



Prodox Vital GmbH – Eichweberstr. 4 – 25821 Bredstedt

Technical Data

Babesia canis Antibody Rapid Test

Relative Sensitivity and Specificity Studies

Specification

Product Name	Babesia canis Antibody Rapid Test
Another name for the same product	Selflab Test Tick-borne disease in dogs - Babesiosis
Intended Use	Immunochromatographic assay for the qualitative detection of Babesia canis Antibody (B.canis Ab)
Specimens	dog's serum, whole blood
Reagents and Materials	<ul style="list-style-type: none"> ■ 1 test pouches, with cards and disposable droppers ■ 1 vials of assay buffer ■ 1 package insert
Storage and Stability	2-30°C, 18 months
Interpretation of Results	<ul style="list-style-type: none"> ■ 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.

Technical Data

1) Relative Sensitivity and Specificity Studies

a. Study Design

Relative sensitivity and specificity studies were performed to a panel of clinical specimen by comparing with a commercial RT-PCR kit. Record the result running by the Babesia canis Antibody Rapid Test and the PCR result into a sheet. Count the amount of positive and negative result by the Babesia canis Antibody Rapid Test and RT-PCR kit. Fill the data into the result sheet. All specimen were enrolled from January 2019 to October 2019. Result by the Babesia canis Antibody Rapid Test were performed on site at room temperature, while the specimen were collected and performed in lab for RT-PCR.

b. Calculation formulations

Specificity = $\text{VN test} / \text{Neg ref} \times 100\%$

Sensitivity = $\text{VP test} / \text{Pos ref} \times 100\%$

Accuracy = $(\text{VN test} + \text{VP test}) / \text{total sample amount}$



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c. Acceptance Criteria

The relative sensitivity of the Babesia canis Antibody Rapid Test specimen in this study should be higher than 90%. The specificity of the Babesia canis Antibody Rapid Test in this study should be higher than 80%.

d. Result

Result		RT-PCR Test	
		Positive	Negative
Babesia canis Antibody Rapid Test	Positive	35	12
	Negative	0	114
Relative Sensitivity		100%	
Relative Specificity		90.5%	
Relative Accuracy		92.5%	

e. Discussion

The relative sensitivity and specificity of the Babesia canis Antibody Rapid Test is acceptable compared with RT-PCR result.

100 Boxes per paper carton, dimension: 63cm*43cm*43cm