A Novel Fecal Elastase Assay for the Detection of Pancreatic Exocrine Insufficiency

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Background

The fecal pancreatic elastase 1(FPE1) is an established screening test for Pancreatic exocrine insufficiency (PEI), a condition that is underdiagnosed and if not treated may cause significant morbidity. The aim of this study was to compare a new FPE1 machine based CLIA kit to an ELISA assay which is considered the de facto gold standard in our laboratory for FPE1 measurement.

Methods

Levels of FPE1 from the 227 stool samples were analyzed by the ScheBo ELISA kit and the CLIA Liaison XL system simultaneously with the same cut-off values for both assays. Performance of the Liaison XL system was assessed by calculating sensitivity, specificity and accuracy.

	Number of cases	Number of correct cases	Positive cases missed	Negative cases missed	Sensitivity	Specificity
Cut-off: 100 µg FPE1/g stool	227	209	9	9	86.8%	94.3%
Cut-off: 200 µg FPE1/g stool	227	206	18	3	84.6%	97.3%

Table 1: Liaison XL system sensitivity and specificity calculations compared with ScheBo ELISA kit results.

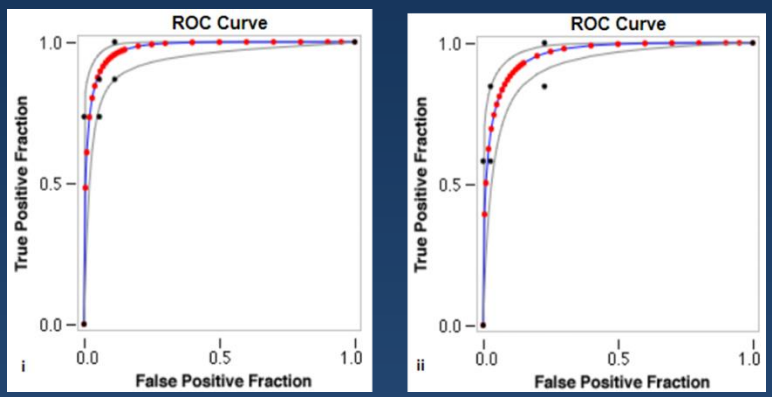

Figure 1: ROC curve analysis. Liaison XL system versus ScheBo ELISA kit. i: Cut-off: 100 µg FPE1/g stool (Accuracy = 92.1%, fitted ROC area = 0.977), ii: Cut-off: 200 µg FPE1/g stool (Accuracy = 90.7%, fitted ROC area = 0.960)

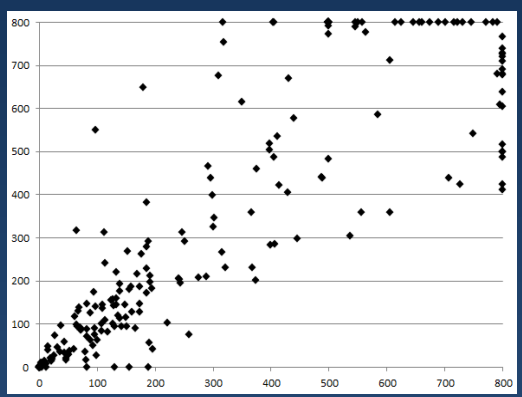

Figure 2: A graphical presentation of the linear correlation between the qualitative results of the Liaison XL system and the ScheBo ELISA kit (R = 0.85, P values < 0.0001). X values – ScheBo ELISA kit measurements. Y values – Liaison XL system measurements.

Results

The comparison between the Liaison XL system performance and the ScheBo ELISA kit as reference revealed a sensitivity, specificity and accuracy of 86.8%, 94.3% and 92.1% respectively using a cut-off of 100 µg FPE1/g stool. When cut-off of 200 µg FPE1/g stool the sensitivity, specificity and accuracy were 86.6%, 97.1% and 90.7% respectively. Furthermore, linear correlation of FPE1 levels between the two assays were found to be significant by Pearson correlation coefficient test (R=0.85, P values < 0.0001).

Discussion

The Liaison XL system showed good laboratory performance with our pre-determined cut-off values when compared to our previous assay. An important advantage of this system is its semi-automated mechanism that enables large scale analysis of FPE1. In addition to that, the Liaison XL system is ideal for both qualitative and quantitative of analysis of FPE1 allowing for its application to the clinical setting.