



**Canine Lyme Antibody+Ehrlichia Antibody+
Anaplasma Antibody+CHW Antigen
Combo Rapid Test Cassette
(Whole Blood/Serum/Plasma)**

Package Insert

REF VILEAC-445	English
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INTENDED USE

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a combined cassette to differentially diagnose the presence of Canine Lyme antibody, Canine Ehrlichia antibody, Canine Anaplasma phagocytophilum and Anaplasma platys antibodies and Canine Heartworm antigen in canine's whole blood, serum or plasma.

For veterinary use only.

PRINCIPLE

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette is based on lateral flow immunochromatographic assay. The test cassette has four testing windows. Each testing window has an invisible T (test) zone and C (control) zone. When sample is applied into the sample well on the cassette, the liquid will laterally flow on the surface of the test strip. If there is enough Canine Lyme antibody, Canine Ehrlichia antibody, Canine Anaplasma phagocytophilum and Anaplasma platys antibodies and Canine Heartworm antigen in the sample, a visible T line will appear in the corresponding testing window. The C line should always appear after a sample is applied, indicating a valid result. By this means, the cassette can accurately indicate the presence of Canine Lyme antibody, Ehrlichia antibody, Anaplasma phagocytophilum and Anaplasma platys antibodies and Heartworm antigen in the sample.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

PRECAUTIONS

- Do not use after expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lot and different products.

MATERIALS

Materials Provided

- Test Cassettes
- Droppers
- Buffer
- Package Insert

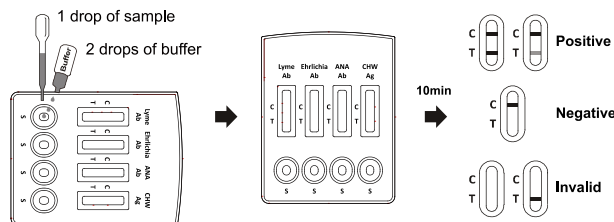
Materials Required but Not Provided

- Timer
- Specimen Containers
- Centrifuge

DIRECTIONS FOR USE

Allow the test cassette, specimen and buffer to equilibrate to room temperature (15-30 °C) prior to testing.

- Collect canine's fresh whole blood, serum or plasma samples and ensure that the samples cannot be turbid or precipitated. Only use clear, non-hemolyzed specimens. Do not leave the specimens at room temperature for prolonged periods. Whole blood, serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, serum and plasma specimens should be kept below -20°C. Do not freeze whole blood specimens.
- Place the test cassette on a clean and level surface.
- Hold the dropper vertically and **transfer 1 drop of sample** (approximately 20 µL) into each specimen well (S) and immediately **add 2 drops of buffer** (approximately 120 µL), then start the timer. See illustration below.
- Read the result in 10 minutes.** Do not interpret results after 15 minutes.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line.

Negative: Only clear C line appears.

Invalid: No colored line appears in C zone, no matter whether T line appears.

ACCURACY

The Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette to commercial control test has been evaluated with specimens obtained from veterinary hospital. Commercial control test is used as the reference method for the Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette. Specimens were considered positive if commercial control test indicated a positive result.

Lyme Ab tests	Commercial control test		Total
	Positive	Negative	
Positive	41	1	42
Negative	1	60	61
Total	42	61	103

Relative Sensitivity: 97.62% (95%CI*: 87.43%-99.94%)

Relative Specificity: 98.36% (95%CI*: 91.20%-99.96%)

Accuracy: 98.06% (95%CI*: 93.16%-99.76%)

*Confidence Interval

Ehrlichia Ab tests	Commercial control test		Total
	Positive	Negative	
Positive	38	1	39
Negative	2	62	64
Total	40	63	103

Relative Sensitivity: 95.00% (95%CI*: 83.08%-99.39%)

Relative Specificity: 98.41% (95%CI*: 91.47%-99.96%)

Accuracy: 97.09% (95%CI*: 91.72%-99.40%)

*Confidence Interval

Canine Anaplasma Ab tests	Commercial control test		Total
	Positive	Negative	
Positive	21	1	22
Negative	1	80	81
Total	22	81	103

Relative Sensitivity: 95.45% (95%CI*: 77.16%-99.88%)

Relative Specificity: 98.77% (95%CI*: 93.31%-99.97%)

Accuracy: 98.06% (95%CI*: 93.16%-99.76%)

*Confidence Interval

CHW Ag tests	Commercial control test		Total
	Positive	Negative	
Positive	22	1	23
Negative	1	79	80
Total	23	80	103

Relative Sensitivity: 95.65% (95%CI*: 78.05%-99.89%)

Relative Specificity: 98.75% (95%CI*: 93.23%-99.97%)

Accuracy: 98.06% (95%CI*: 93.16%-99.76%)

*Confidence Interval

CROSS-REACTIVITY

For Lyme Ab:

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette has been tested by Giardia, LSH Ab, Ehrlichia Ab, Anaplasma Ab, CHW Ag positive sample;

For Ehrlichia Ab:

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette has been tested by Distemper, Parvovirus, LSH Ab, Coronavirus and Rotavirus positive sample;

For Canine Anaplasma Ab:

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette has been tested by Giardia, LSH Ab, Ehrlichia Ab, Rotavirus, CHW Ag positive sample;

For CHW Ag:

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette has been tested by Dipetalonema reconditum, Giardia, LSH Ab, Ehrlichia Ab, Rotavirus positive sample.

The results showed no cross-reactivity.

LIMITATION

Canine Lyme Antibody+Ehrlichia Antibody+Anaplasma Antibody+CHW Antigen Combo Rapid Test Cassette is only for veterinary diagnosis use. All results should be considered with other clinical information available from veterinarian. For an accurate result, it is suggested to apply other method such as PCR or pathogen isolation test or Elisa for final determination in practice.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Manufacturer		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use

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