Clinical validation of a point of care test for fecal calprotectin in distinguishing irritable bowel syndrome from inflammatory bowel disease; P250

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Background

Calprotectin is a small calcium-binding protein that when measured in human stool has shown utility in assessing the degree of bowel inflammation in inflammatory bowel disease (IBD) and in distinguishing IBD from irritable bowel syndrome (IBS). However, most fecal calprotectin (FCP) assays are slow and inconvenient. This study examined the analytical agreement and clinical utility of a point of care (POC) assay for FCP (Figure 1).

Methods

Clinical Study Design - Retrospective observational study using stored frozen fecal specimens from a nested cohort derived from a prospective study of chronic diarrhea patients

Inclusion Criteria - Patients with unexplained diarrhea of at least 4 weeks duration. Study subjects were consecutively enrolled males and females of ages 2 – 70.

Endpoint - Proportion of patients with either IBS or IBD testing positive for FCP.

Specimen Sampling - Specimens were sampled using the Procise Stool Collection Device™ (Figure 2). The plastic probe was inserted into the stool specimen three times in different locations to collect the specimen. The probe was then inserted in the collection medium vial which automatically eluted the specimen into the collection fluid.

FCP POCT Measurement - 200 µL of eluted fecal collection fluid were pipetted into the reaction cartridge and the premeasured contents of a buffer bulb were dispensed and mixed. The cartridge was then inserted in the analyzer for automatic incubation and reading (<5 minutes). The assay was assessed at cut-offs of 50 µg/g and 120 µg/g.

Statistics - The significance of the proportion of patients diagnosed with either IBS or IBD testing positive for FCP was calculated using Fisher's Exact Probability Test. Method comparison analysis was performed by Deming linear regression.

Figure 1: POCT analyzer device and cartridge

Results

A total of 258 patients (IBS=203, IBD=55) were included in the post hoc clinical study. The assay performance was assessed at cut-offs of 50 µg/g and 120 µg/g.

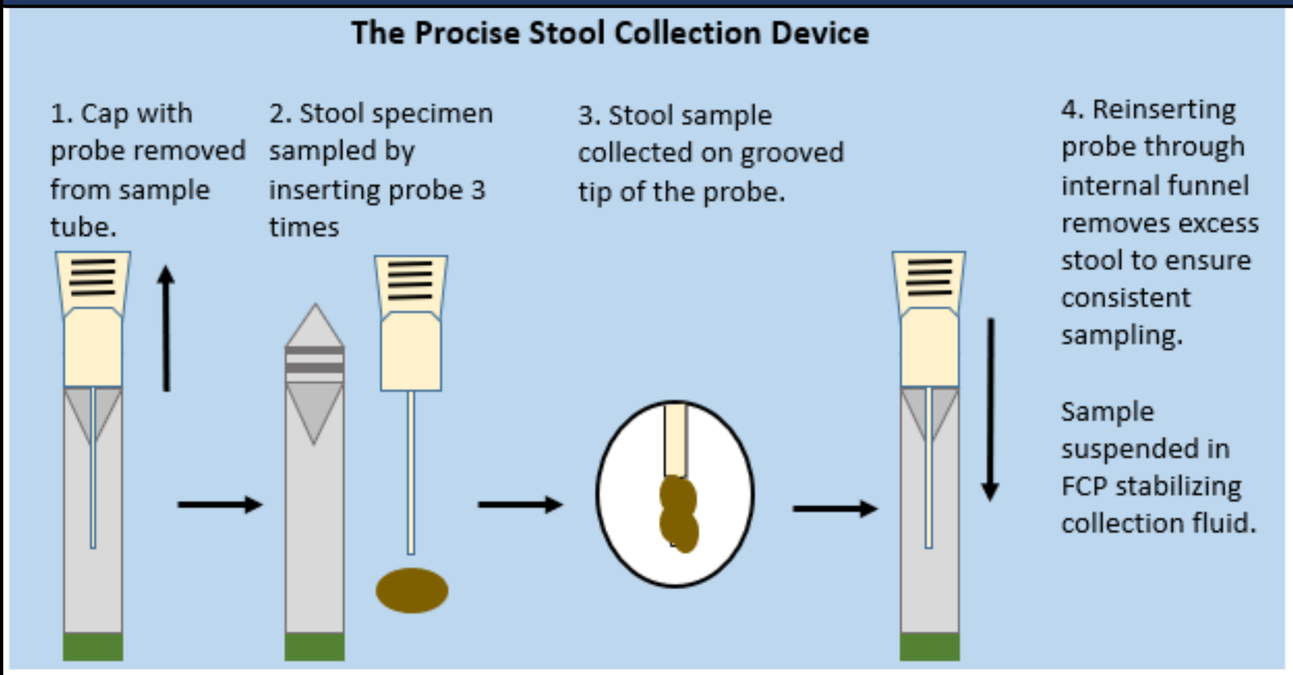

Figure 2. Configuration and Operation of the Procise Stool Collection Device™

Table 1. Shows Fisher's Exact Test in distinguishing IBD from IBS for FCP cut-off 50 µg/g

Group	FCP Positive (% Positive)	FCP Negative (% Negative)	Total
IBS	68 (33.5%)	135 (66.5%)	203
IBD	35 (63.6%%)	20 (36.4%)	55
Total	103	155	258

The Fisher's exact test statistic value is P = 0.0001

Table 2. Shows Fisher's Exact Test in distinguishing IBD from IBS for FCP cut-off 120 µg/g

Group	FCP Positive (%Positive)	FCP Negative (%Negative)	Total
IBS	27 (13.3%)	176 (86.7%)	203
IBD	27 (49.0%)	28 (50.9%)	55
Total	54	204	258

The Fisher's exact test statistic value is p < 0.0001

Figure 3. FCP Method Comparison

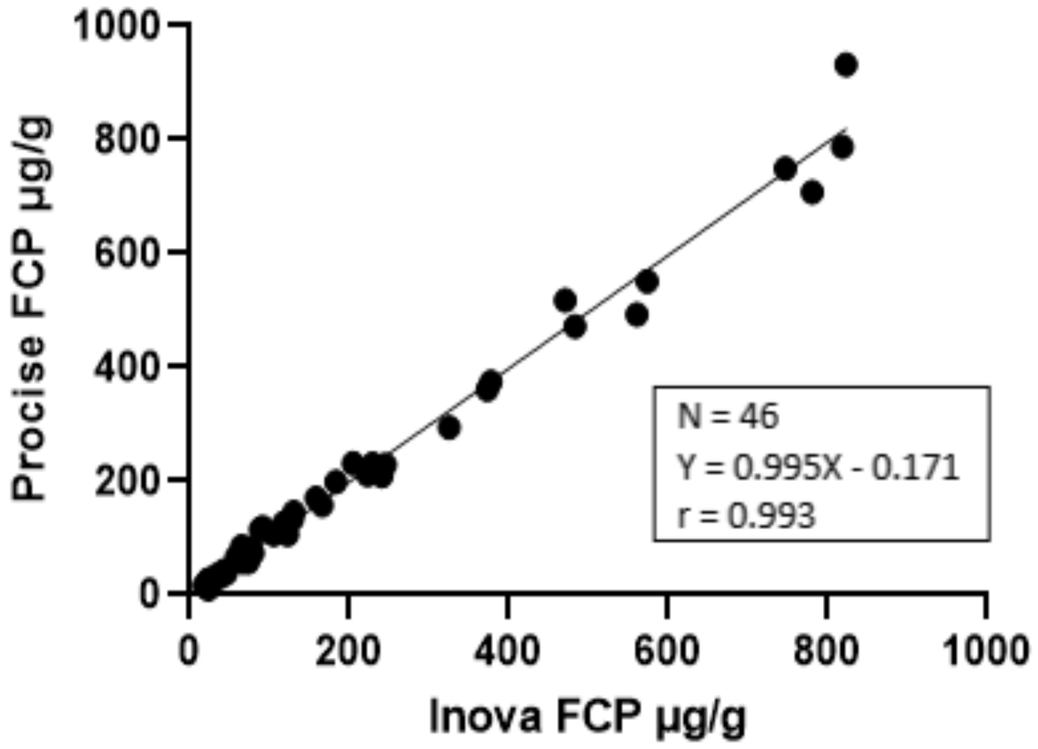

Figure 3. shows Deming linear regression and Pearson correlation between Procise FCP and Inova Quanta Lite Calprotectin assays testing fecal specimens

Conclusions

The Procise FCP assay shows excellent analytical agreement to another commercial FCP assay and can clinically significantly distinguish between IBD and IBS in chronic diarrhea patients. Thus, the assay can aid in the differentiation of IBD from IBS. Distinguishing IBS from IBD with a convenient POC format test enhances the clinical utility of FCP by enabling faster treatment response.

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Conflicts of interest: this study was funded by ProciseDx. Authors are employees of ProciseDx Inc.