

Bringing Calprotectin Testing In-house on the Abbott Architect C8000



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During the evaluation, stool samples that were received into the laboratory were extracted using the BÜHLMANN CALEX cap extraction device and either tested straight away or the extracts were stored at -20C for later analysis of calprotectin by the fCAL turbo assay.

The stool samples were also sent under refrigerated conditions to the referral laboratory, where they were extracted using the Thermo Scientific ELiA extraction device and assayed on the Phadia 250 ELiA. Overall, sixty clinical samples in the range <5 to >3000µg/g faeces were tested during the evaluation, using both the Phadia ELiA and BÜHLMANN fCAL turbo method.

Although we were initially nervous about putting faecal samples on the Architect, we didn't experience any problems. Three quality controls for all the routine chemistries were run after the calprotectin assays and no errors were observed.



A scatterplot of the results is shown in Figure 1 with a Pearson Correlation Coefficient of 0.930 achieved.

This study data correlates with many other studies which have demonstrated the inter assay variability between all of the Faecal Calprotectin assays. A p=0 demonstrates a statistical significance between the two methods with a mean difference of 245 .

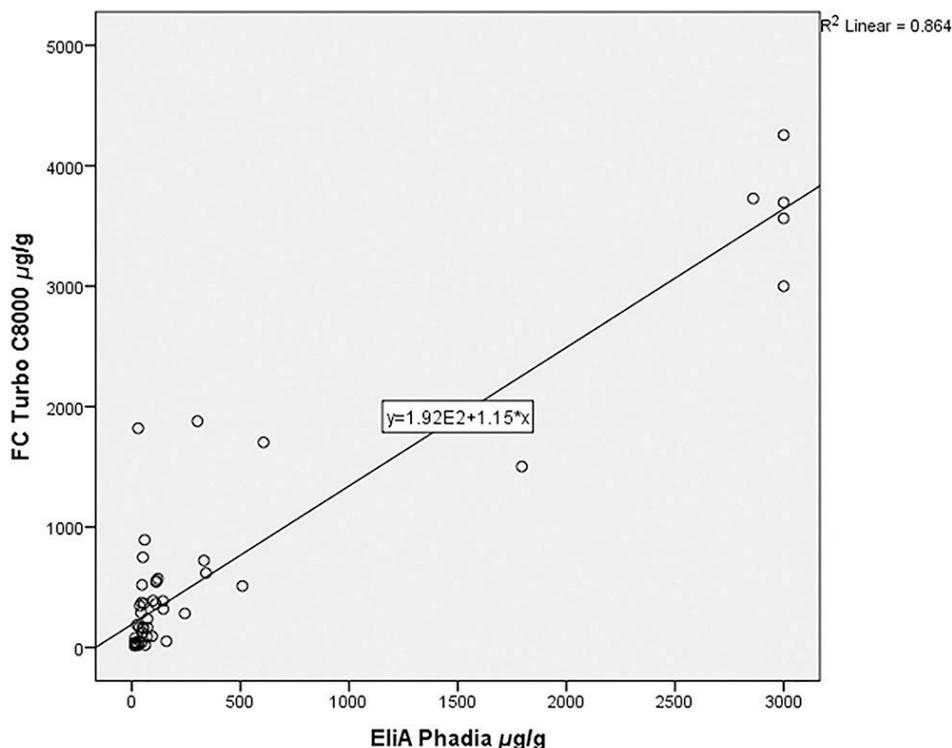
At the Biochemistry Department at Mercy University Hospital (MUH) in Cork we had been sending samples for faecal calprotectin testing away to a referral laboratory for analysis.

This referral laboratory uses the Phadia 250 ELiA™ Fluorezyme-Immunoassay. The problem was that this was quite expensive and the turnaround was initially up to 6 weeks, which is too long for the IBD clinic. To try to improve the service we started to investigate the options for bringing calprotectin testing in-house.

ELISA is the standard method for measuring faecal calprotectin, but is time consuming and requires specific laboratory equipment that we didn't have or the space to accommodate.

BÜHLMANN Laboratories has recently introduced the fCAL™ turbo calprotectin assay which runs on many open clinical chemistry platforms. Since this gives results significantly faster than ELISA with no additional equipment, service contracts or staff training required it looked an attractive option. At the MUH there is capacity on the Abbott Architect C8000 analyser so this is what the fCAL turbo protocol was evaluated on.

Figure 1. Scatterplot of Phadia 250 ELiA vs f CAL Turbo with linear regression



All 60 results from the two methods were reviewed by the IBD medical team (Table 1).

Table 1 : Comparison of the fCAL turbo versus Phadia results for 60 patient samples tested for faecal calprotectin

		Result Interpretation Comparison n=60		
		BÜHLMANN fCAL® turbo		
		Negative	Borderline	Positive
Phadia EliA™ Calprotectin	Negative	20	5	5
	Borderline	-	6	11
	Positive	1	-	12

20 Negatives. 12 Positives. 6 Borderlines.
22 Discrepant results:-
5 Borderline/Negative
5 Positive/Negative
11 Positive/borderline
1 Negative/Positive

Overall the fCAL turbo assay produced a higher result.

ELIA is a trademark of Thermo Fisher Scientific – Phadia GmbH

The patient charts of the 22 discrepant results were reviewed for colonoscopy reports, if they were performed, and clinical presentation, to help determine which of the assays produced the more accurate results. Sample data are shown in Table 2.

Table 2: Colonoscopy and Clinical Presentation of Patients with Discrepant Calprotectin Results

Sample Number	BÜHLMANN fCAL turbo Result µg/g	Phadia 250 EliA Result µg/g	Clinical Picture
1	1820	29	Colonoscopy – Active surface inflammation of terminal ileum
31	519	47	Possibly active, low Humira levels
52	345	37	Left sided abdominal pain, Diarrhoea 5-6 times per day. No extra-articular features of IBD
35	1879	302	Advanced IBD. Failed drugs, non-compliant patient
46	893	59	Colonoscopy – Mild-moderate active ileal inflammation
27	571	120	No colonoscopy. IBDoc 520µg/g the same day
36	749	51	Very symptomatic Inflammatory mass in sigmoid colon
50	554	113	Severe Crohn's disease Resistant to standard therapy
55	365	56	Central abdominal pain & occasional diarrhoea with fresh blood
4	188	24	Colonoscopy – Mild active inflammation of large bowel

The medical team concluded that the fCAL turbo results correlated very well with the participant's clinical presentation and stage of IBD. This is important as they use this data along with the clinical presentation before referring patients for colonoscopy.

At the beginning of October 2017 we introduced the BÜHLMANN fCAL turbo assay for routine on-site testing of faecal calprotectin on our Abbott Architect C8000, using the full assay range to allow for monitoring.

We will also be extracting the samples into the CALEX as soon as possible, since we found during the evaluation that there was deterioration of calprotectin in the faeces even when stored at 4C.

As a Centre of Excellence for the region bringing calprotectin in-house will have huge benefits to the patient and the medical IBD team with a much improved turn-around time for results as well as a cost saving benefit.

BÜHLMANN fCAL® turbo is a very rapid and flexible turbidimetric assay for faecal calprotectin. CE marked protocols are now available on many major clinical chemistry platforms including: Siemens, Roche, Abbott, Beckman, ThermoFisher, Ortho, The Binding Site, Horiba and IDS.

It is based on the standardisation of the BÜHLMANN fCAL® ELISA, which is globally established in laboratories for calprotectin measurements. fCAL turbo is the ideal solution for high throughput applications in the routine laboratory with a time to first result of just 10 minutes.

To find out more and read more case studies please visit: www.alphalabs.co.uk/fcalturbo

For more information about the BÜHLMANN CALEX faecal calprotectin extraction device that simplifies sample handling and improves laboratory workflow, please visit: www.alphalabs.co.uk/calex

