LABQUALITY DAYS

Fecal elastase 1 stability and assay comparison

Jenny Kiviaho*, Mikko Anttonen, Outi Itkonen.
*HUS Diagnostic Center, Lappeenranta, Finland

Introduction

Quantitation of fecal elastase 1 (FE-1) can be used as a non-invasive test for pancreatic function to detect moderate or severe exocrine pancreatic insufficiency. The enzyme-linked immunosorbent assays (ELISA) are well-established tests for FE-1 detection. 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 are lacking.

Aims

We aimed to systematically study the stability of FE-1 in a sample device. In addition, we compared the performance of IDK enzyme-linked immunosorbent assay for FE-1 to that of the most often used assay from ScheBo.

Methods

ELISA kits for quantitation of FE-1 were from IDK (Immunodiagnostik AG, Bensheim, Germany) and ScheBo (ScheBo Biotech AG, Giessen, Germany). Provider ordered clinical samples (n=41) were prepared both with Stool Preparation System IDK Extract device (Immunodiagnostik AG) according to the manufacturer's instructions and weighed manually. Samples were kept stored at room temperature, 4 °C or -20 °C.

Results

FE-1 in the sampling device and in a native sample is stable for at least 29 days at all temperatures studied with deviation < ±20 % from day zero concentration. The FE-1 concentrations obtained with manual weighing and sampling device correlated well with low mean difference estimate. The qualitative agreement in diagnostic outcome result categorization between manual weighing and sampling device was 84.4 %. Qualitative agreement in results categorization between IDK and ScheBo test was 62.5 %.

Conclusions

The IDK and ScheBo assays detect pancreatic exocrine insufficiency equally. FE-1 is stable at various temperatures, both in stool and in sampling device. Thus, the IDK FE-1 assay together with the sample preparation device offers an effective and reliable method to determine pancreatic function.