Fecal elastase 1 stability and assay comparison

Jenny Kiviaho, Mikko Anttonen and Outi Itkonen

Department of Clinical Chemistry, HUS Diagnostic Center, Helsinki University Hospital

Introduction

Quantitation of fecal elastase 1 (FE-1) is a non-invasive test of exocrine pancreatic insufficiency. Traditional sample preparation by manual weighing and extraction is laborious, but new sampling devices allow more effective sample preparation. FE-1 in stool has good stability but systematic studies on FE-1 stability in sampling devices and comparison of FE-1 assays are lacking.

Aims

We aimed to systematically study the stability of FE-1 in the IDK Extract® device and in intact stool samples. Furthermore, we compared the performance of the IDK FE-1 enzyme-linked immunosorbent assay (ELISA) to that of the established ScheBo assay.

Methods

ELISA kits for quantitation of FE-1 were from IDK (Immunodiagnostic AG, Bensheim, Germany) and ScheBo (ScheBo Biotech AG, Giessen, Germany). Samples were prepared using IDK Extract® device and by manual weighing. Samples were kept stored at room temperature, 4 °C or -20 °C.

Results

FE-1 in the IDK Extract® device and in a native sample is stable at least 29 days at all temperatures studied (Fig.1).

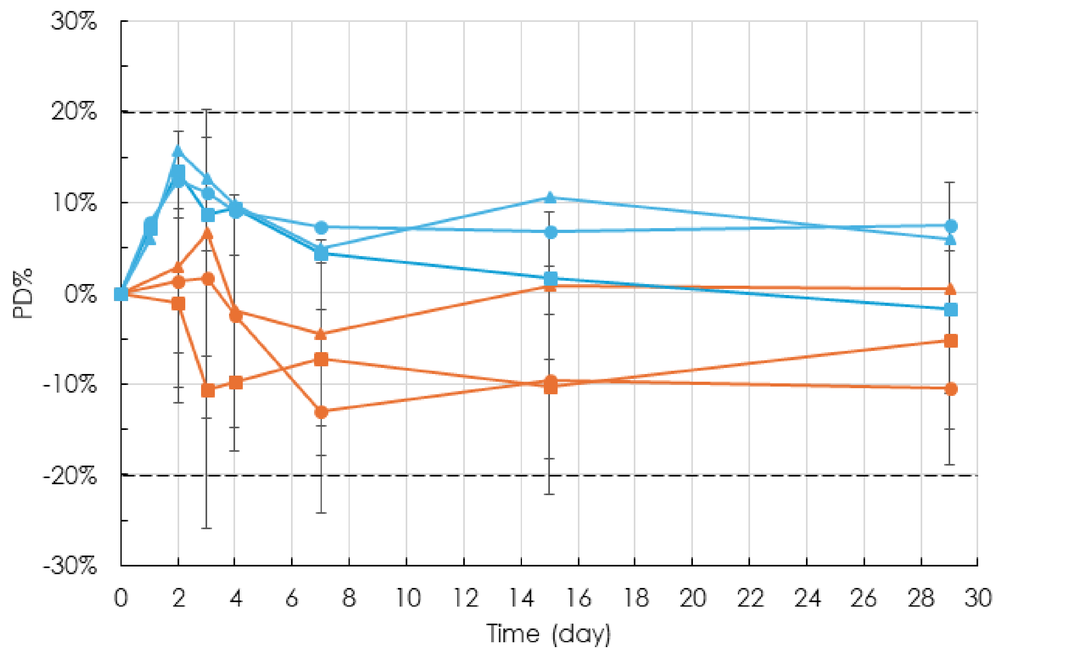

Figure 1. Stability of FE-1 in IDK Extract® device (blue) and intact stool (orange). Point estimation with 95 % confidence intervals for mean elastase 1 concentrations of samples from volunteers (n=8). PD, Percentage deviation.

The concentrations obtained by manual weighing and IDK Extract® device showed good correlation (R2=0,905)(Fig. 2) and the mean difference estimate was 0.46 %. The qualitative agreement in diagnostic classification as to pancreatic insufficiency between manual weighing and IDK Extract® device was 84.4 % (<100 µg/g insufficiency, 100-200 µg/g mild/moderate insufficiency, >200 µg/g sufficient).

Correlation of the results by ScheBo and IDK FE-1 assays was good as well (R2=0,729)(Fig. 3) and the mean difference estimate between the assays was 39.3 %. The qualitative agreement in diagnostic classification between IDK and ScheBo test was 62.5 %.

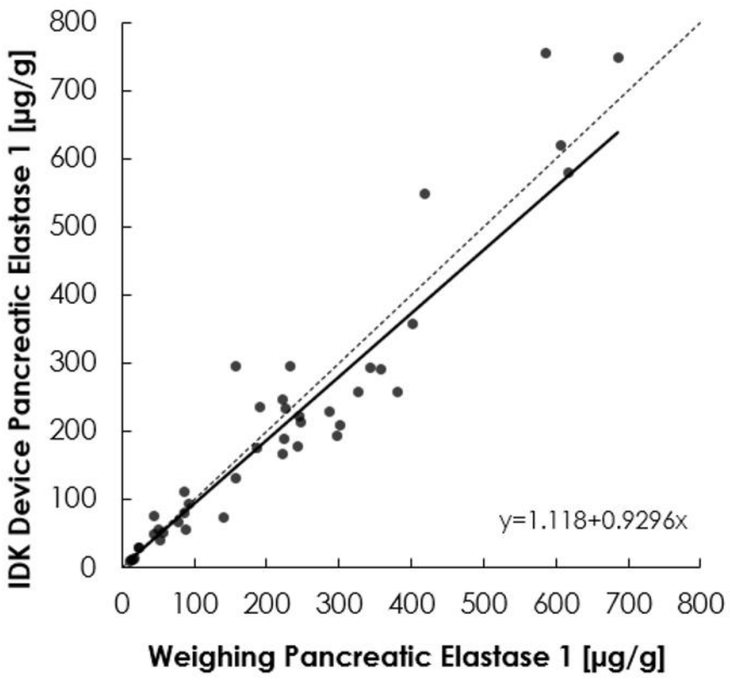

Figure 2. Passing-Bablok regression analysis of fecal elastase 1 (FE-1) results obtained from samples prepared using IDK Device or manual weighing and extraction (n=42).

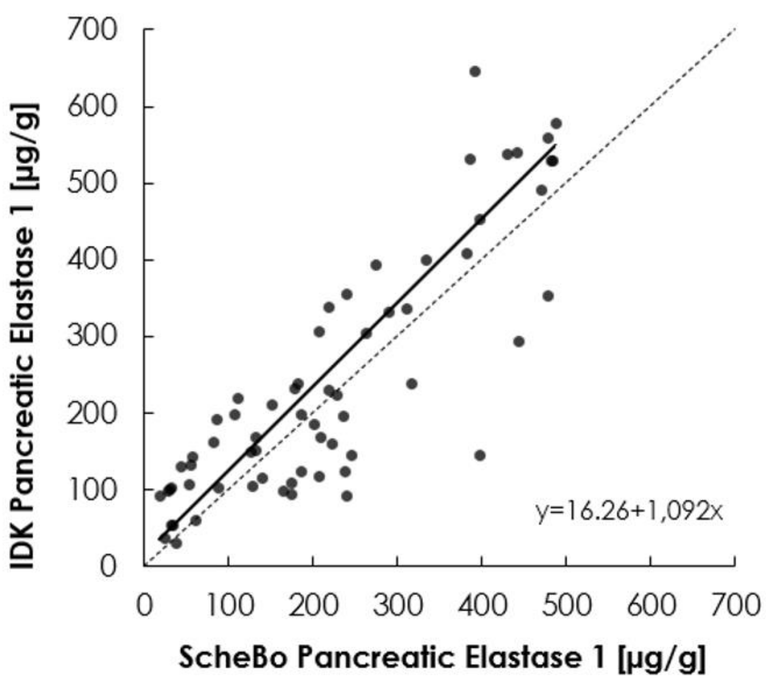

Figure 3. Passing-Bablok regression of fecal elastase 1 (FE-1) concentrations by ScheBo and IDK FE-1 assays using extracts from manually weighed samples (n=64).

Conclusions

FE-1 is stable at various temperatures and the IDK stool extraction device proved to be a reliable tool for sample preparation. Utilizing sampling device in laboratory settings allows effective and quick sample preparation. IDK and ScheBo assays detect pancreatic exocrine insufficiency and sufficiency equally, even though some deviation exists in the diagnostic classification to mild/moderate insufficiency (100-200 µg/g).