Royal United Hospitals Bath
NHS Foundation Trust

Evaluation of the BÜHLMANN fPELA®TURBO Assay on the Beckman Coulter AU5822 Automated Chemistry Analyser

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Background

- Faecal Elastase analyses is used as an aid in the assessment of exocrine pancreatic insufficiency in patients with chronic pancreatitis[1].
- Before June 2024, Royal United Hospital Bath (RUH) referred samples for faecal elastase (FEL) away for analysis.
- Following our recent successful implementation of the fully automated BÜHLMANN fCAL TURBO (faecal calprotectin) assay on the Beckman Coulter AU5822 it was decided to evaluate the BÜHLMANN fPELA TURBO (FEL) assay on the Beckman Coulter AU5822.

Principle of Method

- Faecal samples were extracted using the CALEX® Cap extraction device (within 1-3 days of sample receipt).
- fPELA TURBO method is a particle enhanced turbidimetric immunoassay (PETIA)[2]:
- The extracted sample is incubated with reaction buffer and mixed with polystyrene nanoparticles which are coated with pancreatic elastase-specific antibodies.
- If pancreatic elastase is available in the sample, an immunoparticle agglutination occurs.
- The turbidity of the sample is measured by light absorbance; an increase with pancreatic elastase-immunoparticle complex formation is proportional to pancreatic elastase concentration which is determined from the established calibration curve.

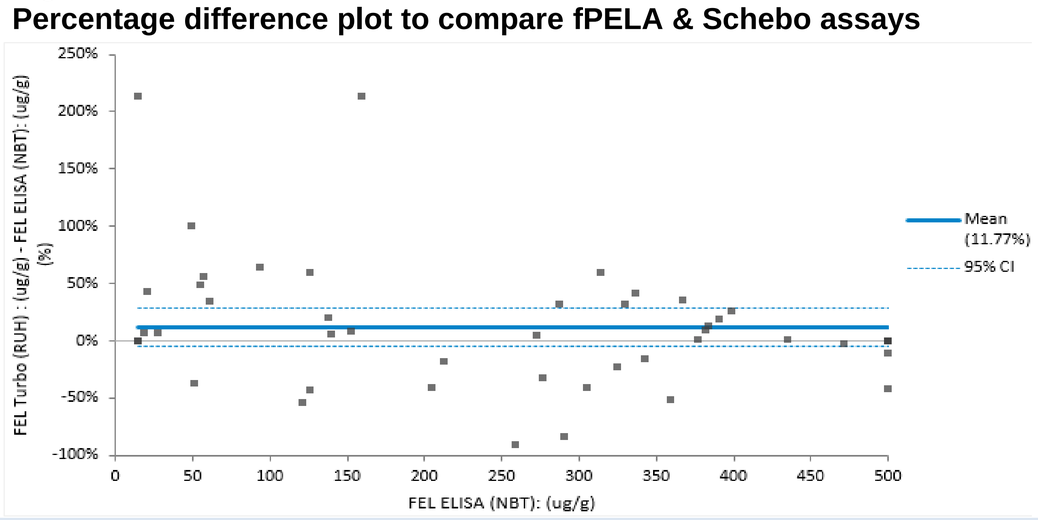
Method

- BÜHLMANN fPELA TURBO was assessed for:
- **Inter-assay precision** (manufacturer IQC run over the course of the verification)
- **Accuracy** using UKNEQAS EQA samples (n=9)
- **Bias** against Schebo pancreatic elastase 1 ELISA performed on DS2
- **Patient faecal samples (n=47) and EQA samples** were extracted using the BÜHLMANN CALEX device and analysed on the fPELA TURBO assay; patient primary stool samples were referred for Schebo assay analysis by our usual referral laboratory.

Results

- Inter-assay precision on the fPELA TURBO assay was very good with %CV of 4.42% and 2.11 % at 150 ug/g and 400 ug/g respectively.
- Satisfactory EQA results were obtained, all results were within ALTM and method mean 2SD ranges.
- The patient comparisons showed a large amount of scatter, likely reflecting the heterogeneous nature of faecal samples (Figure 1).

Figure 1
Percentage difference plot to compare fPELA & Schebo assays



Mean bias of +12% was demonstrated on the fPELA TURBO assay, however wide confidence limits and *P*=>0.05 revealed no statistically significant difference (Figure 1).

It is worth noting that in contrast to the Schebo assay, fPELA is quoted to have a positive of up to 20% in samples containing pancreatin (Creon®).

- The classification of pancreatic function showed a **tendency for an increase in severe and moderate pancreatic insufficiency** when assayed using fPELA TURBO (Table 1).
- Six patient samples showed significant discrepancy between the two assays in terms of quantitation and interpretation; 5 samples interpreted as normal pancreatic function on the Schebo assay were classified as severe or moderate using the fPELA TURBO and 1 sample classified as moderate insufficiency on Schebo was classified as normal using fPELA TURBO. Samples re-analysed on the fPELA TURBO assay with consistent results.

Table 1 Absolute number and percentage of verification patient samples falling into interpretative categories:

Interpretation categories	Schebo FEL ELISA (current)	%Schebo FEL ELISA (current)	fPELA TURBO FEL (new)	% fPELA TURBO FEL (new)
<100 ug/g (severe exocrine pancreatic insufficiency)	12	25.5	14	29.8
100 – 200 ug/g (moderate to mild exocrine insufficiency)	8	17.0	11	23.4
> 200 ug/g (normal pancreatic function)	27	57.4	22	46.8
Total	47	100	47	100

Conclusion

- The **fPELA TURBO assay evaluation was successful** and employed into routine use in June 2024, without amendment to interpretation thresholds.
- Additional clinical advice has been provided with regards to the **20% positive bias with Creon**, in these patients a higher threshold of >250 ug/g should be used to determine pancreatic sufficiency.
- **Faeces is a heterogenous sample type** which may explain some of the discrepant results seen e.g. EQA reports show 20-30% variation in results from the same method likely due to variations in sample transport, storage and extraction techniques. In addition studies quote within-person variation of up to 37%.[3,4]
- The analysis of faecal elastase on-site has **vastly improved the turnaround time** and resulted in an overall cost-saving.

References

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Special thank you to: Amanda Appleton (Alpha Laboratories) & RUH Biochemistry colleagues: Tracy Hunt & Maria Saborido