



Prodox Vital GmbH – Eichweberstr. 4 – 25821 Bredstedt

Technical File

Ehrlichia-Lyme-Anaplasma Antibody
Combo Test

Relative Sensitivity and Specificity Studies



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Specification

Product Name	Ehrlichia-Lyme-Anaplasma Antibody Combo Test
Intended Use	EHR-LYM-ANA Ab Combo Test is a test cassette to diagnose the presence of antibodies against Ehrlichia canis, Borrelia burgdorferi and Anaplasma platys in dog's serum specimen
Specimens	dog's serum specimen, 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.

1. 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 SNAP 4Dx Test Device. Record the result running by the Ehrlichia-Lyme-Anaplasma Antibody Combo Test and the SNAP 4Dx Test Device result into a sheet. Count the amount of positive and negative result by the Ehrlichia-Lyme-Anaplasma Antibody Combo Test and SNAP 4Dx Test Device. Fill the data into the result sheet.

All specimen were enrolled from January 2019 to October 2019. Result by the Ehrlichia-Lyme-Anaplasma Antibody Combo Test were performed on site at room temperature, while the specimen were collected and performed in lab for SNAP 4Dx Test Device.

b. Calculation formulations

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

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

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

c. Acceptance Criteria

The relative sensitivity of Ehrlichia test, Lyme test and Anaplasma test of the Ehrlichia-Lyme-Anaplasma Antibody Combo Test specimen in this study should be higher than 85%. The specificity of Ehrlichia test, Lyme test and Anaplasma test of the Ehrlichia-Lyme-Anaplasma Antibody Combo Test in this study should be higher than 90%.

d. Result

i. Result

A. The Ehrlichia test of the Ehrlichia-Lyme-Anaplasma Antibody Combo Test showed the result below.

Result		SNAP 4Dx Test Device	
		Positive	Negative
Ehrlichia-Lyme-Anaplasma Antibody Combo Test	Positive	95	1
	Negative	1	247
Relative Sensitivity		99.0%	
Relative Specificity		99.6%	
Relative Accuracy		99.4%	

B. The Lyme test of the Ehrlichia-Lyme-Anaplasma Antibody Combo Test showed the result below.

Result		SNAP 4Dx Test Device	
		Positive	Negative
Ehrlichia-Lyme-Anaplasma Antibody Combo Test	Positive	23	2
	Negative	0	215
Relative Sensitivity		100%	
Relative Specificity		99.1%	
Relative Accuracy		99.2%	

C. The Anaplasma test of the Ehrlichia-Lyme-Anaplasma Antibody Combo Test showed the result below.

Result		SNAP 4Dx Test Device	
		Positive	Negative
Ehrlichia-Lyme-Anaplasma Antibody Combo Test	Positive	87	3
	Negative	0	168
Relative Sensitivity		100%	
Relative Specificity		98.2%	
Relative Accuracy		98.8%	



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e. Discussion

The relative sensitivity and specificity of the Ehrlichia-Lyme-Anaplasma Antibody Combo Test is acceptable compared with SNAP 4Dx Test Device result.