

# IDEXX SNAP<sup>®</sup> cPL<sup>™</sup> Test— Reference Laboratory Accuracy Pet-side

More answers for canine patients presenting with vomiting, anorexia, and abdominal pain—  
when the culprit could be pancreatitis.

Canine pancreatitis is difficult to diagnose and, in severe cases, can be fatal.<sup>1</sup> A fast, accurate pet-side test for pancreatitis is needed to help veterinarians quickly diagnose or rule out pancreatitis in patients that present with acute clinical signs.

IDEXX has introduced a pet-side SNAP<sup>®</sup> version of the current IDEXX Reference Laboratories Spec cPL<sup>®</sup> (canine pancreas-specific lipase) Test for canine pancreatitis. The new SNAP<sup>®</sup> cPL<sup>™</sup> (canine pancreas-specific lipase) Test is an ELISA assay that has a 95% correlation to the reference test method. The SNAP cPL Test can be used pet-side with confidence when working up dogs presenting with vomiting, anorexia, abdominal pain or other clinical signs of pancreatitis.

## Background

The canine pancreatic lipase immunoreactivity (cPLI) test was developed at Texas A&M University by Dr. David Williams and Dr. Jörg Steiner, and measured levels of lipase enzyme that originate specifically in the pancreas. Until 2005, this assay was the most sensitive laboratory test for canine pancreatitis.<sup>2,3</sup>

In 2005 IDEXX collaborated with Drs. Williams and Steiner to develop an enhanced and commercially available version of the cPLI test called Spec cPL. The Spec cPL Test, available from IDEXX Reference Laboratories, provides the same diagnostic benefits as the original cPLI test but with a faster turnaround time (next-day results).

As the Spec cPL Test became the standard of care in testing for canine pancreatitis, the benefit of a pet-side test using the same methodology became obvious.

## Requirements for Development of the SNAP cPL Test

Extensive market research indicated that veterinarians wanted a pet-side assay that could be used along with other blood work to provide direction when patients presented with common, nonspecific signs such as vomiting, anorexia, weakness and abdominal pain. Veterinarians wanted a test that was fast, accurate and easily interpreted.

An effective test would produce results that correlated closely with results from the reference laboratory test. Additionally, a pet-side test needed to be optimized for maximum sensitivity and provide abnormal results for any sample outside the Spec cPL reference range of >200.

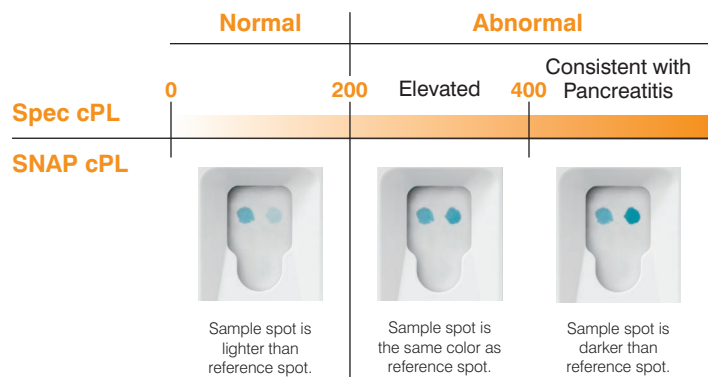
## SNAP cPL, the Pet-side Version of Spec cPL

In July 2007 IDEXX introduced SNAP cPL, a pet-side version of Spec cPL that uses IDEXX SNAP ELISA technology. SNAP cPL is part of the growing family of IDEXX SNAP tests used by thousands of veterinarians worldwide.

The SNAP cPL Test uses the same biological reagents as the Spec cPL Test, but displays results in 10 minutes.

The test result is displayed as a colored sample spot that must be compared to a reference spot. If the color intensity of the sample spot is lighter than the color intensity of the reference spot, then cPL concentration is normal. If the color intensity of the sample spot is equal to or darker than the reference spot, then cPL concentration is abnormal (either “elevated” or “consistent with pancreatitis.”)

## Reference Laboratories' Spec cPL Concentration Compared to SNAP cPL Results



## Validation of the SNAP cPL Test

To determine whether the SNAP cPL Test met the objectives described above, the IDEXX R&D team performed two validation studies.

### Study 1: Correlation with Spec cPL

The optical density of results from the SNAP cPL Test were compared to results from the reference laboratory Spec cPL Test, day-to-day and across lots.

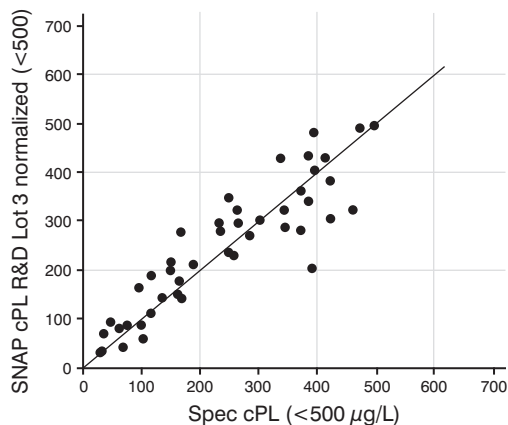
#### Study Design:

A series of canine serum samples was measured using the Spec cPL assay to determine cPL concentration. The same samples were then run on the SNAP cPL assay. A densitometer was used to measure the optical density of results from the SNAP cPL Test for direct comparison and correlation with Spec cPL.

#### Results:

Densitometer readings produced a correlation coefficient of .92. Importantly, none of the cPL concentrations greater than 400 (i.e. "consistent with pancreatitis") were read as Normal using the SNAP cPL Test.

#### Correlation of SNAP cPL with Spec cPL



#### Correlation of Normals and Abnormals

Sample N = 70

	Total Spec cPL	Total SNAP cPL	Correlation SNAP cPL/Spec cPL
Normal	24	Normal 23	95.8%
Elevated and Consistent with Pancreatitis	46	Abnormal 44	95.6%

Note that 100% of the Consistent-with-Pancreatitis samples were correctly interpreted on SNAP cPL. SNAP cPL called one Normal sample Abnormal and two Elevated samples as Normal.

<sup>1</sup> Mix K, Jones C. Diagnosing Acute Pancreatitis in Dogs. *Compendium*, March 2006;226-232.

<sup>2</sup> Steiner JM, Willard MD, ed. Diagnosis of Pancreatitis. *The Veterinary Clinics of North America—Small Animal Practice*. 2003;33:1181-1193.

<sup>3</sup> Steiner JM, Broussard J, Mansfield CS, Gumminger SR, Williams DA. Serum canine pancreatic lipase immunoreactivity (cPLI) concentrations in dogs with spontaneous pancreatitis. *J Vet Int med*. 2001;15:274.

<sup>4</sup> Steiner JM. Is it pancreatitis? *Veterinary Medicine*. 2006;101:158-167.

## Study 2: Readability

Trained technicians from local veterinary practices visually interpreted the results of the SNAP cPL Test for samples with known Spec cPL concentrations.

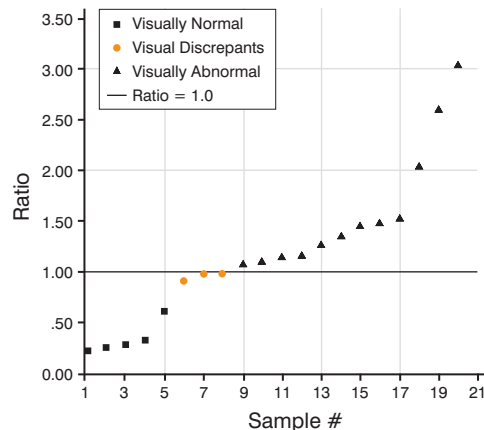
#### Study Design:

- Twenty canine serum samples with known Spec cPL concentrations were assayed on SNAP cPL devices.
- Each device was visually interpreted twice by each of 14 veterinary professionals for a total of 28 observations per sample (total n=560). The study was conducted twice, for an n>1,000.
- Veterinary professionals were blinded as to the Spec cPL concentrations of the samples.

#### Results:

The results of the readability study showed a 95% correlation on both sensitivity and specificity measures against Spec cPL, with over 1,000 sample reads. Densitometer readings were performed on the discrepant samples. As might be expected, the interpretations which caused the most difficulty were at the transition point between the high end of the normal range and the low end of the elevated range (noted as visual discrepant below).

#### SNAP cPL Readability, Visual Results



## Summary and Conclusions

The SNAP cPL Test was developed to fill the market need for an accurate, reliable, pet-side tool to aid veterinarians in diagnosing or ruling out pancreatitis in dogs presenting with clinically acute signs.

SNAP cPL has a 95% correlation to the reference laboratory Spec cPL Test, the most accurate test currently available for canine pancreatitis.<sup>3,4</sup>

IDEXX recommends that veterinarians run the SNAP cPL Test pet-side or the Spec cPL Test at the reference laboratory on dogs presenting with signs of vomiting, anorexia, abdominal pain or other clinical signs of pancreatitis.

If the SNAP cPL Test results are abnormal, veterinarians are encouraged to order the Spec cPL Test as a followup to establish a baseline cPL concentration and to monitor treatment.