Evaluation and implementation of the BÜHLMANN fCAL® turbo assay and CALEX® extraction tubes on the Abbott Alinity C

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Introduction

The BÜHLMANN fCAL® turbo is an automated diagnostic test which can be utilised on a variety of chemistry platforms for quantitative determination of calprotectin in human stool[1]. The measurement of calprotectin can assist in distinguishing Inflammatory Bowel Disease (IBD), specifically Crohn's disease or ulcerative colitis, from Irritable Bowel Syndrome (IBS) in patients with overlapping gastrointestinal symptoms. Calprotectin can also aid disease monitoring of patients with IBD[2]. The CALEX® sample extraction tubes allow for at home patient sampling and direct loading onto suitable analysers[1].

Aim

To evaluate and verify the BÜHLMANN fCAL® turbo particle enhanced turbidimetric immunoassay (PETIA) and CALEX® sample extraction tubes on the Abbott Alinity C analyser compared to the current Alegria® Calprotectin ELISA based method for the measurement of Calprotectin in human stool.

Materials & Method

Intra-assay imprecision was performed using 20 replicates of 2 levels of internal quality control (IQC) material. Inter-assay impression was performed over 5 days using 5 replicates of 2 levels of IQC each day. Stool samples from 51 patients were extracted, analysed on the Alinity C (using CALEX® extraction devices) and the Alegria® (using the current extraction procedure) simultaneously and compared by regression analysis. Ten samples from the NEQAS Faecal Markers were analysed using the Alinity C and compared to the all laboratory trimmed mean (ALTM).
A COGNOS search was performed on APEX to gather turnaround data for January to March 2023 (Alegria®) and January to March 2024 (BÜHLMANN fCAL® on Alinity C). The number of samples, median and average TAT were established as well as the time taken to generate 95% of results from receipt in lab to result availability.

Results

Intra and Inter-assay imprecision meet the manufacturer acceptance criteria of CV < 15% [Table 1]. Patient comparison between the Alegria and BÜHLMANN fCAL® turbo on Alinity C showed R^2= 0.826 [Figure 2], acceptable criteria R^2 >0.95. EQA correlation between the BÜHLMANN fCAL® turbo on Alinity C and ALTM was R^2= 0.9621 [Figure 2], acceptable criteria R^2 >0.95. There was a slight increase in workload between Jan-Mar 2023 where 1417 samples were received, compared to 1456 between Jan-Mar 2024. The time from sample receipt until 95% of test results were available reduced after the switch to the BÜHLMANN fCAL® on Alinity C from 8 days 19 hours to 4 days and 22 hours in the period between Jan-March [Table 2]. Non-compliant rate also more than halved.

	Intra-assay Imprecision			Inter-assay Imprecision		
	Mean	SD	CV	Mean	SD	CV
	µg/g	µg/g	(%)	µg/g	µg/g	(%)
Serum QC L	85.7	3.4	1.5	92.3	5.1	5.5
Serum QC H	287	4.2	1.5	289	3.7	1.3

Table 1: Intra and Inter-assay imprecision of the BÜHLMANN fCAL® turbo assay.

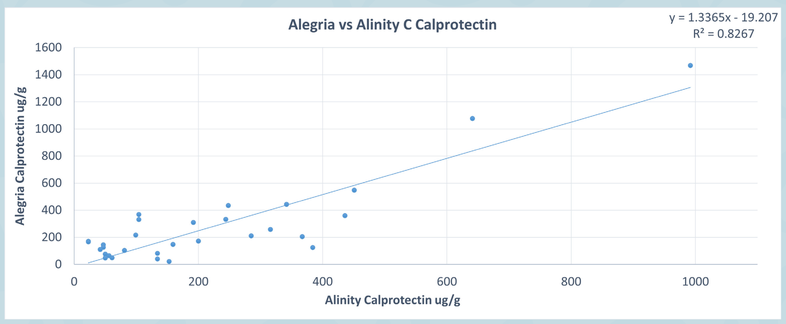

Figure 1: Patient comparisons: Alegria FCal vs fCAL® turbo on Alinity C.

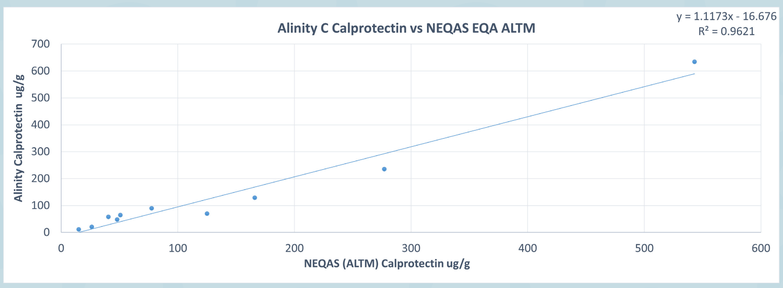

Figure 2: EQA Correlation: fCAL® turbo on Alinity C Result v NEQAS Faecal Marker ALTM.

	Number of samples	Median TAT	Average TAT	Time from sample receipt until 95% of test results available	Non-compliant Rate
Jan-Mar '23	1417	2 days 5 hours	3 days 20 hours	8 days 19 hours	1.3%
Jan-Mar '24	1456	1 day 19 hours	2 days 5 hours	4 days 22 hours	0.6%

Table 2: Turnaround times between January-March 2023 using Alegria® and January-March 2024 using Buhlmann fCAl on the Alinity C.

Conclusions

The BÜHLMANN fCAL® turbo method demonstrates acceptable performance on the Alinity C using intra and inter-assay imprecision. Correlation of the two methods using patient samples did not meet the acceptance criteria. Discrepancy would be expected when comparing BÜHLMANN fCAL® method to the Alegria® due to different methodologies. In addition the sample type has great variability as calprotectin in not evenly distributed throughout the stool sample and it is not possible to 'pick' the exact same location for comparison[3]. Results obtained from EQA regression analysis showed satisfactory assay performance.
Due to the higher number of Alinity C users in the EQA scheme the decision was taken to move to the BÜHLMANN fCAL® method to improve performance monitoring.
As well as improved assay performance monitoring, the introduction of CALEX® extraction devices has improved workflow due to its ease of use and ability to be directly loaded onto the Alinity C, significantly reducing staff time performing extractions. The ability to use the assay on routine chemistry analysers has increased the availability of backup platforms. The department has already noticed a reduction in turnaround times and these will improve further as the roll out of CALEX patient packs continues to all requesting areas.

References:
1. BÜHLMANN. BÜHLMANN fCAL®: IFU Calprotectin turbidimetric assay for professional use; 2023. 2. Burri, Beglinger, Faecal calprotectin – a useful tool in the management of inflammatory bowel disease. Swiss Med Wkly; 142. 2012
3. Alpha Laboratories (2023): Calprotectin Information for patients. Available from: https://www.calprotectin.co.uk/about-calprotectin/information-for-patients/#1625652930187-dd8e44ab-4c25. Accessed April 15th 2024