

Canine Ehrlichia Antibody Rapid Test Device (Whole Blood/Serum/Plasma)

Package Insert

VR-CE-AB-10

English

INTENDED USE

The Canine Ehrlichia Antibody Rapid Test Device is an indirect lateral flow immunochromatographic assay for the qualitative detection of Ehrlichia Canis antibodies (Ehrli Ab) in canine whole blood/ serum/plasma.

PRINCIPLE

The Canine Ehrlichia Antibody Rapid Test Device is based on lateral flow immunochromatographic assay. The test device has a testing window. The testing window has an invisible T (test) zone and C (control) zone. When sample is applied into the sample well on the device, the liquid will laterally flow on the surface of the test strip. If there are enough Ehrlichia Canis antibodies in the sample, a visible T line will appear. The C line should always appear after a sample is applied, indicating a valid result. By this means, the device can accurately indicate the presence of Ehrlichia Canis antibodies 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 device 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 device 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 devices
- Droppers
- Buffer
- Package Insert

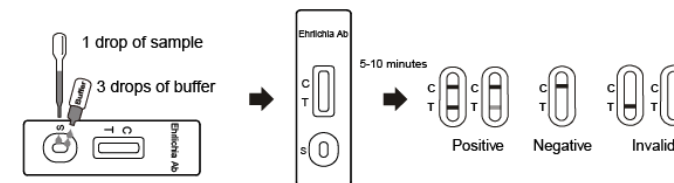
Materials Required but Not Provided

- Timer
- Specimen containers
- Centrifuge (for plasma)

DIRECTIONS FOR USE

Allow the test device, specimen, buffer, and/or controls 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. 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.
- Place the test device on a clean and level surface.
- Hold the dropper vertically and **transfer 1 drop of sample** (approximately 10 µl) and immediately add **3 drops of buffer** (approximately 80 µl) into the specimen well (S), then start the timer. See illustration above.
- Read the result in 5-10 minutes.** Do not interpret results after 15 minutes.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line, no matter T line is clear or vague.

Negative: Only clear C line appears.

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

PERFORMANCE CHARACTERISTICS

Relative Sensitivity: 92.77% (95%CI*: 84.93% - 97.30%)

Relative Specificity: 96.15% (95%CI*: 89.17% - 99.20%)

Accuracy: 94.41 % (95%CI*: 89.65% - 97.41%)

*CI = confidence interval compared to PCR method.

LIMITATION

Ehrlichia Canis Antibody Rapid Test Device is for in vitro veterinary diagnosis use only. 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 for final determination in practice.

Index of Symbols					
	Attention, see instructions for use		Tests per kit		Do not reuse
	For in vitro diagnostic use only		Use by		Catalog #
	Store between 2-30°C		Lot Number		Consult Instructions For Use
	Do not use if package is damaged		Manufacturer		



Manufactured by Rapid Labs Ltd.

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