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Clinical performance of four fecal calprotectin assays from smartphone-based home test to high throughput central lab methods

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INTRODUCTION

Endoscopy is the gold standard for detecting mucosal inflammation to differentiate between Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD) as well as for monitoring mucosal inflammation in diagnosed IBD patients. Fecal calprotectin has been established as an excellent surrogate biomarker of intestinal inflammation as it correlates well with endoscopic and histological disease activity. Most IBD diagnosis and treatment guidelines recommend using fecal calprotectin as an aid in diagnosis and to measure it routinely to follow the disease course in IBD patients. As there is no international standard to date, fecal calprotectin assay manufacturers rely on their own internal calprotectin standardization. Assays can be based on various technologies from traditional enzyme-linked immunosorbent assays (ELISA), particle enhanced turbidimetric high throughput assays (PETIA), to rapid lateral flow immunoassays (LFA). LFAs can be read by conventional tabletop lateral flow readers or by everyday smartphone applications using the phone's camera to acquire an image, detect the test cassette and calculate a quantitative result. It is essential that the biomarker is measured comparably across all assay methods. In this work, all available assay methods from BÜHLMANN Laboratories were compared with clinical samples using a clinically relevant assay range.

METHODS

128 raw stool samples from patients with signs and symptoms suggesting intestinal inflammation and who underwent endoscopic evaluation to determine if patients had IBD or IBS were used in this study[1]. Samples were extracted using the BÜHLMANN CALEX® Cap stool extraction device. Each extract was measured on the BÜHLMANN fCAL® ELISA (fCAL ELISA), BÜHLMANN fCAL® turbo (fCAL turbo), Quantum Blue® fCAL extended lateral flow assay (QB fCAL) and smartphone based IB*Doc*® Calprotectin home test (IBDoc). For the home test two phones, iPhone 11 and Samsung Galaxy S7 (Samsung S7), were used to measure the test cassettes. Each sample was measured one time on each assay and a Receiver Operating Characteristic (ROC) curve analysis was performed.

RESULTS

ROC curves (Figure 1) for each method were calculated in respect of differentiating between IBS and IBD with area under the curve (AUC) values ranging from 0.827 (Samsung S7) to 0.835 (fCAL turbo). There was no significant difference between the methods. Based on numerous studies BÜHLMANN recommends a cut-off of 80 µg/g and 160 µg/g for IBS/IBD differentiation and 100 µg/g and 300 µg/g for IBD monitoring. For all methods, the sensitivity at the cut-off level at 80 µg/g was 90.8 % and specificity at 160 µg/g ranged from 67.3% to 71.2 %. Sensitivity at a cut-off of 100 µg/g ranged from 85.5% to 88.2% and specificity at 300 µg/g ranged from 82.7% to 86.5% (Table 1).

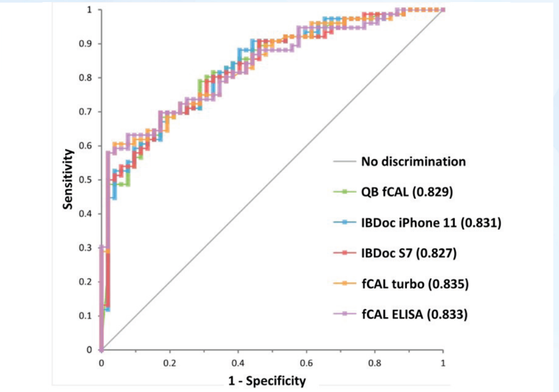

Figure 1: Receiver Operating Characteristic (ROC) curve analysis for different fecal calprotectin methods.

	IBDoc (iPhone 11)	IBDoc (Samsung S7)	QB fCAL	fCAL turbo	fCAL ELISA
Sensitivity at 80 µg/g	90.8%	90.8%	90.8%	90.8%	90.8%
Specificity at 160 µg/g	71.2%	82.7%	71.2%	71.2%	67.3%
Sensitivity at 100 µg/g	86.8%	88.2%	88.2%	85.5%	88.2%
Specificity at 300 µg/g	84.6%	82.7%	84.6%	86.5%	84.6%

Table 1: Sensitivity and specificity for IBS/IBD differentiation (80/160 µg/g) and IBD monitoring cut-off (100/300 µg/g) of different fecal calprotectin methods.

CONCLUSION

This study shows that all BÜHLMANN fecal calprotectin assays are highly comparable and have an excellent clinical performance irrespective of the method used. This allows for safe interchangeable use of the different methods depending on the needs of the patients and their care team.

[1]Berinstein, J.A. et al., 2019, The Clinical Accuracy of the BÜHLMANN fCAL ELISA in the Differentiation of Inflammatory Bowel Disease From Irritable Bowel Syndrome: A Multicenter Prospective Case-Control Study, Crohn's & Colitis 360

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