# 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 nonspecific 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 analyzed once with the Catalyst Pancreatic Lipase Test on a Catalyst One® Chemistry Analyzer. 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 analyzed eight times per day for 10 days on each of two Catalyst One® and two Catalyst Dx® chemistry analyzers. 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 hemoglobin, 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 hemolysate†, Intralipid®‡, and ditaurobilirubin§ were used to investigate the potential impact of hemolysis, lipemia, 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 analyzed on a Catalyst One analyzer.

### *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 nonpancreatic 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.[¶] 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 summarized in figures 1 and 2. For the classification of results, there was strong agreement between the two methods.

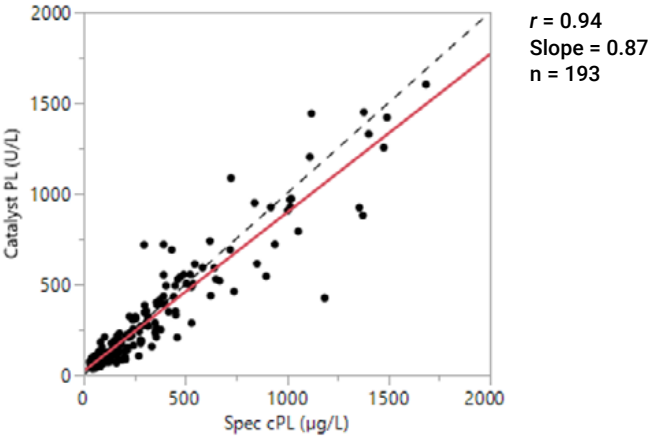



**Figure 1:** Correlation graph of pairwise comparisons of the Catalyst Pancreatic Lipase (PL) and Spec cPL concentrations in canine samples. The line of best fit (linear regression) for the data is shown on the graph (solid line) with the slope and *r*-value. The x = y is shown as the dashed line in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

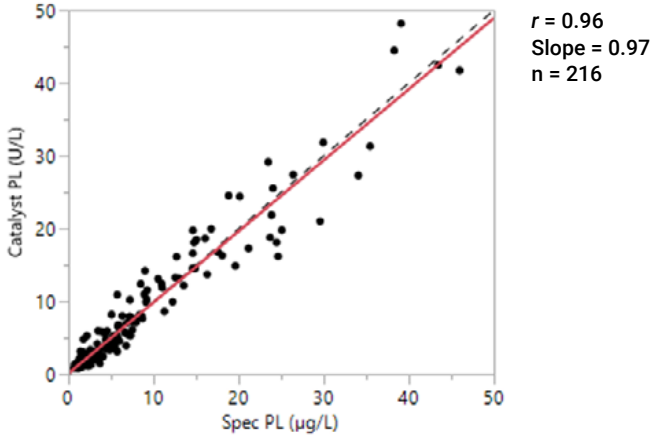



**Figure 2:** Correlation graph of pairwise comparisons of the Catalyst Pancreatic Lipase (PL) and Spec fPL concentrations in feline samples. The line of best fit (linear regression) for the data is shown on the graph (solid line) with the slope and *r*-value. The x = y is shown as the dashed line in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

| | | Spec cPL | | |
|---|---|---|---|---|
| **Catalyst PL** | | ≤ 200 µg/L | 201–399 µg/L | ≥ 400 µg/L |
| | ≤ 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 | | |
|---|---|---|---|---|
| **Catalyst PL** | | ≤ 4.4 µg/L | 4.5–8.7 µg/L | ≥ 8.8 µg/L |
| | ≤ 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 Analyzer | 249 | 11 | 4.4 | 160 |
| | | 580 | 24 | 4.2 | 160 |
| | | 1339 | 118 | 8.8 | 160 |
| | Catalyst One® Chemistry Analyzer | 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 Analyzer | 3.9 | 0.3 | 6.6 | 160 |
| | | 5.3 | 0.4 | 8.5 | 159 |
| | | 14.0 | 0.9 | 6.5 | 160 |
| | Catalyst One® Chemistry Analyzer | 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 lipemic or icteric samples. Interference leading to decreased Catalyst PL concentration may be observed in samples with moderate to marked hemolysis (≥ 250 mg/dL).
The results of the interfering substances study are outlined in tables 5 and 6.

| Canine interferences | | | | | |
|---|---|---|---|---|---|
| **Hemolysis** | | **Lipemia** | | **Icterus** | |
| Hemoglobin 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.

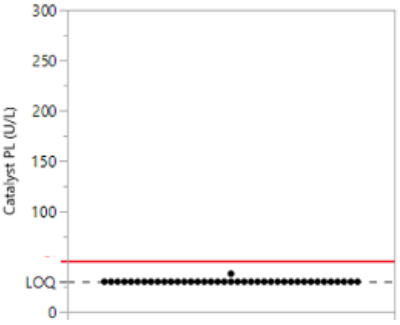
| Feline interferences | | | | | |
|---|---|---|---|---|---|
| **Hemolysis** | | **Lipemia** | | **Icterus** | |
| Hemoglobin concentration (mg/dL) | Mean Catalyst PL concentration (U/L) | Intralipid® concentration (mg/dL) | Mean Catalyst PL concentration (U/L) | Ditaurobilirubin concentration (mg/dL) | 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 nonpancreatic sources.

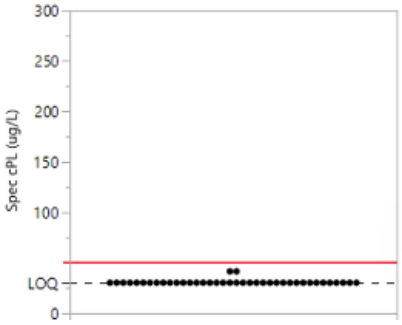
3a




Catalyst PL

**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).

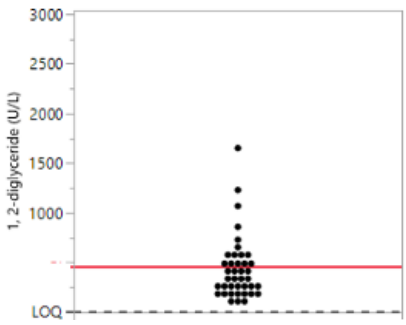
3b




Spec cPL

**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).

3c




1,2-diglyceride

**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 hemolysis, Catalyst Pancreatic Lipase Test results may be impacted by samples with moderate to marked levels of hemolysis. 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.

*The Catalyst Pancreatic Lipase Test uses 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6′ -methylresorufin) ester (DGGR) as a substrate.
[†]Lysate from canine red blood cells washed in saline and lysed in water with no surfactant.
[‡]Intralipid® (Sigma-Aldrich, Inc., St. Louis, Missouri, USA), a phospholipid-stabilized soybean oil.
[§]Bilirubin conjugate (Scripps Laboratories, San Diego, California, USA; catalog number: B0114), a synthesized ditaurobilirubin.
[¶]Vitros® Chemistry Lipase slide reference number 166 8409, performed on Vitros® 350 chemistry system, QuidelOrtho Corporation, San Diego, California USA.
[#]1,2 diglycerides lipase reference interval established for the Catalyst Pancreatic Lipase Test.

**References**

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