CLINICAL PERFORMANCE OF A TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTIFICATION OF FECAL PANCREATIC ELASTASE

IFCC WORLDLAB DUBAI 2024 MAY 26-30

P0993

D. Trapani[1], U. Aldinger[1], H. Ilgü[1], J. Afonso[1], M. Schneider[1], T. Schuster[1], S.Neu[1], L. Voigtländer[2], H. Laumen[2], J. Rosendahl[2] and C.-B. Gerhold[1,*]

*correspondence to: cbg@buhlmannlabs.ch; +41 61 487 12 52

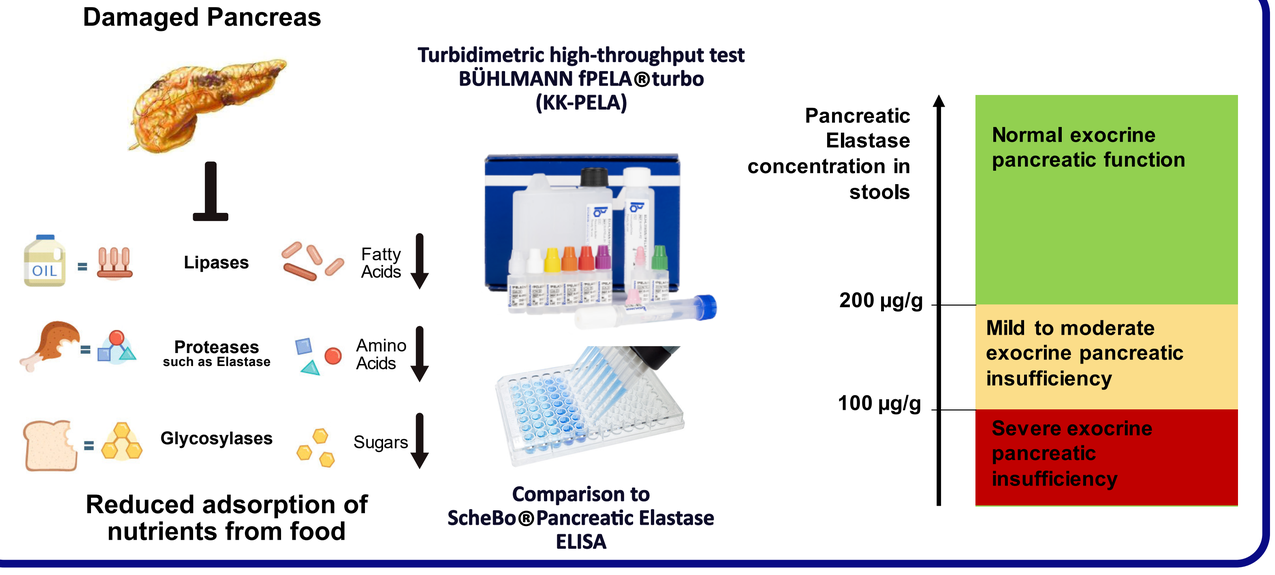
[1] BÜHLMANN Laboratories AG - 4124 Schönenbuch, Switzerland

[2] UKH Universitätsklinikum Halle (Saale), Department für Innere Medizin I, Halle, Germany

Background

Pancreatic exocrine insufficiency (PEI) can be defined as reduced pancreatic enzyme activity that leads to fat malabsorption, weight loss, and malnutrition-related complications. Fecal pancreatic elastase is an ideal biomarker for the assessment of pancreatic function in patients suffering from PEI, due to its important role in the digestive process as a proteolytic enzyme and the high stability of the enzyme during intestinal transit.

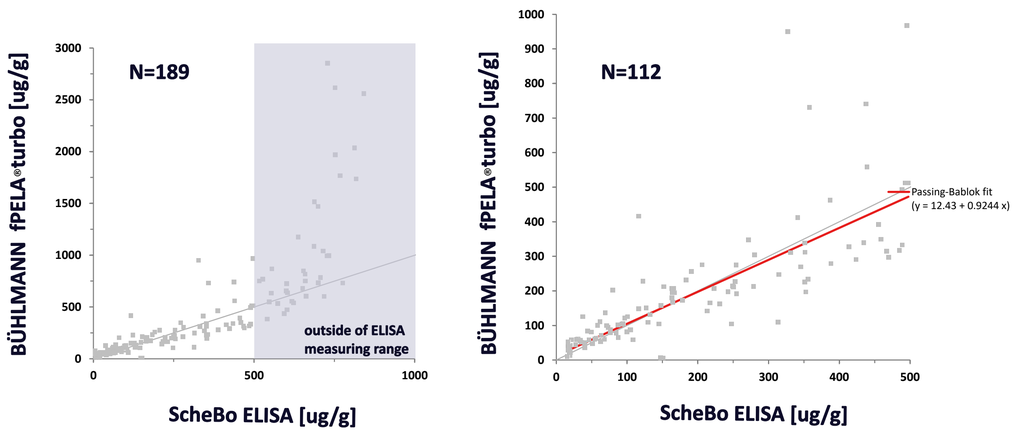
The cause for PEI can be manifold (chronic pancreatitis , Diabetes mellitus, IBD or pancreatic cancer), consequences are diarrhea, malnutrition and hence, reduced quality of life. After diagnosis of PEI, treatment with pancreatic enzyme replacement therapy (PERT) alleviates symptoms.



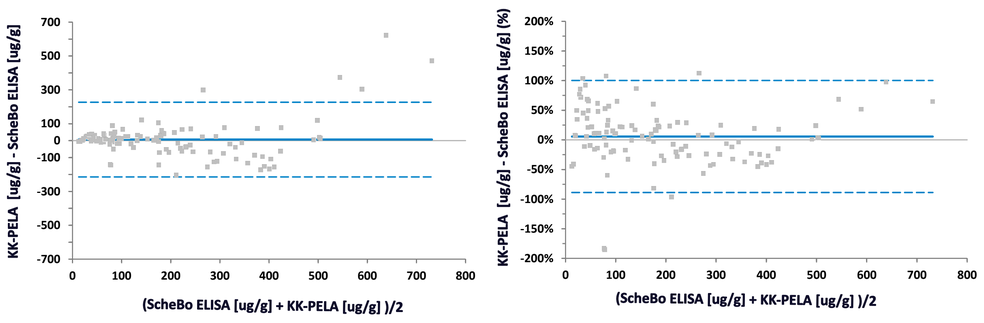
Methods

The aim of this work was to evaluate the clinical performance of BÜHLMANN fPELA® turbo, a particle-enhanced turbidimetric immunoassay (PETIA) that allows automated quantification of pancreatic elastase in fecal extracts on clinical chemistry analyzers. A comparative evaluation between BÜHLMANN fPELA® turbo and a reference ELISA assay was performed on 189 fecal samples from 113 diagnosed PEI patients (without taking elastase concentration into account) and 76 controls. Sensitivity and specificity using a cutoff of 100 and 200 µg/g were calculated for both assays. Additionally, the overall agreement and Cohen's kappa value between both assays were assessed on samples within the measuring range. Sample collection is still ongoing and thus final values may differ upon completion of the study.

Method comparison - Passing-Bablok

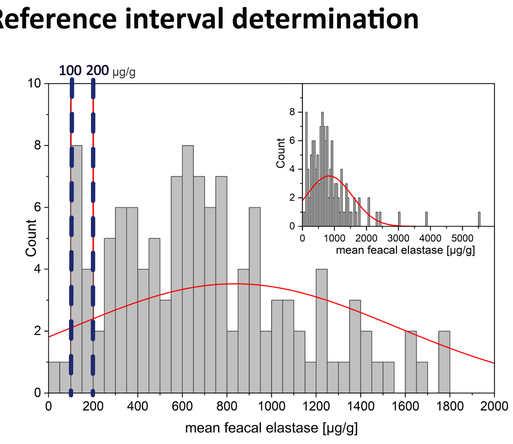


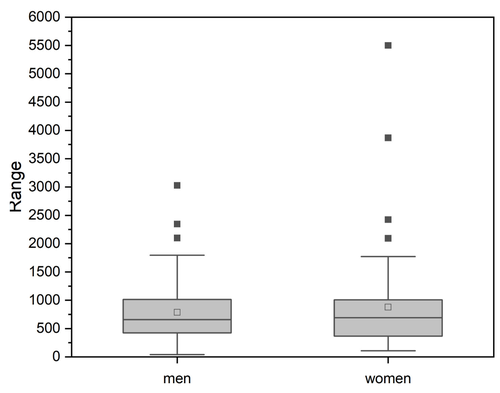
Method Comparison - Bland-Altman



Current agreement between the gold standard (ScheBo ELISA) and the BÜHLMANN fPELA®turbo is high with a Passing-Bablok Regression slope of 0.9244 and a mean bias of 5.72% according to Bland-Altman for samples within the measuring range of the ScheBo ELISA (N=112).

Reference interval determination



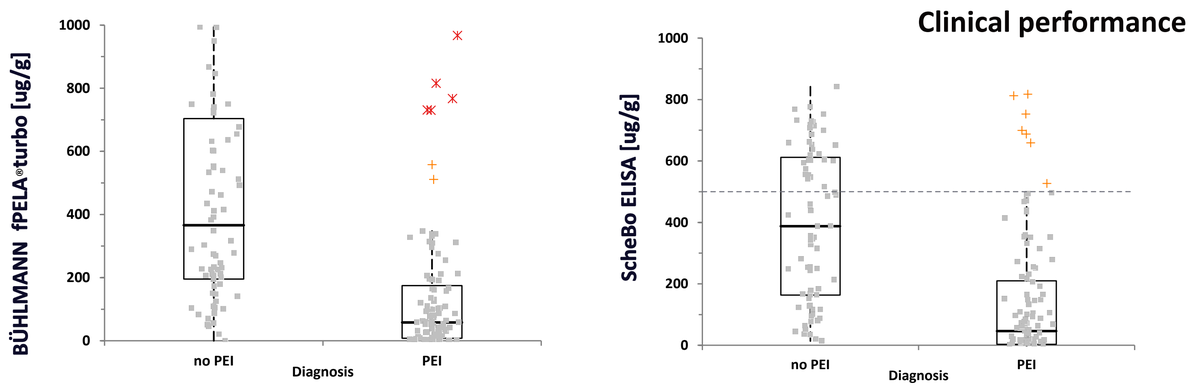


Percentile	Elastase [µg/g]	90% Confidence Interval [µg/g]
2.5	108.0	39.7 – 134.2
25	*388.0*	*Na*
75	*1'015.5*	*Na*
97.5	3'029.0	2'093.8 – 5501.5

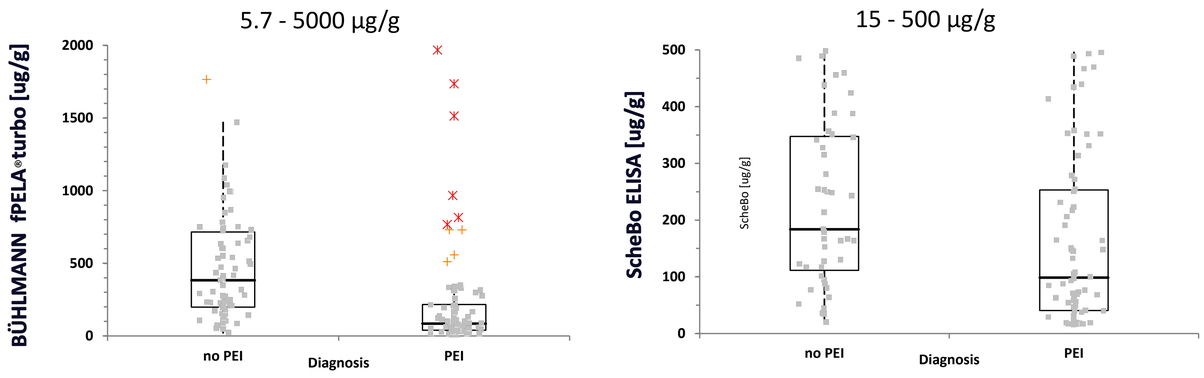
Fecal Elastase Concentration	Number of healthy subjects
200 to >500 µg/g	114
<200 µg/g	14

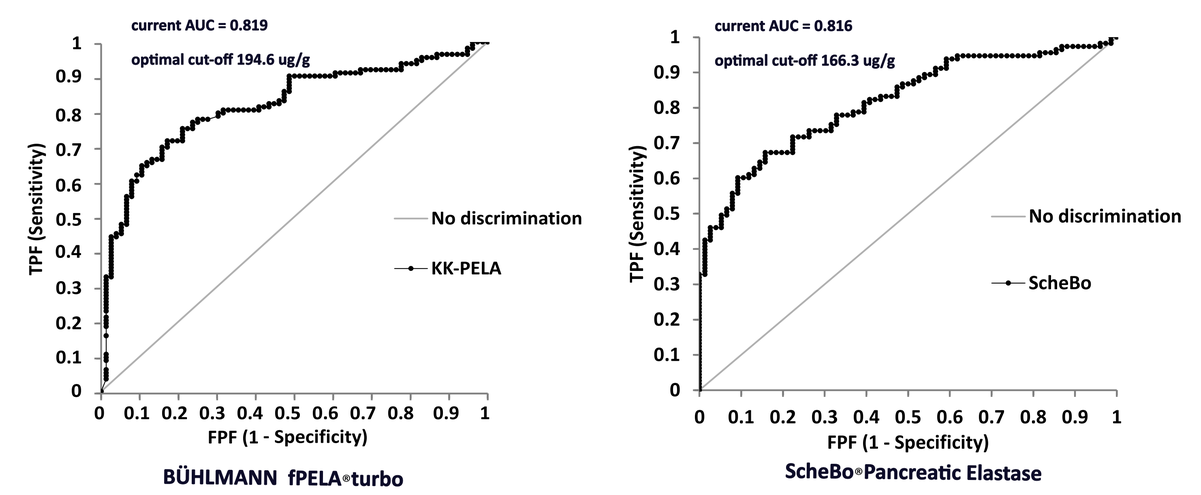
Stool samples of 128 self-declared healthy volunteers were measured over three days by two operators with two lots of BÜHLMANN fPELA® turbo to determine the reference interval according to CLSI C28-A3.

Clinical performance



Values within measuring range





	Cutoff 100 µg/g		Cutoff 200 µg/g	
	Sensitivity	Specificity	**Sensitivity**	**Specificity**
KK-PELA	0.65	0.89	**0.78**	**0.74**
ScheBo	0.64	0.86	**0.74**	**0.68**

Results - Summary

The BÜHLMANN fPELA® turbo revealed a sensitivity and specificity of 78% and 74%, respectively, with comparable clinical performance compared to the reference ELISA assay (sensitivity and specificity of 74% and 68%, respectively). The method comparison, with 104 clinical samples, showed a relative bias at the cutoff (200 µg/g) of -8.0%. The overall analytical agreement between BÜHLMANN fPELA® turbo and the reference ELISA assay was 84.6%. Moreover, the Cohen's kappa agreement currently shows a substantial agreement (0.66). The study is anticipated to be completed in 2024.

Conclusions

BÜHLMANN fPELA® turbo shows good diagnostic performance and strong agreement with the reference ELISA assay. The BÜHLMANN fPELA® turbo, a particle-enhanced turbidimetric immunoassay, is an accurate, non-invasive, automated test and an ideal assay for large-scale determination of pancreatic elastase levels in fecal extracts.