Verification of the BÜHLMANN Automated Elastase Assay on Abbott Alinity analysers

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Introduction

Elastase-1 is a pancreas specific enzyme that is secreted into the intestinal tract and excreted in faeces. Since it is not degraded during intestinal transit, its concentration in faeces reflects exocrine pancreatic function. Low faecal elastase-1 values are indicative pancreatic insufficiency. At University Hospitals Birmingham NHS Foundation Trust, the current method for measuring pancreatic elastase is a manual, 2-day ELISA (Schebo kit).

Due to increasing workload, the aim of this project was to verify a semi-automated method for analysing faecal elastase on Abbott Alinity analysers. The BÜHLMANN faecal elastase® (fPELA) turbo test is a particle-enhanced turbidimetric immunoassay that enables relatively quick quantification of elastase in faecal extracts on clinical chemistry analysers.

Method

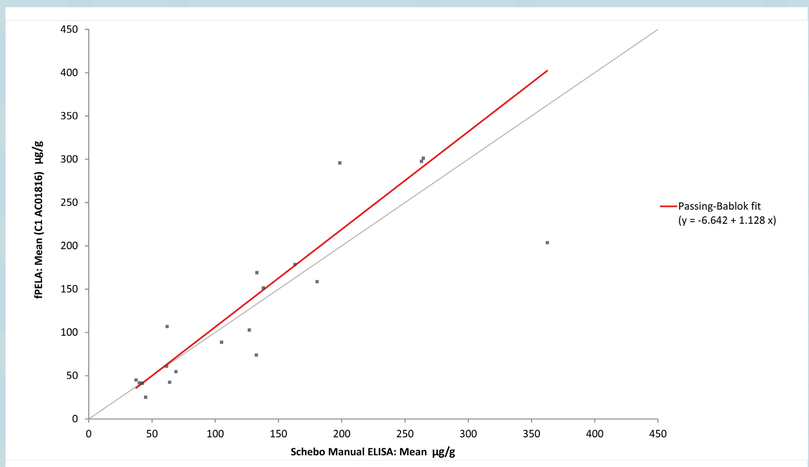
Accuracy, imprecision, limit of quantitation (LoQ) and linearity of the BÜHLMANN fPELA® turbo assay on the Abbott Alinity was evaluated. A sample comparison with the manual Schebo ELISA assay was also performed (n=26).

Bland-Altman and Passing-Bablok statistics were used to assess these results. Stability of stool samples for elastase measurement was also assessed at room temperature and 2-8°C.

Results

Precision: The precision data showed acceptable within-run and total CVs (within the acceptance target of 15%).

Sample	Observed mean (ug/g)	Calculated CVs	
		Within-run	Total
QC1 (kit)	153.0	1.0%	1.4%
QC2 (kit)	394.6	0.9%	0.9%
Extraction QC (pooled patient material)	164.2	8.3%	14.8%



Bias

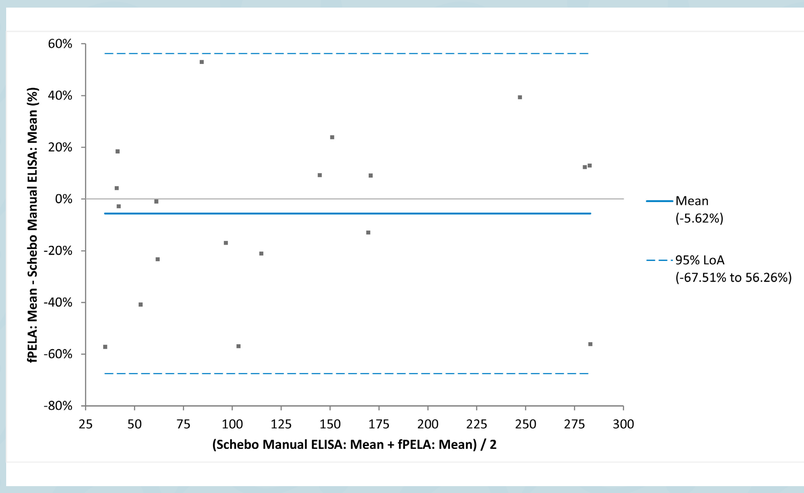
Patient comparison: When compared to the manual (weighing) Schebo pancreatic elastase-1 ELISA assay, the BÜHLMANN fPELA® assay showed an overall negative bias of -5.6%. Of the 26 patient samples analysed using both the manual ELISA and fPELA methods, 22 samples showed agreement for the interpretation of numerical results, which included all possible outcomes (severe insufficiency, mild-to-moderate insufficiency, and normal exocrine function). Four patient samples showed disagreement; however, of these, 3 were still classified as having exocrine insufficiency and therefore this would not change patient management. One patient sample was interpreted as mild-to-moderate insufficiency using the Schebo Biotech pancreatic elastase-1 ELISA kit, but normal according to the BÜHLMANN fPELA® turbo Abbott Alinity method. The ELISA result for this sample (199 µg/g) was close to the cut-off for normal exocrine function (>200 µg/g). Due to the heterogenous nature of stool samples, this was deemed to be clinically acceptable.

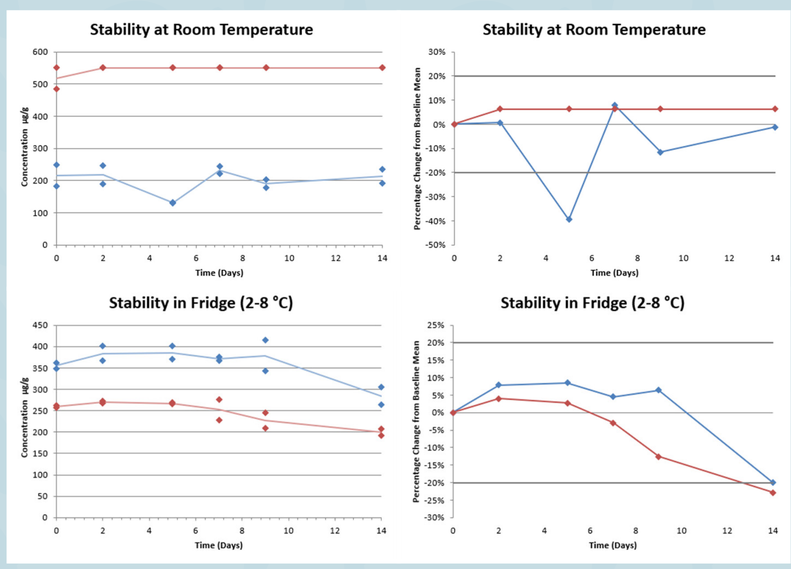
		fPELA Interpretation			
		Normal	Mild	Severe	Total
Schebo Manual ELISA Interpretation	Normal	9	0	0	9
	Mild	1	5	2	8
	Severe	0	1	8	9
	Total	10	6	10	26

EQA: The BÜHLMANN fPELA® assay showed an overall bias of -17.7% against the EQA ALTM. This is within the acceptable target bias of ±30% taken from the UKNEQAS EQA target. The z-scores for all samples were ≤2.

LOQ: The lower limit for the BÜHLMANN fPELA® turbo method was verified by repeated analysis (n = 6) of a low-level sample giving a CV of 18.9% at a mean concentration of 9.9 µg/g. This is below the target CV of ≤20%.

Stability: An in-house stability study showed that stool samples for faecal elastase are stable for 9 days between 2 and 8°C and for 14 days at room temperature.





Conclusion

The BÜHLMANN fPELA® turbo assay for faecal elastase is acceptable for clinical use – it has acceptable precision and accuracy, and will reduce turnaround time and throughput in the laboratory.

References:
Whitcomb DC, Buchner AM and Forsmark CE. AGA Clinical Practice Update on the Epidemiology, Evaluation, and Management of Exocrine Pancreatic Insufficiency: Expert Review. Gastroenterology. 2023;165(5):1292-1301.
BÜHLMANN fPELA turbo Abbott Alinity c Application Note