Catalyst® Pancreatic Lipase Test: an in-house quantitative pancreatic lipase test for dogs and cats.

Introduction

The diagnosis of pancreatitis in dogs and cats can be challenging due to the non-specific and sometimes subtle clinical signs associated with this disease. Veterinarians must rely on a combination of patient history, clinical signs, laboratory findings and diagnostic imaging techniques.[1,2] The digestive enzymes amylase and general lipase have been used as biomarkers for pancreatitis, but diagnostic utility is limited by the influence of nonpancreatic sources of the enzymes (e.g., gastric, hepatic) on the assays. The Spec cPL® and Spec fPL® tests (IDEXX Laboratories, Westbrook, Maine) are immunologic assays that specifically measure lipase of pancreatic origin and have been validated in the peer-reviewed literature.[3,4]

The Catalyst® Pancreatic Lipase Test is an activity assay* specifically designed to align with the Spec cPL and Spec fPL tests to provide quantitative pancreatic lipase results at the point-of-care for dogs and cats. The Catalyst Pancreatic Lipase Test has a wide dynamic range (canine 30–2000 U/l; feline 0.5–50 U/l) and provides results within 10 minutes in serum or lithium plasma samples (or whole blood using the lithium heparin whole blood separator).

This study aimed to compare the performance of the Catalyst Pancreatic Lipase Test to the Spec cPL and Spec fPL tests, assess the precision of the assay, evaluate the influence of common interfering substances and evaluate the specificity of the Catalyst Pancreatic Lipase Test for pancreatic lipase in a population of German shepherd dogs (GSDs) with exocrine pancreatic insufficiency (EPI).

Materials and methods

Method comparison

One hundred ninety-three canine and 216 feline serum samples, originally submitted to IDEXX Reference Laboratories for clinical purposes, were obtained following laboratory terms and conditions. Samples were analysed once with the Catalyst Pancreatic Lipase Test on a Catalyst One® Chemistry Analyser. Six replicates (reps) of each sample were also performed on the Spec cPL (canine samples) and Spec fPL (feline samples) tests. The result of each Catalyst Pancreatic Lipase Test was paired with the mean of the Spec cPL and Spec fPL reps on the corresponding sample. Correlation plots were created with the calculation of r-value and slope. Results from each method were assigned to one of three categories based on the cutoffs used for medical interpretation of the assays (as shown in tables 1 and 2). The classifications were then compared in a contingency table for each species.

Precision

Precision was assessed by repeated analysis of control fluids at concentrations representing high, mid-level and low results for each species. Each fluid was analysed eight times per day for 10 days on each of two Catalyst One® and two Catalyst Dx® chemistry analysers. The results of one feline sample were excluded due to suppression of the result due to instrument error. The total percentage coefficient of variation (CV) was calculated as the ratio of the standard deviation to the mean of the concentration.

Interfering substances

Interference caused by haemoglobin, lipid or bilirubin was assessed per CLSI EP07-A2 method guidelines.[5] Canine and feline serum samples, which were visibly clear of interferents, were collected, pooled and spiked with various recombinant canine or feline pancreatic lipase concentrations. Canine red blood cell haemolysate[†], Intralipid®[‡] and ditaurobilirubin[§] were used to investigate the potential impact of haemolysis, lipaemia and icterus, respectively. Aliquots of the pooled samples were prepared and spiked with varying concentrations of the interfering substances (as shown in tables 3 and 4). Sixteen to thirty-six reps of each aliquot were then analysed on a Catalyst One analyser.

Evaluation of specificity in a population of EPI dogs

One method to evaluate the specificity of a lipase assay is to measure lipase in a population of animals expected to have extremely low concentrations of pancreatic lipase, such as German shepherd dogs (GSDs) with exocrine pancreatic insufficiency (EPI). EPI causes decreased production and secretion of digestive enzymes by the exocrine pancreas. Some GSDs have an inherited trait, pancreatic acinar cell atrophy, which leads to EPI.[6] Measurement of significant amounts of lipase in this population suggests measurement of lipase of non-pancreatic origin.

Forty serum samples from GSDs with a serum trypsin-like immunoreactivity (TLI) assay result of less than 1 µg/l, originally submitted to IDEXX Reference Laboratories for clinical purposes, were obtained. Samples were analyzed with the Catalyst® Pancreatic Lipase Test (4 reps), Spec cPL® Test (6 reps) and a 1,2 diglycerides lipase (2 reps) assay.[1] The mean of the reps for each sample was used in the analysis.

Results

Method comparison

The canine and feline method comparison studies show excellent correlation between the Catalyst Pancreatic Lipase Test and the Spec cPL and Spec fPL® tests. Findings are summarised in figures 1 and 2. For the classification of results, there was strong agreement between the two methods.
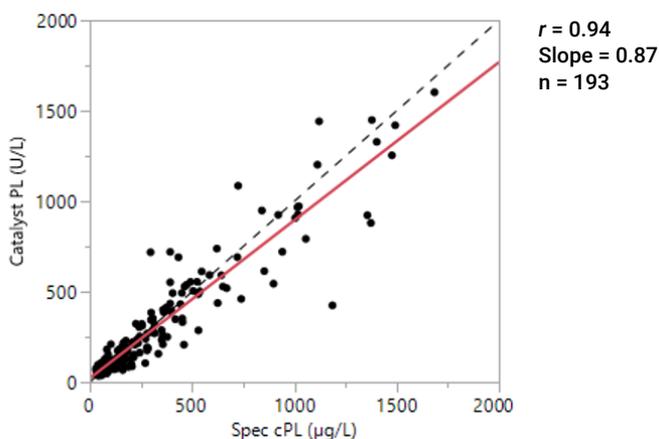

$r = 0.94$
Slope = 0.87
n = 193

$r = 0.96$
Slope = 0.97
n = 216

Figure 1: Correlation graph of pairwise comparisons of the Catalyst Pancreatic Lipase (PL) and Spec cPL concentrations in canine samples. The line of best fit (linear regression) for the data is shown on the graph (solid line) with the slope and *r*-value. The x = y is shown as the dashed line in the graph.
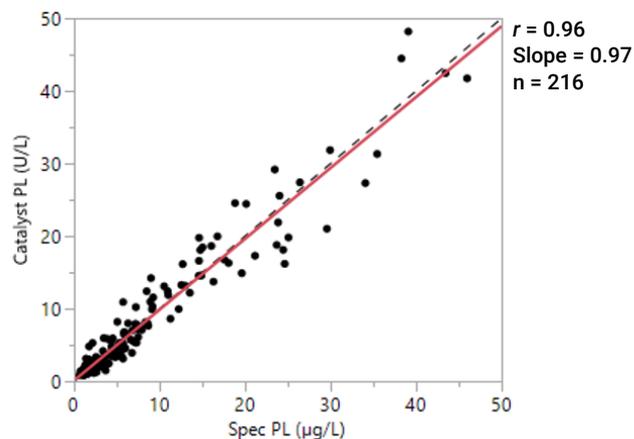
Figure 2: Correlation graph of pairwise comparisons of the Catalyst Pancreatic Lipase (PL) and Spec fPL concentrations in feline samples. The line of best fit (linear regression) for the data is shown on the graph (solid line) with the slope and *r*-value. The x = y is shown as the dashed line in the graph

		Spec cPL		
		≤ 200 µg/l	201−399 µg/l	≥ 400 µg/l
Catalyst PL	≤ 200 U/l	51.4%	6.2%	0.0%
	201−399 U/l	1.8%	13.0%	2.8%
	≥ 400 U/l	0.0%	4.5%	20.4%

Table 1: Canine contingency table. n = 193; overall concordance = 84.8%.

		Spec fPL		
		≤ 4.4 µg/l	4.5−8.7 µg/l	≥ 8.8 µg/l
Catalyst PL	≤ 4.4 U/l	52.7%	8.1%	0.0%
	4.5−8.7 U/l	2.7%	14.2%	0.4%
	≥ 8.8 U/l	0.0%	1.4%	20.5%

Table 2: Feline contingency table. n = 216; overall concordance = 87.5%.

Precision

The results of the precision analysis are shown in tables 3 and 4. The Catalyst® Pancreatic Lipase Test had a total coefficient of variation (CV) of < 10% at all concentrations in both species, indicating excellent assay precision.

Species	Instrument	Mean Catalyst PL concentration (U/l)	Standard deviation (U/l)	% CV	Observations
Canine	Catalyst Dx® Chemistry Analyser	249	11	4.4	160
		580	24	4.2	160
		1339	118	8.8	160
	Catalyst One® Chemistry Analyser	239	9	3.9	160
		561	19	3.4	160
		1338	38	2.8	160

Table 3: Summary of results from the canine precision study.

Species	Instrument	Mean Catalyst PL concentration (U/l)	Standard deviation (U/l)	% CV	Observations
Feline	Catalyst Dx® Chemistry Analyser	3.9	0.3	6.6	160
		5.3	0.4	8.5	159
		14.0	0.9	6.5	160
	Catalyst One® Chemistry Analyser	3.7	0.2	5.9	160
		5.1	0.3	6.0	160
		13.9	0.7	5.0	160

Table 4: Summary of results from the feline precision study.

Interfering substances

No interference was observed with lipaemic or icteric samples. Interference leading to decreased Catalyst PL concentration may be observed in samples with moderate to marked haemolysis (≥ 250 mg/dl).
The results of the interfering substances study are outlined in tables 5 and 6.

Canine interferences					
Haemolysis		Lipaemia		Icterus	
Haemoglobin concentration (mg/dl)	Mean Catalyst PL concentration (U/l)	Intralipid® concentration (mg/dl)	Mean Catalyst PL concentration (U/l)	Ditaurobilirubin concentration (mg/dl)	Mean Catalyst PL concentration (U/l)
21	500	0	536	0	491
193	467	125	537	2	492
256	450	250	527	5	490
559	399	500	482	15	502

Table 5: Summary of results from canine interfering substances study.

Feline interferences					
Haemolysis		Lipaemia		Icterus	
Haemoglobin concentration (mg/dl)	Mean Catalyst PL concentration (U/l)	Intralipid® concentration (mg/dl)	Mean Catalyst PL concentration (U/l)	Ditaurobilirubin concentration (mg/dl)	Mean Catalyst PL concentration (U/l)
34	7.7	0	7.7	0	7.8
165	6.8	125	7.2	2	8.3
290	6.5	250	7.5	5	8.1
584	5.8	500	7.0	15	8.1

Table 6: Summary of results from feline interfering substances study.

Evaluation of specificity in a population of EPI dogs

Catalyst® Pancreatic Lipase Test and Spec cPL® Test results from GSDs with EPI were low with most samples being at or below the lower limit of quantitation (Catalyst PL < 30 U/l; Spec cPL < 30 µg/l) of the assays. Lipase activity measured by the 1,2 diglycerides method had values extending across the reference interval, likely due to the measurement of lipase activity from non-pancreatic sources.
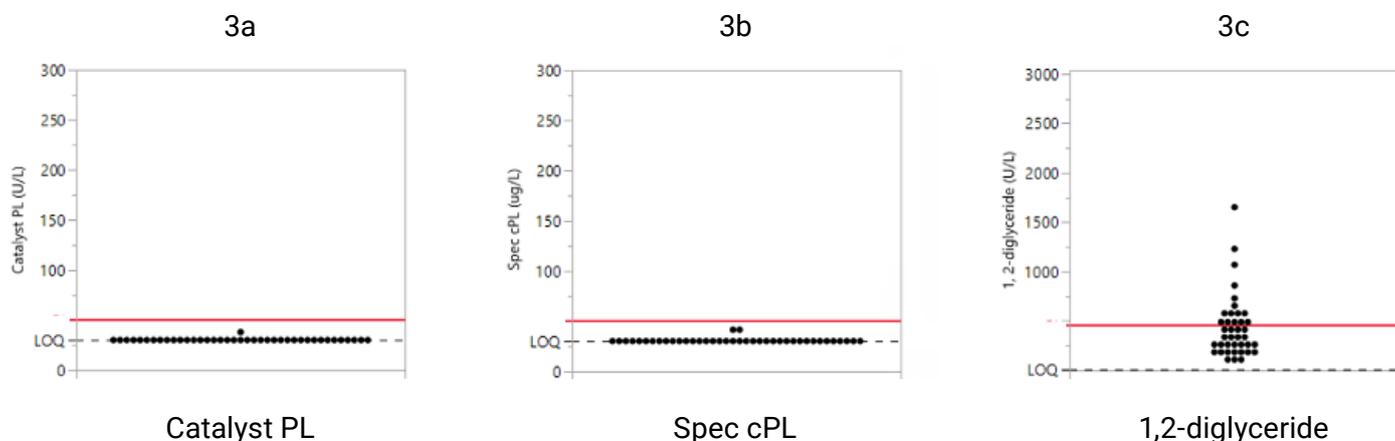
3a

Catalyst PL

3b

Spec cPL

3c

1,2-diglyceride

Figure 3a: Catalyst Pancreatic Lipase Test results of samples from GSDs with EPI. 100% of samples were in the lower 25% of the reference interval. The red line indicates 25% of the reference interval (RI ≤ 200 U/l).

Figure 3b: Spec cPL Test results of samples from GSDs with EPI. 100% of samples were in the lower 25% of the reference interval. The red line indicates 25% of the reference interval (RI ≤ 200 µg/l).

Figure 3c: 1,2 diglycerides lipase method results of samples from GSDs with EPI. 62.5% of samples were in the lower 25% of the reference interval. The red line indicates 25% of the reference interval (RI 200–2800 U/l).#

Conclusion

The Catalyst® Pancreatic Lipase Test provides veterinarians with a quantitative pancreatic lipase test that is precise and correlates well with the Spec cPL® and Spec fPL® tests at the point-of-care. When monitoring pancreatic lipase over time, it is recommended to use the same methodology for the most accurate assessment. Based on laboratory testing of samples with contrived haemolysis, Catalyst Pancreatic Lipase Test results may be impacted by samples with moderate to marked levels of haemolysis. Based on the evaluation of lipase results across 3 different methods, the Catalyst Pancreatic Lipase Test appears to be as specific as the Spec cPL Test in a population of GSDs with EPI.

References
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