The Truth of Accuracy: VetScan Feline FeLV/FIV Rapid Test

Introduction

The Feline Leukemia Virus (FeLV) is a common infectious pathogen of cats. It is associated with many disease conditions including neoplasia (lymphoma) and increased susceptibility to secondary infection. It can attack any system in the cat's body causing a chronic wasting disease or an acute life threatening event. The disease usually affects the cat's immune system and then secondarily may affect other body systems.

Good sensitivity and specificity are important for all infectious disease testing, but especially for this disease state. Poor sensitivity (leading to a false negative result) can lead to misdiagnosis as well as the possibility of infected cats transmitting disease because their disease status is unknown. Poor specificity (high number of false positive results) can cause unnecessary treatment or even for cats to be unnecessarily euthanized.

Study Design

Abaxis performed a clinical trial to obtain the data necessary for approval by the United States Department of Agriculture (USDA) for the Feline Leukemia Rapid Test. The first part of this data was used in that approval process. Two-hundred sixty one samples were obtained from veterinary facilities and shelters across the country. Samples were tested by Immunofluorescence (IFA), IDEXX SNAP FIV/FeLV Combo Test and the Abaxis VetScan FeLV/FIV Rapid Test.

Analysis of Data Part 1

For Abaxis test approval and for this comparison (per requirements of USDA), samples were considered positive if both IFA and SNAP were positive. Samples were considered negative if both IFA and SNAP tests were negative. Samples that did not agree between IFA and SNAP were removed from the study. Results are listed in Table 1.

Table 1:

N = 233	SNAP & IFA +	SNAP and IFA -
Abaxis +	89	1
Abaxis -	4	139

Confidence Interval

Sensitivity = 89/93 x 100= 95.7 % (CI 95%: 88.7-98.6%)
Specificity = 139/140 x 100 - 99.3 % (CI: 95%: 95.4-99.9%)

Analysis of Data Part 2

Since the same samples were evaluated by all three methods, further comparisons can be done. Tables 2 and 3 shows the sensitivity and specificity data of the Abaxis VetScan Rapid Test and IDEXX SNAP Test against the IFA method:

Table 2:

N = 261	IFA +	IFA -
Abaxis +	89	10
Abaxis -	17	145

Sensitivity = 89/106 x 100= 84.0% (CI 95%: 75.2-90.1%)
Specificity = 145/155 x 100= 93.5% (CI: 95%: 88.1-96.7%)

Table 3:

N = 261	IFA +	IFA -
IDEXX SNAP +	93	15
IDEXX SNAP -	13	140

Sensitivity = 93/106 x 100= 87.7% (CI 95%: 79.6-93.0%)
Specificity = 140/155 x 100= 90.3% (CI: 95%: 84.3-94.3%)

Conclusions and Discussion

All point-of-care infectious disease tests must be approved by the USDA before being sold. The clinical trial data presented here was collected for the approval of the Abaxis VetScan FeLV/FIV Rapid Test. By comparing the Abaxis VetScan Rapid Test against 2 methods (IFA and SNAP), the sensitivity and specificity could truly be determined. In this comparison both the sensitivity and specificity of the Abaxis VetScan Rapid Test should be considered excellent. Both tests were also compared to IFA, a separate methodology. The sensitivity and specificity for both tests were similar based on the confidence interval, the sensitivity, and specificity, both tests were similar on their ability to diagnose FeLV infected patients. SNAP had a 30% higher level of false positives than the Abaxis which could lead to a significant number of unnecessary euthanasias.

No point-of-care test is perfect. All tests will have occasional false positive and false negative tests. Clinical signs and appropriate confirmation testing should be included in the determination of disease and treatment protocols. The data presented here indicates both the Abaxis VetScan Rapid Test and the SNAP Test for Feline Leukemia provide good to excellent results. Veterinarians can be comfortable in making the determination of which test to use based on factors such as cost, ease of use and a comfort level with whom they are doing business.

IDEXX Recent Claims against the Abaxis VetScan FeLV/FIV Rapid Test

IDEXX recently claimed poor sensitivity of the Abaxis FeLV/FIV Rapid Test. Comparing the data presented here with what IDEXX presented, many differences between the data sets should be evident:

1. **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.
2. **The Abaxis data compares results from different methodologies.**
   IDEXX uses its own test (Pet-Check 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 Abaxis VetScan Rapid Test. This would of course lead to a higher level of agreement for the SNAP test.
3. **The Abaxis data presented was submitted to the USDA for the approval of the VetScan 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 prudent manner and evaluated fairly.
4. **Both the Abaxis Rapid and the IDEXX SNAP tests actually provide excellent results.**
   A fair analysis of the data leads to the conclusion that you should expect – both tests made by quality companies provide the results you expect.
5. **During the clinical trials, Abaxis found that its level of false positives was 1/3 lower than the IDEXX SNAP test when compared to the IFA alone.**
   While IFA is not necessarily a gold standard test, this finding suggests that in the IDEXX study as many as one third of these animals that were tested FeLV positive may have been false positives leading to potentially unnecessary euthanasia.

Based on the data set that was submitted to the USDA for test approval, IDEXX's claims of inaccuracy are unsubstantiated. There are too many incorrect assumptions and variables in the IDEXX study for any comparison data to be credible. Both the IDEXX SNAP FeLV/FIV Combo Test and Abaxis VetScan FeLV/FIV Rapid Test are equal in producing accurate results for FeLV.

Abaxis VetScan FeLV/FIV Rapid Test data is obtained through approved external multi-site studies that were submitted to the USDA for test approval.