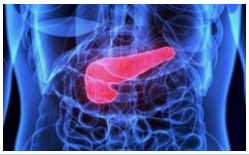

Comparison of two laboratory methods for the measurement of faecal elastase.

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Introduction

- Laboratory measurement of Faecal Elastase (FE1) is a test for pancreatic exocrine insufficiency (PEI). PEI is often associated with acute and chronic pancreatitis, cystic fibrosis and pancreatic cancer.[1]
- Patients with PEI are unable to secrete adequate digestive enzymes into the duodenum. FE1 concentration of <200 µg/g is considered diagnostic of PEI.[2]
- The Biochemistry Department at Cwm Taf Morgannwg UHB (CTMUHB) use the ScheBo enzyme-linked immunosorbent (ScheBo ELISA) method to measure FE1.
- A new method for FE1 testing, Bühlmann particle enhanced turbidimetric immunoassay (Bühlmann PETIA) is suitable for automation on analysers and is less time-consuming than the current method (ScheBo ELISA).
- Adopting the new method at CTMUHB could potentially improve turn-around times, laboratory time management, service improvement and ultimately patient care.

Aims

- To compare analytical and clinical performance of the new Bühlmann PETIA with the current ScheBo ELISA for FE1 testing
- To establish if the new method is suitable for routine use for FE1 testing in patients at CTMUHB.

Methods

- Precision of the new method was assessed by running Internal Quality Control (IQC) samples at two different concentrations (low: 155 µg/g and high: 410 µg/g) five times per day over five days.
- Patient and external quality assurance stool samples (EQA) (n = 37) were extracted using Schebo Quick Prep Devices for the current method and Bühlmann Clex Cap Devices for the new method. Extracted samples were analysed on the same day using the Bühlmann PETIA on the Roche analyser and the Schebo ELISA on the Dynex DS2 analyser to assess bias and agreement between the two methods.
- EQA samples (n=9) were analysed using the new method to assess accuracy compared with UK laboratories using the Bühlmann PETIA participating in the EQA scheme.

Results

Precision: Data analysis using ANOVA statistical test demonstrated acceptable analytical precision for Bühlmann PETIA using both low (1.16%) and high IQC sample (2.35%) compared with EQA Analytical Goals of <6% and <15% respectively.

Method Comparison:

(1) Comparison of the two methods using Passing-Bablok (***Figure 1***) and Bland-Altman (***Figure 2***) statistical tests to assess differences between patient and EQA FE1 results demonstrated that Bühlmann PETIA exhibited a positive proportional bias (mean bias = 9.05%) compared with the ScheBo ELISA. This is acceptable as defined by the EQA Bias Goal of <30%.

(2) Cohen's Kappa statistic assessed qualitative agreement between the two methods for clinical outcome using the cut-off value <200 µg/g for abnormal FE1 results. Data analysis demonstrated substantial agreement (k=0.76). Four results, however, produced different clinical outcomes: **two results** abnormal for Bühlmann, normal for Schebo; **two results** normal for Bühlmann, abnormal for Schebo (***Table 1***).

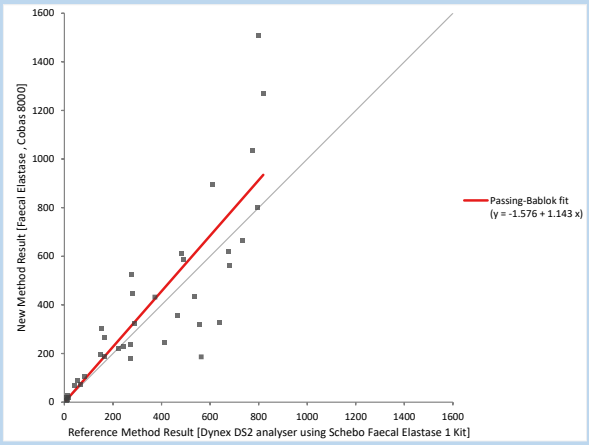

Figure 1. *Passing-Bablok analysis to assess agreement between Schebo ELISA method (current) and Bühlmann PETIA method (new) for faecal elastase measurement in patient and EQA samples (n=37).*

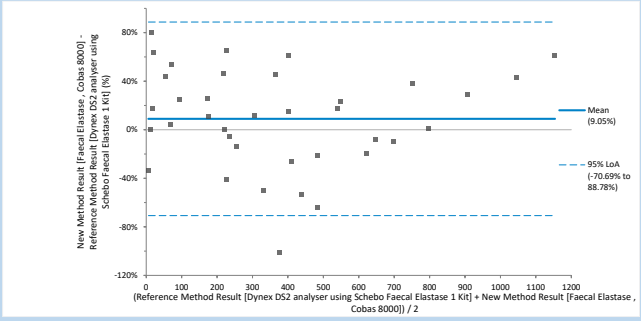

Figure 2. *Bland Altman analysis to assess agreement between the Schebo ELISA method (current) and Bühlmann PETIA method (new) for faecal elastase measurement in patient and EQA samples (n=37).*

Table 1. *Qualitative agreement between the two methods for clinical outcome using patient and EQA samples, n=37*
<200 µg/g = abnormal result; ≥200 µg/g = normal result

	Bühlmann PETIA		
ScheBo ELISA	**<200 µg/g (n)**	**≥200 µg/g (n)**	Total
<200 µg/g (n)	22	**2**	24
≥200 µg/g (n)	**2**	11	13
Total	24	13	37

Results

Accuracy – All EQA results were within acceptable limits of the method group for Bühlmann PETIA, except for one result which exhibited an unacceptable positive bias.

Conclusion

- ***Overall Bühlmann PETIA compared well with the current method which is encouraging. However, some of the results were outside the analytical range for both methods and maybe unreliable.***
- ***Furthermore, the qualitative comparison did not quite achieve perfect agreement; four out of 37 results produced different outcomes. This may be attributed to differences in stool sample extraction methods, degree of homogeneity of the stool sample and/or the fact that FE1 assays are not standardised due to lack of a suitable reference material.***
- ***Further work is required to evaluate the Bühlmann PETIA using more samples within the analytical range and to minimise pre-analytical variables of the sample preparation and extraction process.***

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