Evaluation of the BÜHLMANN fCAL® turbo assay on the Abbott Architect C8000

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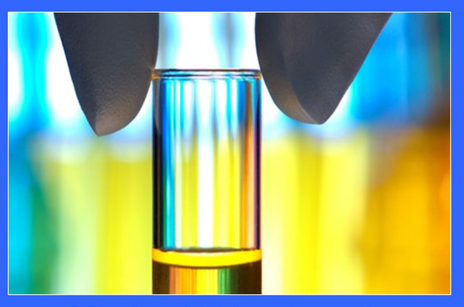

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Introduction

Faecal calprotectin (fCAL) is a well established biomarker for intestinal inflammation, routinely used to aid in diagnosis, in distinguishing organic, inflammatory disease of the gastrointestinal tract (inflammatory bowel disease, IBD; Crohn's disease or ulcerative colitis) from functional disease (irritable bowel syndrome, IBS), in patients with chronic abdominal pain, above the age of three. It also supports inflammatory status monitoring during. The BÜHLMANN fCAL® turbo assay, (immunoturbidimetric method), and the BÜHLMANN CALEX® sample extraction tubes, which are available from Alpha Laboratories Ltd, allows fCAL testing on a variety of open chemistry platforms, improving the workflow, and turn around times.

Aim

Evaluation and validation of the CALEX® sample extraction tubes and the BÜHLMANN fCAL ® turbo assay on our in-house Abbott Architect C8000 analyser, compared to the current Phadia 250 ImmunoCap (EliA) method.

Materials and Methods

Patient samples (n=111) that had been previously analysed using the EliA 2 Extraction kit (Phadia) and assayed on the Phadia 250 ImmunoCap (<2-3 days), were re-extracted using the CALEX® Cap extraction device and analysed using the BÜHLMANN fCAL turbo® assay on our Architect C8000 analyser. Imprecision and inaccuracy were also estimated along with dilution linearity and sample stability post-extraction. Calibrators, QC, reagent and CALEX® extraction tubes were all provided by Alpha Laboratories Ltd, for this evaluation. Six point calibrators (Fig. 1) are provided with a Low (apx 70 µg/g) and High QC (apx 250 µg/g).

Results

Patient sample comparison demonstrated a mean bias of 8.46%, compared to the Phadia 250 method (Fig. 2). Interassay imprecision was (9.8%) ,and intra-assay precision 6.7% (low) and 3.1% (high). Dilution linearity was (*r* 0.9999), with a method mean bias of -3.4% compared to the EQA ALTM for this method. Extracted sample stability (n=5) at a range of temperatures (RT, 4^{o}C and -20^{o}C) over a 5 day period, and multiple freeze thaw cycles (n=3) demonstrated <10% bias compared with basal results. There was no significant carry-over (<0.1%) observed with other chemistry tests, when elevated calprotectin extracted samples (>6000 µg/g) were assayed on the Architect C8000 analyser.

Results

Table 1. Performance characteristics of the fCAL® turbo assay.

Performance Characteristic	Result
Extraction precision	5.68 – 8.33 % CV
Assay imprecision	Low QC 70 ug/ug (6.7 % CV) High QC 250 ug/ug (3.1 % CV)
Assay inaccuracy	NEQAS method mean bias -3.4%
Linearity Dilution	Mean CV <5%, *r* 0.9999 (n=5)
Extracted sample stability (RT, 4^{o}C & -20^{o}C (5 days)	<10% CV for stored samples
Sample to Sample carryover	No significant carry-over (sample >6000 µg/g, <0.1%)

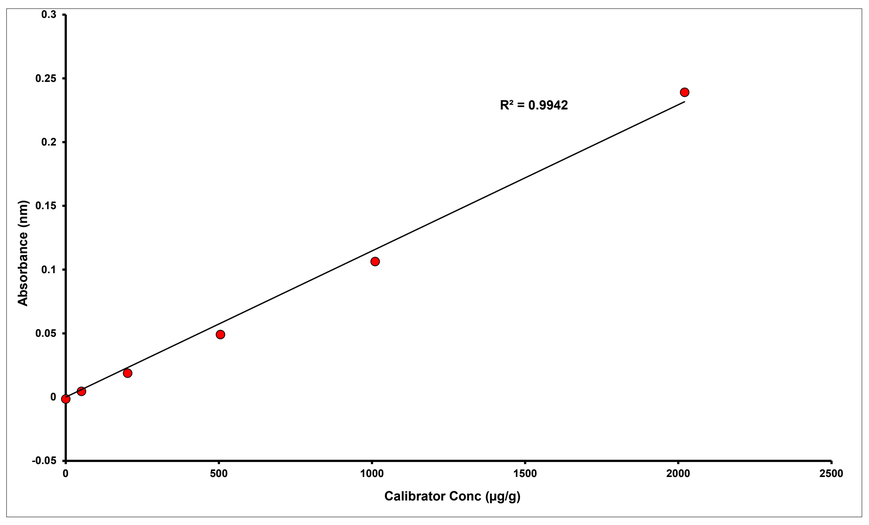

Fig 1. Architect C8000 fCAL Calibration (µg/g)

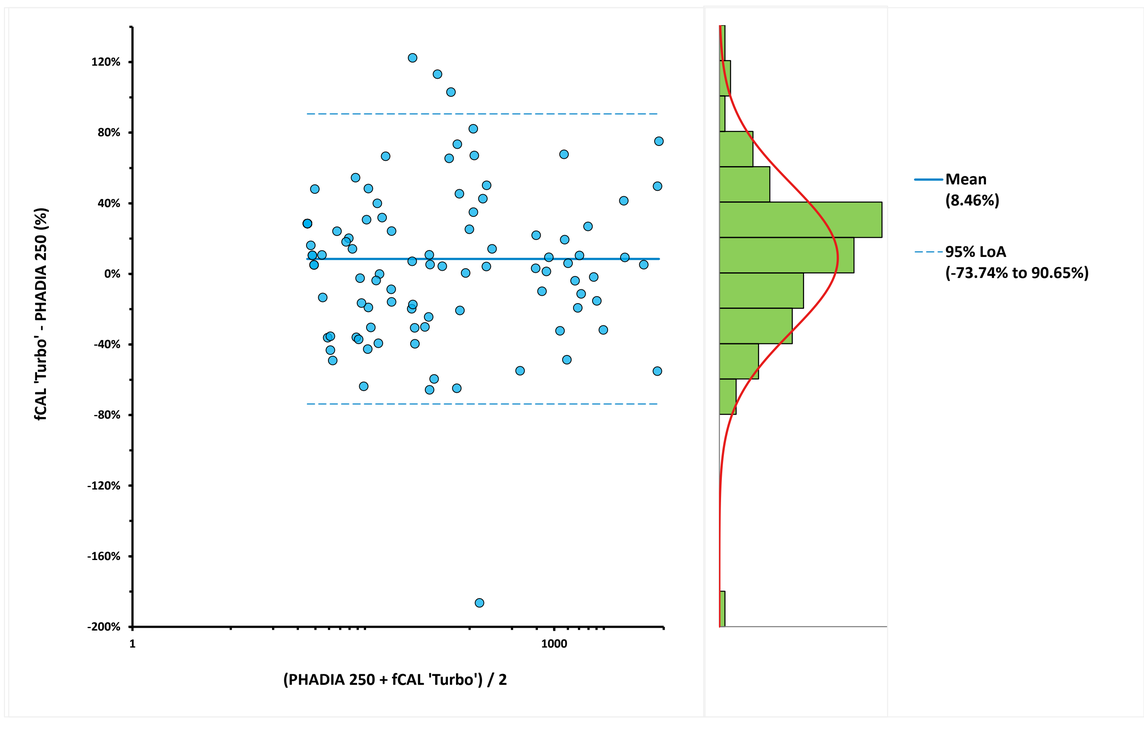

Fig 2. Bland Altman: fCAL® turbo vs. Phadia 250 methods

Conclusions

The CALEX® cap extraction devices and fCAL turbo® method on the Abbott Architect C8000 analyser, demonstrate good comparability with other established methods, with no significant interference with other chemistries and have led to improved workflow for faecal calprotectin analysis.