



The Truth of Accuracy: VetScan Canine Ehrlichia Rapid Test

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Introduction

The genus *Ehrlichia* consists of tick-transmitted gram-negative obligate intracellular bacteria from the order *Rickettsia* and family *Anaplasmataceae* that primarily infect leukocytes.¹ The three most relevant species found in dogs at this time are *E. canis*, *E. chaffeensis*, and *E. ewingii*, with *E. chaffeensis* having significance as a human pathogen.²

The vector for *E. canis* is the brown dog tick (*Rhipicephalus sanguineus*) which has worldwide distribution throughout tropical and temperate climates, including all of the United States except Alaska. The vector for *E. ewingii* is the Lone Star Tick (*Amblyomma americanum*) which is found from Texas, Oklahoma, Kansas, Missouri and Iowa in the Midwest and eastward to the Atlantic coast. The primary vector for *E. chaffeensis* is the Lone Star Tick as well, but the organism is also found in the American dog tick (*Dermacentor variabilis*).³

Clinical signs of *E. canis* infection range from non-specific (depression, lethargy, anorexia, weight loss), to red/purple subcutaneous bleeding, nose bleeds, ocular signs (retinal hemorrhage/ Inflammation), and / or neuromuscular signs (e.g. seizures, balance issues, or pain). Diagnosis of canine ehrlichiosis can be made by the observation of infected morulae in macrophages in blood smears or monocytes in tissue aspirates or impression smears.⁴

With *E. chaffeensis* infection, clinical signs are similar to, but often less apparent, than those of dogs infected with *E. canis*. Thrombocytopenia is common, but other observations, including identification of morulae, are not routinely observed.⁵

With *E. ewingii*, infection can be mild or unapparent, however symptomatic, infected dogs display signs of fever, lethargy, anorexia, polyarthritis, vomiting, diarrhea, and / or neurologic signs.⁶

After infection with *Ehrlichia* species organisms; an acute, subacute or chronic infection can occur. The acute phase can last from 1 to 4 weeks. Most dogs that are treated appropriately with antibiotics during the acute phase will recover. Dogs that are either untreated or inappropriately treated may clinically recover, but then enter the subclinical phase for months to years. Dogs that are persistently infected may spontaneously recover or develop severe chronic disease. Dogs in acute phases are often antibody negative while dogs in subacute and chronic phases are generally antibody positive. In chronic disease, the bone marrow is typically infected resulting in pancytopenia. The severity of chronic ehrlichiosis can vary in severity from mild to life-threatening.⁷

Materials and Methods

Four hundred twenty-six samples were obtained from private practices, humane societies and laboratories. The overall sensitivity and specificity of the VetScan® Test were determined versus commercially available immunofluorescence assay (IFA).

Results

Of the 426 samples tested in this study, 214 were found to be negative and 212 samples were positive by IFA. The sensitivity and specificity are calculated below.

Results	VetScan Canine Ehrlichia Rapid Test Negative	VetScan Canine Ehrlichia Rapid Test Positive
IFA Negative	207	7
IFA Positive	14	198

Sensitivity = 93.4% (95% CI: 88.9 - 96.2%)
Specificity = 96.7% (95% CI: 93.1 - 98.6%)

There were 14 samples which were positive by IFA but negative on the VetScan Ehrlichia Rapid Test. However 8 of those 14 were confirmed as negative when tested on a commercially available kit and ELISA. These are likely false positives on IFA. Taking this into consideration the actual sensitivity of the VetScan Ehrlichia Rapid Test is 97%.⁸

From a subset of these positive samples, species identification was accomplished by using a combination of commercially available IFA reagents for *E. canis* and *E. chaffeensis*, commercially available Ehrlichia antibody test kits, and Abaxis proprietary ELISA tests. Of these, 45 were found to be positive for *E. canis*, 40 for *E. chaffeensis*, and 47 for *E. ewingii*.

Results for *E. canis*

Results	VetScan Canine Ehrlichia Rapid Test Negative	VetScan Canine Ehrlichia Rapid Test Positive
All criteria positive for <i>E. canis</i>	1	44

Sensitivity for *E. canis* = 97.7% (95% CI: 88.2 - 99.9%)

Discussion

In general, Canine *Ehrlichia* infection (or Ehrlichiosis) is not only evaluated in sick patients, but also evaluated to identify asymptomatic chronically infected canines in endemic regions. Diagnosis of Ehrlichiosis is based upon history, tick infestation, hematologic abnormalities and serologic findings. Polymerase Chain reaction (PCR testing) has also been used to determine infection and monitor response to medications.

The VetScan Canine Ehrlichia Rapid Test is ideally suited to detect antibodies to all three species of *Ehrlichia*, and is labeled for all three species. Recent developments in laboratory methodology and the corresponding in-clinic VetScan Canine Ehrlichia Rapid Test offer a cost-effective and time-saving option. The VetScan Canine Ehrlichia Rapid Test is both a sensitive and specific test for the detection of antibodies to three *Ehrlichia* species.

Conclusions

This study demonstrates that the VetScan Canine Ehrlichia Rapid Test is a reliable, cost effective and time saving point of care assay to detect the presence of antibodies against *E. canis*, *E. chaffeensis*, and *E. ewingii* species affecting dogs, allowing for the effective diagnosis and treatment of infected patients.

IDEXX Claims Against the Abaxis VetScan Canine Ehrlichia Rapid Test

IDEXX claims poor sensitivity of the Abaxis VetScan Canine Ehrlichia Rapid Test without providing sufficient information about the testing and results to consider the claims valid. Comparing the data presented here with what IDEXX presented, many differences between the data sets should be evident:

- The samples obtained for the Abaxis study were from clinical sites around the country.**
IDEXX's internally generated study does not disclose the source of the samples, which could potentially bias the data. Without appropriate documentation of the sampling set, the results should be considered inherently biased.
- The Abaxis data compares results from different methodologies.**
IDEXX uses its own test (proprietary ELISA) as the "gold standard" so the methodologies are essentially testing for the same marker in the same way for SNAP yet different for the VetScan Canine Ehrlichia Rapid Test. This would of course lead to a higher level of agreement for the SNAP test.
- The Abaxis data presented was submitted to the USDA for the approval of the VetScan Canine Ehrlichia Rapid Test.**
The IDEXX study was created to show a weakness in a competitive product that simply does not exist when research is conducted in a balanced and prudent manner and evaluated as an accurate comparison.
- The VetScan Canine Ehrlichia Rapid Test has been approved by the USDA to evaluate for *E. canis*, *E. ewingii*, and *E. chaffeensis*.**
The SNAP 4Dx Plus Test is not approved to detect for *E. chaffeensis*. Therefore their claim to having good ability to evaluate *E. chaffeensis* cannot be substantiated.

Based on the multi-site testing data set described above and submitted to the USDA, IDEXX's claims of inaccuracy are unsubstantiated. There are too many incorrect assumptions and variables in the IDEXX comparison for the data to be considered the result of a credible study.

Bibliography

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- ⁸ Walker et al. (2014). Serology of Tick-Borne Diseases in Dogs. Cambridge HealthTech Institute Conference "Targeting Tick-Borne Diseases." Boston. Oct 28-29. Poster presentation. For a copy of the poster handout, go to: www.abaxis.com

Results for *E. chaffeensis*

Results	VetScan Canine Ehrlichia Rapid Test Negative	VetScan Canine Ehrlichia Rapid Test Positive
All criteria positive for <i>E. chaffeensis</i>	2	38

Sensitivity for *E. chaffeensis* = 95.0% (95% CI: 83.1 - 99.4%)

Results for *E. ewingii*

Results	VetScan Canine Ehrlichia Rapid Test Negative	VetScan Canine Ehrlichia Rapid Test Positive
All criteria positive for <i>E. ewingii</i>	1	46

Sensitivity for *E. ewingii* = 97.9% (95% CI: 88.7 - 99.9%)