ZOMEDICA®

TRUFORMA® Point-of-Care

The Effect of having Quantitative cPL Results at the Point-of-Care on Clinical Practice

The objectives of this study were to:

- Evaluate the frequency of equivocal versus disease state cPL results in clinical practice.
- Compare the workflow of a point-of-care (POC) quantitative cPL test to an alternative, non-quantitative point-of-care offering combined with reference lab quantitative testing.

Background and Clinical Significance

Canine pancreatic lipase (cPL) assays are considered the best blood test available for diagnosing pancreatitis. These tests can be quite sensitive as a screening option for ruling out the disease, but there are limitations to making a diagnosis of presumed pancreatitis. There exists an equivocal zone of 200-400 µg/L, where a diagnosis of pancreatitis cannot be definitively diagnosed or excluded. The specificity of the assay does, however, increase with results greater than 400 µg/L. When results are within the equivocal zone, further diagnostics are recommended to distinguish pancreatitis from other potentially life-threatening diseases. A limitation of non-quantitative cPL assays is that they cannot distinguish a cPL result in the equivocal zone from a result that is consistent with pancreatitis. Therefore, when a non-quantitative cPL test shows an abnormal result, the recommendation is to send the sample for quantitative testing to diagnose and also to establish a baseline value to be used for monitoring response to treatment.

Study Design

A dataset containing 1,000 sequential TRUFORMA® cPL results run across 80 unique clinics was retrieved from an internal database. Results < 200 µg/L were considered “Normal,” results from 200-400 µg/L were considered “Equivocal,” and results > 400 µg/L were considered “Consistent with Pancreatitis.”

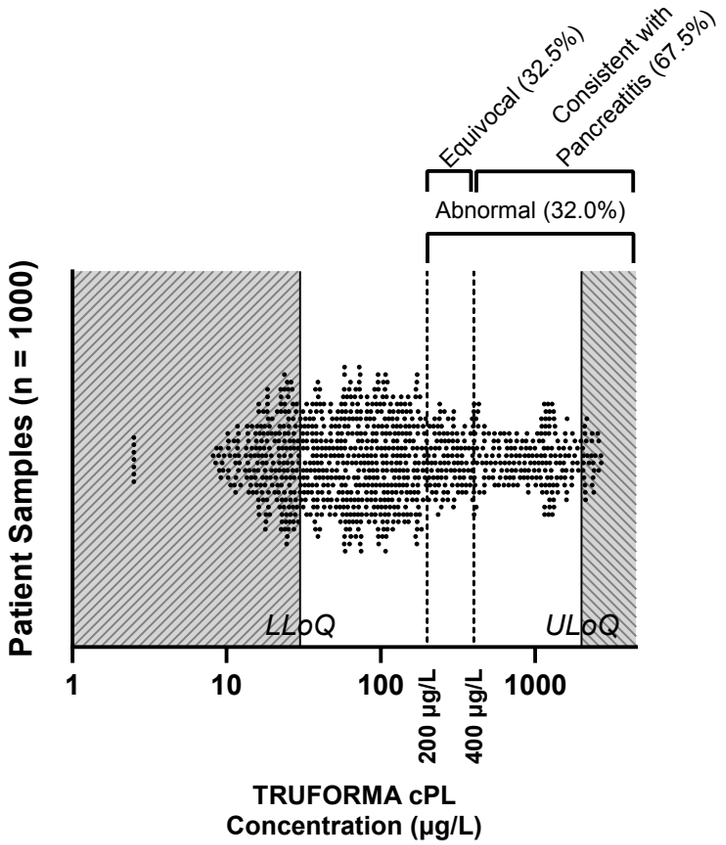
Results

Of these 1,000 cPL results, 209 were below the lower limit of quantitation (LLoQ) of the TRUFORMA cPL Assay (30 µg/L) while 28 fell above the upper limit of quantitation (ULoQ; 2000 µg/L). Seven (7) results had a cPL concentration value of 0 µg/L and these were artificially set to 2.5 µg/L for visualization purposes (**Figure 1**).

Using a "Normal"/ "Abnormal" cutoff value of 200 µg/L as inferred from an in-clinic non-quantitative analysis assay, 320 results (32.0%) had concentrations that would be consistent with an "Abnormal" result. Of these 320 Abnormal results, 104 (32.5%) had cPL concentrations within the "Equivocal" range (200 – 400 µg/L) while 216 (67.5%) had cPL concentrations that would be "Consistent with Pancreatitis" (> 400 µg/L).

Effectively, 1 in 3 serum samples analyzed with the TRUFORMA cPL Assay in clinic would be expected to return an "Abnormal" non-quantitative result and require reference lab quantitative analysis for complete evaluation of clinical status. Furthermore, of these "Abnormal" animals, 1/3 would have results in the equivocal zone that could be indicative of acute pancreatitis or other disorders like foreign body obstructions, enteropathies, infection, neoplasia, hyperadrenocorticism, etc.

Figure 1. Distribution of 1,000 sequential TRUFORMA cPL Results from Patient Samples



Discussion

Based on the results of this analysis, 1 in 3 patients with "Abnormal" results on a non-quantitative cPL test would fall in the equivocal range of the TRUFORMA assay and further diagnostics may be required to determine whether the patient truly has a cPL result consistent with the disease. Some diseases that can cause false positive cPL results, such as foreign body obstruction, can be life threatening. Therefore, having reliable quantitative results that can distinguish this equivocal zone is necessary for optimal patient diagnosis and treatment. Once treatment has been implemented, a quantitative result will also allow for monitoring response to treatment and/or progression of disease, whereas a non-quantitative test cannot reliably be used in this manner.

When a non-quantitative cPL test returns an "Abnormal" value, the recommendation is to follow-up with a quantitative cPL test. From the analysis of cPL clinical use performed here, 1 in 3 cPL samples require this additional testing. Sending to a reference lab for quantitative testing requires additional time and expense. Alternatively, using a quantitative cPL test at the POC provides the full diagnostic value of a cPL result with a single, less than 20-minute diagnostic test (**Figure 2**). Together, this analysis suggests that a quantitative POC cPL assay can improve patient care by providing timely results that can immediately be used to aid in diagnosis and monitoring.

Figure 2. Workflow comparison of a non-quantitative cPL test paired with quantitative reference lab testing to a point-of-care, quantitative cPL test.