BÜHLMANN fCAL® turbo Faecal Calprotectin Assay on Abbott Architect C8000

Mary O'Connell B.Sc., M.Sc., Biochemistry Laboratory,
Mercy University Hospital,
Cork, Ireland

Introduction

Faecal calprotectin has been long established as a valuable biomarker for intestinal inflammation, being used to distinguish between IBS and IBD and to monitor IBD positive patients.[1]

Traditional calprotectin testing has been based on ELISA technology, but as the volume of testing has increased new assays have become available to cope with the changing demands on both the laboratory and the clinic.

In the laboratory there are new assays that will run on many routine biochemistry analysers improving the workflow, range, accuracy and speed of the results, and in the clinic there are patient self-tests to assist with remote monitoring of IBD positive patients.

The BÜHLMANN IB*Doc*®[2] is a calprotectin home self-test. This uses the CALEX® extraction device, a calprotectin test strip and the IB*Doc* App to read the result using the patient's Smart phone, making the result available immediately for the patient and the clinic. The core of this test is the IB*Doc* web portal for managing patient data.

The aim of this study is:
1. To evaluate the BÜHLMANN fCAL® turbo assay on the Abbott Architect C8000[3] analyser with comparison to the Thermo-Fisher Phadia ELiA
2. To compare the BÜHLMANN IB*Doc*® home self-test kit to the BÜHLMANN fCAL turbo and the Phadia EliA

Materials and Methods

A total of 60 samples received for calprotectin testing were evaluated using the BÜHLMANN fCAL turbo assay on the in-house Abbott Architect C8000 analyser and the Phadia 250 ELiA system.

The original stool samples were:
1. Extracted into the CALEX® Cap extraction device and either analysed using the BÜHLMANN fCAL turbo immediately or were stored at -20C for later testing
2. Sent at 4C to the referral laboratory for extracting with the EliA extraction kit and testing on the Phadia EliA

A total of 15 IB*Doc* participant samples were also compared to both the BÜHLMANN fCAL turbo and the Phadia 250 ELiA. Where results were discrepant between the two laboratory assays the IBD team reviewed the colonoscopy results and clinical picture to see which assay gave the better reflection of the clinical picture.

Results

The BÜHLMANN fCAL turbo values were consistently higher than the Phadia EliA values (see Figure 1) which was statistically significant p=0.

Figure 1. Scatterplot of Phadia 250 EliA vs. fCAL turbo with linear regression

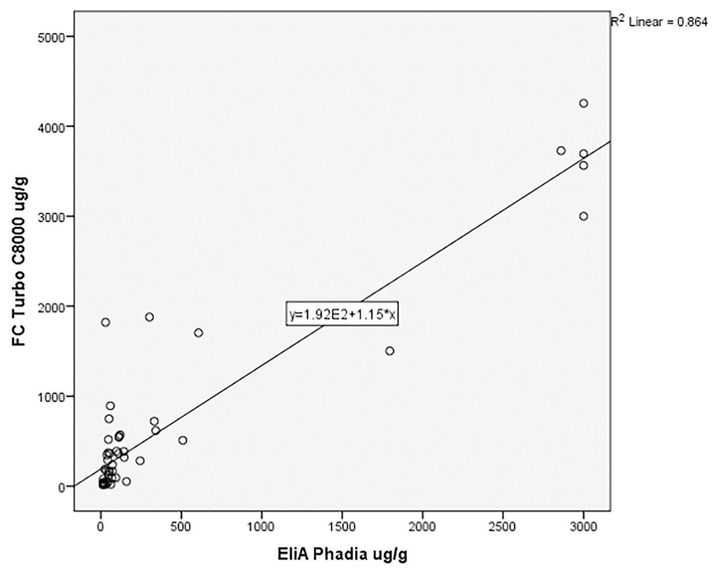

Table 1: Performance Characteristics of fCAL turbo on Architect C8000

Performance Characteristic	Result
Extraction Precision	7.55 – 9.4%CV
Assay Precision	0.74 – 3.3%CV
Linearity	16 - 1922µg/g
Measuring range	20 – 19,220µg/g
Correlation coefficient of results compared to Phadia EliA 250	0.930

Twenty two results gave different interpretations using the BÜHLMANN fCAL turbo and the Phadia EliA. A review of participant medical charts of these discrepant results by the Mercy IBD team confirmed the accuracy of the BÜHLMANN fCAL turbo in comparison to the Phadia EliA (Table 2).

Table 2: Colonoscopy Report and/or Clinical Presentation of Discrepant results

Sample Number	fCAL turbo µg/g	Phadia µg/g	Colonoscopy Report/Clinical Presentation
1	1820	29	Colonoscopy –Active surface Inflammation of Terminal Ileum(Ulcerative Colitis)
3	122	48	Ulcerative Colitis. On Humira. No Colonoscopy
4	188	24	Colonoscopy- Mild active inflammation of Large Bowel
7	167	35	Crohn's Disease- Ileocolitis. No Colonoscopy
18	54	35	For Colonoscopy-? Eosinophilis Enteritis
21	238	72	Colonoscopy – No evidence of Colitis. Severe acute Gastroenteritis & Abdominal cramps. ? Small Bowel disease. MRI Enterography to follow.
23	319	145	Ulcerative Colitis patient. On Infliximab. No Colonoscopy
27	571	120	IBD patient. No colonoscopy. IBDOC 520ug/g same date.
30	371	44	Crohn's Disease. Feels well. No Colonoscopy
31	519	47	Crohn's Disease. Possibly Active, Low Humira levels. No Colonoscopy
33	543	112	Ulcerative Colitis. No Colonoscopy. Feels well at present
35	1879	302	Active advanced IBD. Failed drugs, non –compliant patient
36	749	51	For Colonoscopy. Inflammatory mass in sigmoid colon, combination of IBD and Diverticulosis. Very symptomatic.
38	78	<15	Probably not GI. ? Fatty liver disease. For liver biopsy.
40	362	110	Crohn's Disease, Feels well. No colonoscopy.
43	385	143	Could not locate the chart
44	<20	62	Crohn's Disease, Possible flare up. No colonoscopy.
46	893	59	Colonoscopy-Mild to Moderate active Ileal inflammation
48	388	98	Crohn's Disease, No significant pain. No Colonoscopy,
50	554	113	Severe Crohn's Disease affecting Colon + Perianal area. Resistant to standard Medical Therapy.
52	345	37	Diverticulosis + Hyperplastic Poly. Left sided Abdominal pain. Diarrhoea 5-6 times per day. No extra-articular features of IBD. ? Superimposed IBS.
53	288	43	Ulcerative Colitis. On 6-Mercaptopurine + Infliximab Infusions. No Colonoscopy
55	365	56	Crohn's disease of terminal Ileum diagnosed in 2011. Some central abdominal pain and occasional diarrhoea with bright red blood. No current colonoscopy.

Comparison of the BÜHLMANN fCAL turbo and IB*Doc* results gave a coefficient of determination of 0.817 and no statistical difference in results with a p=0.226; however, p=0.003 was found with the IB*Doc* versus the Phadia (Table 3).

Table 3. Method comparison of BÜHLMANN fCAL turbo versus IB*Doc* versus Phadia EliA

Sample Number	fCAL turbo µg/g	IB*Doc* µg/g	Phadia µg/g
1	618	545	341
2	<20	<30	<15
3	1342	947	245
4	1592	728	337
5	166	413	72
6	<20	<30	<15
7	436	570	133
8	337	160	116
9	28	<30	No result
10	119	117	15
11	<16	<30	15
12	571	520	120
13	429	380	42
14	<16	<30	15
15	<16	<30	No result

Conclusion

The fCAL turbo is very adaptable and suited for rapid analysis on the Abbott Architect C8000 Clinical Chemistry Analyser with no interference to any of the other chemistries. The CALEX cap extraction devices are easy to use and practical.

This study also demonstrated good correlation with the BÜHLMANN fCAL turbo and IB*Doc* home test. This study demonstrated that the BÜHLMANN fCAL turbo assay result gives a high correlation to the disease state and as such is a valuable tool for the clinical team.

References:

1. Bressler et al 2015. 'Canadian Journal of Gastroenterology and Hepatology (7)369-372
2. BUHLMANN Laboratories. Available at www.buhlmannlabs.ch
3. Abbott Laboratories. Available at www.abbott.com