

## Summary of Bionote Study

# Validation of a point-of-care assay for serum canine pancreatic lipase and C-reactive protein in the clinical setting

Elizabeth Rozanski, DVM, DACVIM, DACVECC | Jamie Wells, BS, Veterinary Student

## Do you know the facts about Vcheck's cPL test?

*Initial indicators show that the Vcheck cPL 2.0 assay from Bionote is a promising point-of-care assay for in-house measurement of cPL for the diagnosis or exclusion of canine acute pancreatitis.*

## Background

Acute pancreatitis is a common yet challenging diagnosis in dogs amidst limited diagnostic options at the point of care. Serum canine pancreatic lipase (cPL) is currently the most sensitive biomarker available for confirmation of acute pancreatitis. Additionally, C-reactive protein (CRP) is an acute phase protein produced by the liver in response to inflammation which has been suggested as a possible prognostic biomarker in dogs with pancreatitis. Point-of-care cPL and CRP measurement has the potential to facilitate diagnosis for earlier treatment and decrease diagnostic costs.

## Objectives

Our goal was to validate the point-of-care Bionote Vcheck cPL 2.0 and CRP assays for clinical use. We wanted to ensure adequate correlation with the IDEXX cPL and Cornell CRP send-out values to confirm accuracy. We also compared sensitivity and specificity of the cPL 2.0 to the most common point-of-care test, the IDEXX SNAP cPL.

## Methods

Forty-eight dogs were recruited, including samples from 20 dogs hospitalized with pancreatitis, 22 dogs hospitalized for other conditions, and 6 healthy control dogs. Samples were drawn at two time points throughout treatment for two of the dogs, totaling 50 samples. One IDEXX SNAP cPL and three consecutive Bionote cPL 2.0 tests were run in-house. Serum samples were sent out to IDEXX for Spec cPL values and to Cornell Clinical Pathology Laboratory for CRP values to compare with in-house results.

## Results

The Bionote vCheck cPL 2.0 assay was strongly correlated with the IDEXX Spec cPL, with a Pearson's  $r$  of 0.967,  $p < 0.00001$ . The mean coefficient of variation for repeated samples was 7.9%, with a range of 0.43-18.18%. The assay was 95.2% sensitive and 100% specific for

pancreatitis. The Bionote CRP assay was strongly correlated with the Cornell CRP, with a Pearson's  $r$  of 0.803,  $p < 0.00001$ . The majority of dogs with pancreatitis had elevated CRP (73.7%, 14/19).

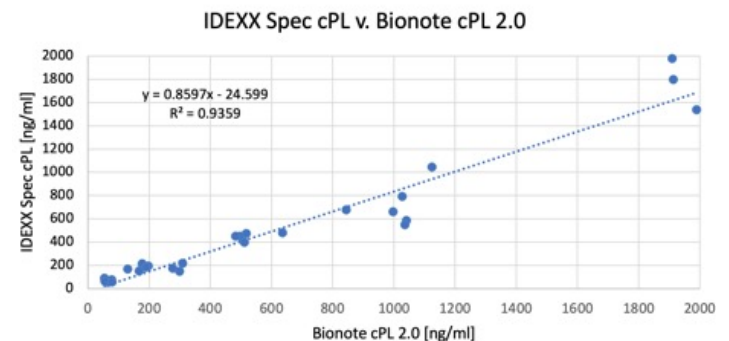
## Conclusions

The Bionote Vcheck cPL 2.0 assay is a promising point-of-care assay for in-house measurement of cPL for the diagnosis or exclusion of canine acute pancreatitis. Results were highly correlated with the Spec cPL test and demonstrated excellent repeatability. The test was similarly sensitive but more specific than the SNAP cPL, perhaps due to quantitative result. Similarly, the Bionote Vcheck CRP 2.0 was highly correlated with the Cornell CRP value. Additional studies are needed to evaluate the effect of hemolysis and lipemia on test accuracy.

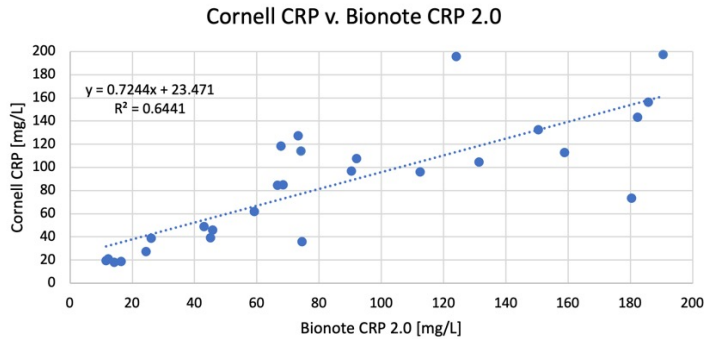
**Table 1:** Comparison of sensitivity and specificity calculations for cPL tests in this population.

Test	Sensitivity (%)	Specificity (%)
IDEXX SNAP cPL	100	80
Bionote cPL 2.0	100	96.7

**Figure 1:** Send-out value from IDEXX Spec cPL vs. point-of-care value from Bionote cPL 2.0.



**Figure 2:** Send-out value from Cornell CRP vs. point-of-care value from Bionote CRP 2.0.



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