TRUFORMA®

cPL Test

FOR THE QUANTITATIVE DETECTION OF CANINE PANCREATIC LIPASE (cPL) LEVELS IN CANINE SERUM

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

For Customer Assistance:
734-369-2555 (Option 1)

Distributed and Manufactured by:
Zomedica
Ann Arbor, MI 48108 USA
www.zomedica.com

INTENDED USE

The TRUFORMA® cPL Test is used for the quantitative detection of canine pancreatic lipase levels in canine serum to diagnose pancreatitis and monitor the response to therapy.

OVERVIEW

Lipases are a class of enyzmes that catalyze the hydrolysis of fats and can be found in various tissues. Canine pancreatic lipase (cPL) is secreted solely by the pancreas and aids in digestion. Elevated levels of cPL in the blood may represent inflammation of the pancreas (pancreatitis).

This test employs a single-use cartridge containing the assay for the detection of cPL in canine serum. The TRUFORMA cPL Test works as a sandwich immunoassay, utilizing a biotin-labeled anti-cPL monoclonal detection antibody (dAb) and a monoclonal capture antibody immobilized onto a Bulk Acoustic Wave (BAW) sensor solid phase. During the test, sample is mixed with biotin-labeled detection antibody and flows across the biosensor surface. Antibodies in solution attach to cPL molecules present in the sample, and this complex is captured by the immobilized antibody on the sensor surface. Next, a streptavidin-enzyme conjugate is flowed over the sensor surface, where it is immobilized to the detector antibody via the streptavidin-biotin interaction. After several wash steps, an enzyme substrate is exposed to the BAW biosensor surface.

The enzyme converts the substrate into an insoluble product that accumulates on the BAW biosensor surface and is measured as a shift in frequency by the BAW biosensor. The signal is proportional to the amount of enzyme present on the BAW biosensor surface. The change in frequency is used to calculate the concentration of cPL present in the sample using the stored calibration curve. As a sandwich immunoassay, a sample containing a high concentration of cPL results in a higher amount of dAb-biotin-streptavidin-enzyme complex attached to the solid phase and a larger signal. Thus, concentrations of serum cPL are proportional to the amount of cPL that is bound to the solid phase.

cPL concentrations that fall outside of the normal reference range may be indicative of abnormal levels of cPL as a result of pancreatitis.

PRECAUTIONS & WARNINGS

- Do not use a cartridge after the expiration date printed on the cartridge pouch.
- Do not remove the cartridge from pouch until ready for use.
- Use a new disposable bulb pipette for each test.
- Do not use a cartridge from a pouch that appears to be tampered with, torn or damaged.
- Do not use a cartridge if it appears to be cracked, broken, leaking liquid or otherwise damaged.
- For veterinary in vitro diagnostic use of canine serum samples only.
- As with any diagnostic test procedure, all other test procedures including the clinical status of the patient should be considered prior to final diagnosis.

STORAGE & HANDLING

- Store cartridges at refrigerated temperature (2–8 °C/35–46 °F).
- Do not freeze cartridges.
- Serum samples may be stored under refrigerated conditions (2–8 °C/35–46 °F) for up to 4 days prior to testing.
- Cartridges may be left at room temperature (20–25 °C/68–77 °F) for up to 24 hours in the protective pouch, and up to 4 hours out of the protective pouch prior to use. If not used in this time period, dispose of the cartridge.

COMPONENTS

1. cPL Cartridge(s)
2. Disposable Bulb Pipette(s)
3. Instructions for Use

SERUM COLLECTION

Have non-diabetic animals fast for 8-12 hours (diabetic animals for 6 hours) prior to blood draw. Collect blood in blood collection tubes without anticoagulant. After complete clotting has occurred, separate serum by centrifugation.

The TRUFORMA cPL Test has been tested with red-top tubes and has not been evaluated with all types of blood collection tubes. Results may vary depending on the tube used due to the presence of additives such as clot activators, gels, or preservatives.

TEST PROCEDURE

1. Confirm that the cartridge has not expired by reviewing the expiration date on the pouch label.

2. While wearing gloves, remove the cartridge from pouch and place on a flat surface. The pouch contains a desiccant that can be disposed of as normal waste.

3. Using the supplied bulb pipette, dispense the sample into the sample port (approximately 150 µL). Recommended technique for adding sample: With sample-filled bulb pipette (**Figure 1**), wet the sample port filter by placing the bulb pipette tip on top of the sample port filter and lightly squeeze the pipette (**Figure 2**), dispensing a small amount of sample. Lift bulb pipette tip off sample port filter and dispense remaining sample into sample port as shown in **Figure 3.**

4. Ensure all of the sample has been absorbed into the sample port with no pooling. Sample pooling in the port may be an indicator that the port has been overfilled. Do NOT overfill the sample port.

5. Place the cartridge into the instrument by holding the sample port end with the cartridge label facing up and following the arrow indicated insert direction displayed on the cartridge label. Gently push the cartridge into the cartridge receiver until the instrument accepts and draws in the cartridge.

6. After the test is completed, the results will be displayed on the TRUFORMA system results screen and will also be electronically sent to myZomedica.com®.

7. Dispose of the used cartridges and bulb pipettes in a biohazardous waste container.

USING BULB PIPETTE

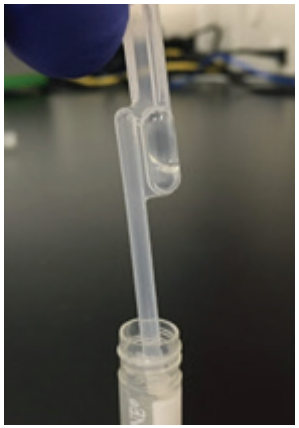


Figure 1

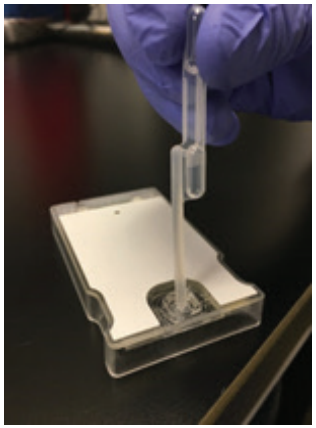


Figure 2

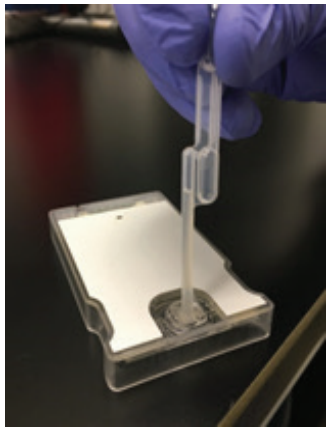


Figure 3

EXPECTED VALUES

The reference ranges listed in **Table 1** are those established for the canine patient population. Test results should be interpreted in conjunction with a patient's clinical signs.

Table 1: Canine Reference Range

Reference Range	TRUFORMA cPL (µg/L)
Normal	≤ 199
Equivocal	200 - 400
Consistent with Pancreatitis	≥401

Table 2: Dynamic Range

	TRUFORMA cPL
Dynamic Range (µg/L)	30 - 2000

Figure 4: cPL Precision

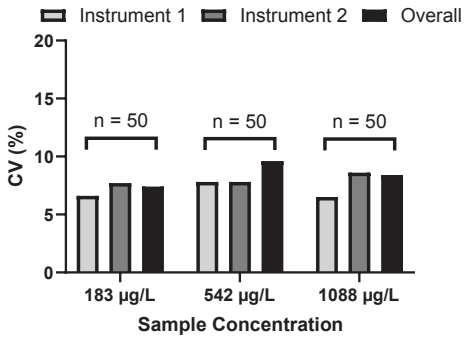
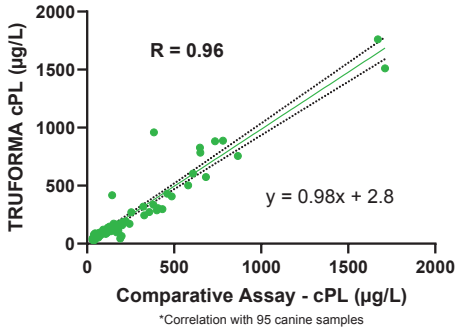


Figure 5: Correlation of TRUFORMA cPL with Comparative Method



*Correlation with 95 canine samples

PERFORMANCE DATA

See Tables and Figures for data representative of the test's performance. Test performance results are reported in micrograms per liter (µg/L). Unless otherwise noted, all data were generated using canine serum samples collected in red-top serum collection tubes. All performance data were generated on the TRUFORMA system unless otherwise noted. The dynamic range for the TRUFORMA cPL Test is found in **Table 2**.

PRECISION

Precision was evaluated by testing three canine serum samples with varying cPL concentrations. Each sample was tested with five replicates on five separate days on two different instruments for a total of 150 results, see **Figure 4.**

CORRELATION

Correlation analysis evaluates the agreement and commutability of a new test method with a comparative or reference method. cPL levels were measured in 95 canine serum samples using TRUFORMA and a comparative assay. All samples were analyzed on the same freeze-thaw cycle for both methods, and the results were used to generate correlation statistics in **Figure 5.**

The TRUFORMA system will display the cPL serum concentration results. Interpretation guidelines for test results are available on myZomedica.com.

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