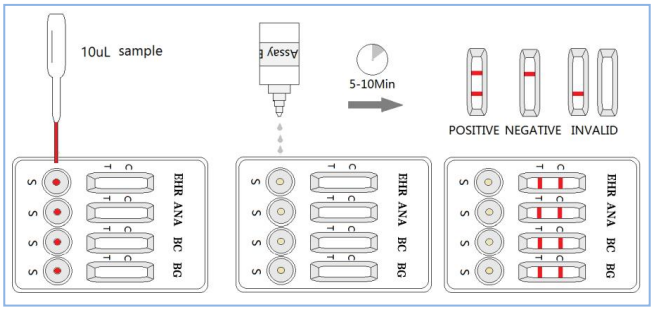
1. Specimen should be obtained and treated as below.

- Serum or plasma: collect the whole blood for the patient dog, centrifuge it to get the serum, or place the whole blood into a tube which contains anticoagulants to get plasma.
- Whole blood: directly use in the assay.

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 each sample well "S" of the test card. Then drop 3 drops (approx. 90μL) of the assay buffer into each 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

The Canivet EHR-ANA-BC-BG Combo Testis 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 confirmative method such as microscopy when positive result was observed.

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