Dynamiker Pets Biotechnology (Tianjin) Co., Ltd.

Ehrlichia-Lyme-Anaplasma-Heartworm Combo Test

Catalogue No: DNP-024

User Manual / 10 tests

1. INTENDED USE

The Ehrlichia-Lyme-Anaplasma-Heartworm Combo Test (TBD-4) is a test cassette to diagnose the presence of tick-borne diseases antibodies against Ehrlichia canis, Ehrlichia ewingii, Borrelia burgdorferi, Anaplasma phagocytophilum and Anaplasma platys, and Dirofilaria immitis in dog's serum or plasma specimen.

Assay Time: 5-10 minutes Specimen: Serum, plasma

2. PRINCIPLE

The Ehrlichia-Lyme-Anaplasma-Heartworm Combo Test is based on sandwich lateral flow immunochromatographic assay.

3. REAGENTS AND MATERIALS

Components	Quantity
Test Cassette in Foil Bag	10 Tests
Desiccant in Foil Bag	10 Pcs
Disposable Dropper in Foil Bag	10 Pcs
Assay buffer for EHR-LYM-ANA (Ehrlichia, lyme, anaplasma)	10*1.0 mL
Assay buffer for CHW (Heartworm)	1 Bottle
Disposable Capillary Dropper	10 Pcs
User Manual	1 Pc

4. STORAGE AND STABILITY

The kit can be stored at room temperature (4-30°C). The test kit is stable through the expiration date marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

5. SPECIMEN PREPARATION AND STORAGE

5.1 Specimen should be obtained and treated as below. Serum or plasma: collect the whole blood from the patient dog, centrifuge it to get the plasma, or place the whole blood into a tube which contains anticoagulants to get serum.

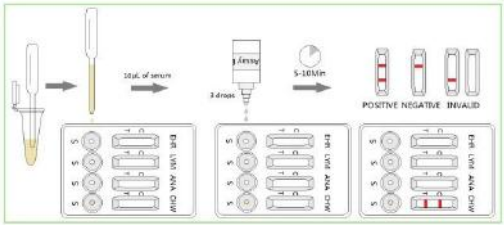
5.2 All specimen should be tested immediately. If not for testing right now, they should be stored at 2-8℃.

6. TEST PROCEDURE

6.1 Allow all materials, including specimen and test cassette, recover to 15-25℃ before testing.

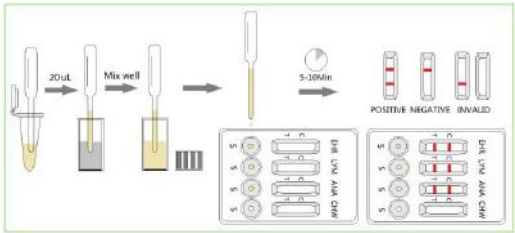
6.2 Take out the test cassette from the foil bag and place it horizontally.

6.3 Place 10μL of the prepared specimen into the sample well, matching the window CHW. Then add 3 drops (approx. 100μL) of assay buffer CHW into the sample well. Start the timer.



6.4 Collect 20μL of the prepared specimen into a vial of EHR-LYM-ANA assay buffer and mix well. Then add 3 drops (approx. 120μL) of the diluted sample into the sample well labelled "S" of the test cassette, respectfully matching the windows EHR, LYM, ANA. Start the timer.

6.5 Interpret the result in 5-10 minutes. Result after 10 minutes is considered as invalid.



7. INTERPRETATION OF RESULTS

- Positive (+): Presence of both "C" line and "T" line, no matter "T" line is clear or vague.
- Negative (-): Appearance of single "C" line. No red "T" line.
- Invalid: No red "C" line appears. No matter if "T" line appears.

8. PRECAUTIONS

- All reagents must be at room temperature before testing.
- Do not remove test cassette from its bag 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.

9. LIMITATION

The Ehrlichia-Lyme-Anaplasma-Heartworm Combo Test is 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.

10. MANUFACTURER

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[SYMBOLS USED]

Symbol	Description
	Use-by date
LOT	Lot Number
	Manufacture Date
	Keep Away from Sunlight
30C 4C	Temperature Limitation

REVISED: 04/2023