

SNAP fPL Test—reference laboratory accuracy pet-side



Pancreatitis, an inflammatory condition of the exocrine pancreas, is a multifactorial disease in cats, with a variable clinical course and outcome. Feline pancreatitis is more common than many practitioners realize.

Diagnosis of this elusive disease can be challenging. The presenting signs are most commonly nonspecific and may include anorexia, lethargy, and dehydration. Mild cases of pancreatitis can remain undetected because of the lack of clinical signs.^{1,2} A fast, accurate pet-side test for pancreatitis is needed to help veterinarians quickly rule in or rule out pancreatitis in patients presenting with nonspecific signs of gastrointestinal (GI) illness.

Background

Dr. Jörg Steiner and Dr. David Williams developed and validated the feline pancreatic lipase immunoreactivity (fPLI) assay at the Gastrointestinal Laboratory at Texas A&M University for the diagnosis of pancreatitis. The fPLI assay demonstrates both sensitivity, for detecting significant pancreatitis, and specificity, for helping to rule out pancreatitis.³

IDEXX collaborated with Dr. Steiner and Dr. Williams to develop a feline pancreas-specific lipase (fPL) assay, the Spec fPL[®] Test, available through IDEXX Reference Laboratories. The Spec fPL Test uses monoclonal antibody technology.

The reference interval and sensitivity and specificity for the Spec fPL Test (see figure 1) were determined in a study for which results were presented at the ACVIM Forum/Canadian VMA Convention in Montreal, Canada, in June 2009.⁴ The Spec fPL Test reference interval for healthy cats was determined to be 0.7–3.5 $\mu\text{g/L}$. Elevated fPL concentration was defined as $>3.5 \mu\text{g/L}$. Results consistent with pancreatitis were defined as $\geq 5.4 \mu\text{g/L}$.

Requirements for development of the SNAP[®] fPL[™] Test

As the Spec fPL Test became the standard of care in testing for feline pancreas-specific lipase, the benefit of a pet-side test using the same methodology became obvious.

An effective pet-side test would have high agreement with results from the Spec fPL reference laboratory test. It would be a sensitive screening tool for pancreatitis by providing an abnormal result for any sample with an fPL concentration greater than the Spec fPL Test cutoff of 3.5 $\mu\text{g/L}$. IDEXX developed the SNAP fPL Test to meet these requirements and to provide fast, accurate, and easily-interpreted pet-side results.

The SNAP fPL Test, the pet-side version of the Spec fPL Test

The SNAP fPL Test uses the same biological reagents as the Spec fPL Test but provides results in 10 minutes. The result is displayed as a colored sample spot that is compared to

a reference spot. If the color intensity of the sample spot is lighter than the color intensity of the reference spot, then the fPL concentration is normal. If the color intensity of the sample spot is equal to or darker than the reference spot, then the fPL concentration is abnormal.

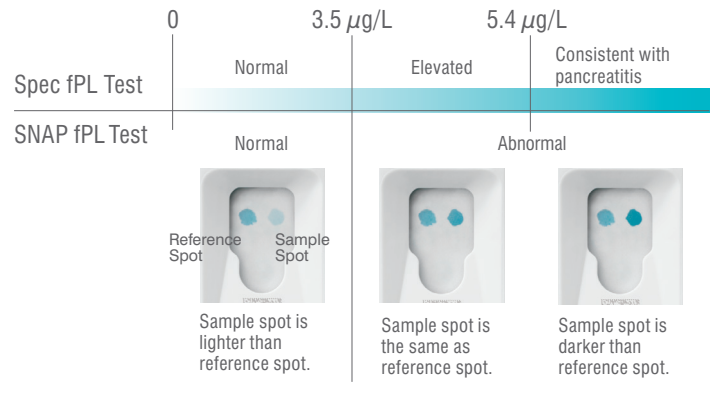


Figure 1. Correlation of Spec fPL Test results with SNAP fPL Test results

Validation of the SNAP fPL Test

Two studies were performed that compared results of the SNAP fPL Test with Spec fPL Test results

Study 1: In-clinic performance of the SNAP fPL Test⁵

Trained technicians from four veterinary practices visually interpreted the results of the SNAP fPL Test using serum samples collected from their feline patients.

Study design

Unique feline serum samples from 80 cats (20 at each location) were assayed on the SNAP fPL Test. Each sample was tested once on three independent lots of the SNAP fPL Test, for a total of 240 tests. Samples were then submitted for Spec fPL testing.

Results

Of the 80 feline samples, 61 had normal fPL concentrations, as defined by the Spec fPL Test results ($\leq 3.5 \mu\text{g/L}$). The percent agreement between the SNAP fPL Test results and the Spec fPL Test results for the normal population ranged from 89% to 93% across the three lots of the SNAP fPL Test.

There were 7 samples with elevated fPL concentrations, as defined by the Spec fPL Test results (see figure 1). The SNAP fPL Test correctly identified these samples across all three lots of the SNAP fPL Test. The percent agreement between the SNAP fPL Test results and the Spec fPL Test results was 100%.

There were 12 samples with fPL concentrations consistent with pancreatitis, as defined by the Spec fPL Test results ($\geq 5.4 \mu\text{g/L}$). The SNAP fPL Test correctly identified these samples in 35 of 36 testing events. The percent agreement between the SNAP fPL Test results and the Spec fPL results ranged from 92% to 100%.

| Spec fPL Test Concentration | n | Percentage agreement SNAP fPL/Spec fPL Tests |
|---|----|--|
| Normal ($\leq 3.5 \mu\text{g/L}$) | 61 | 89%–93% |
| Elevated ($> 3.5 \mu\text{g/L}$ to $< 5.4 \mu\text{g/L}$) | 7 | 100% |
| Consistent with pancreatitis ($\geq 5.4 \mu\text{g/L}$) | 12 | 92%–100% |

Sample n = 80

Table 1. Agreement between Spec fPL and SNAP fPL Test results

Study 2: Agreement of SNAP fPL Test results with clinically defined samples⁵

A population of cats with extensive clinical evaluations was previously used to determine the appropriate reference intervals for the Spec fPL Test. This study was presented at the ACVIM Forum/Canadian VMA Convention in Montreal, Canada, in June 2009.⁴ A subset of samples from this population was tested on the SNAP fPL Test.

Study design

A total of 49 samples from cats with known Spec fPL concentrations and known clinical evaluations were tested on the SNAP fPL Test. Of the total sample population, 26 cats were clinically defined as healthy, 6 cats were clinically defined as “definitely pancreatitis,” and 17 cats were clinically defined as “probably pancreatitis.” Each SNAP fPL Test device was visually read by a technician blinded to the known clinical diagnosis and Spec fPL concentrations.

Results

All of the samples from the 26 healthy cats were interpreted as normal on the SNAP fPL Test, for a specificity of 100%.

Of the 6 cats clinically defined as “definitely pancreatitis” (with Spec fPL Test results of 1.9–137 $\mu\text{g/L}$), the 5 that had Spec fPL Test results $> 5.4 \mu\text{g/L}$ also had abnormal results on the SNAP fPL Test.

Of the 17 cats clinically defined as “probably pancreatitis” (with Spec fPL Test results of 0.9–222 $\mu\text{g/L}$), 15 had abnormal results on the SNAP fPL Test, and 2 had normal results. The 2 cats with normal SNAP fPL Test results had fPL concentrations $< 3.5 \mu\text{g/L}$ (i.e., in the normal range).

Overall, the percent agreement between the SNAP fPL Test and the Spec fPL Test for this population was 98%.

| Clinical assessment | | Total SNAP fPL Test | | Specificity | Sensitivity |
|-------------------------|----|---------------------|-------------|-------------|-------------|
| | | Sensitivity | Specificity | | |
| Normal | 26 | 26 | 0 | 100% | |
| Definitely pancreatitis | 6 | 1 | 5 | | 87% |
| Probably pancreatitis | 17 | 2 | 15 | | 87% |

Sample n = 49

Table 2. Agreement between clinical assessment and SNAP fPL Test results

Summary and conclusions

Diagnosing feline pancreatitis can be difficult, especially because most cats present with nonspecific GI signs.

The SNAP fPL Test has a high percentage of agreement with the reference laboratory Spec fPL Test, the most accurate test available for feline pancreatitis. The SNAP fPL Test provides an accurate, reliable, pet-side tool to help veterinarians quickly rule in or rule out pancreatitis. Included as part of the initial workup, the SNAP fPL Test provides valuable diagnostic information sooner to help the veterinarian determine whether pancreatic inflammation is likely and, if so, to speed time to treatment.

In those cats with abnormal SNAP fPL Test results, consider follow-up testing with the Spec fPL Test to determine fPL concentration and to assess disease severity. Periodic monitoring with the Spec fPL Test can help to assess response to therapy.

References

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- Data on file at IDEXX Laboratories, Inc. Westbrook, Maine USA.