

# IBDoc® Self-care/Point of care Calprotectin Test: Early Value in a District General Hospital Inflammatory Bowel Disease Service

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## Background

Faecal Calprotectin samples at Dorset County Hospital Trust are currently a send away test. These can take 3-6 weeks to come back and while the value of the result is high even with these lead times; a faster result is desirable as a treatment decision often has to be made without the benefit of the calprotectin result.

A more timely result would benefit both the Trust and patients, who may be having distressing symptoms, by initiating treatment quickly, avoiding admission and the spiralling costs seen in IBD patients who are admitted to hospital[1].

This study compared the calprotectin results obtained using the BÜHLMANN IBDoc® with the send away test performed using an ELISA assay from CALPRO™

The plan is to use the kit in two ways to maximise the benefits:

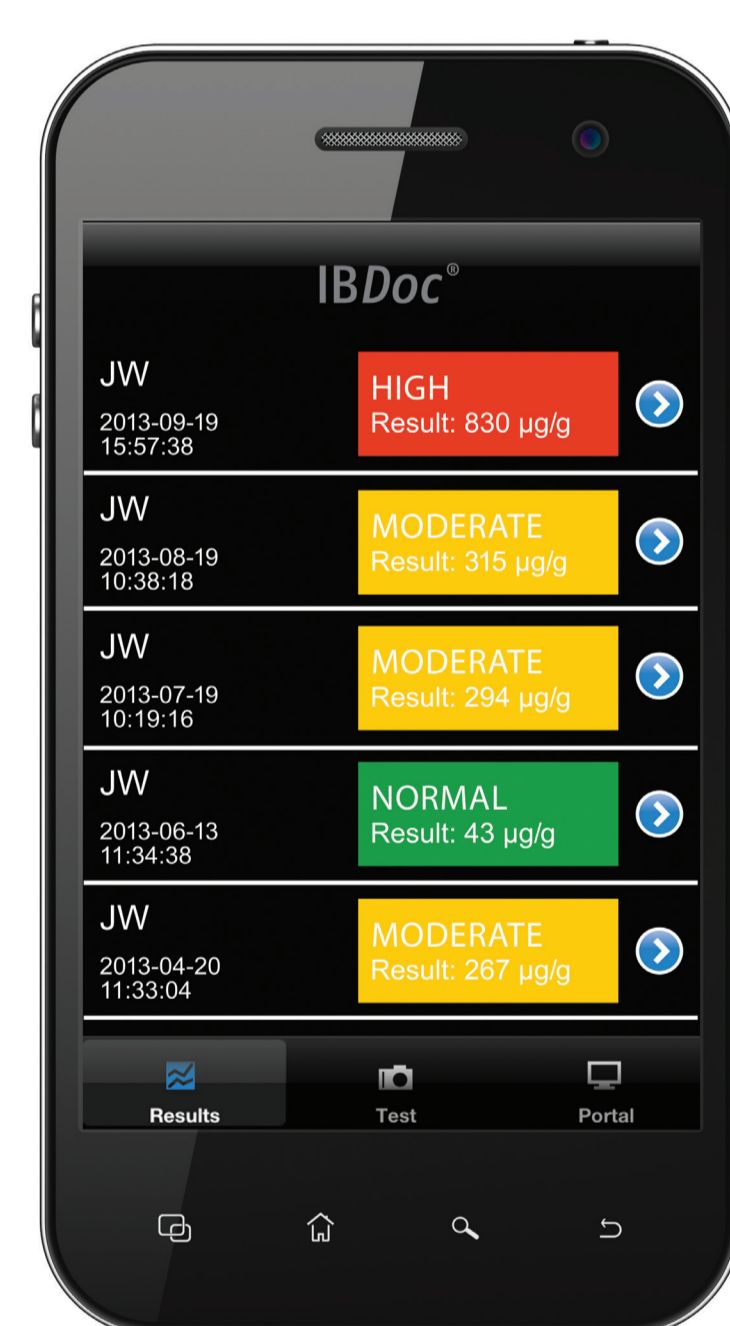
- As a point-of-care test with the sample being collected by the patient and the test carried out by the IBD nurses in clinic
- As a self-test by patients at home

## Methods

One of the IBD nurses underwent face to face training on how to perform the IBDoc test which was backed up with online support materials. The IBD Nurse found the training to be effective and was able to perform the test in clinic which took approximately 20 minutes. The same stool sample was sent away to the current calprotectin provider who uses the CALPRO ELISA assay® and the results compared.

Fifteen IBD patients (5 with Ulcerative colitis and 10 with Crohn's Disease) were selected to take part in the study. The selection of these patients occurred randomly from patients who presented via the Advice line or that were seen in clinic appointments. Seven patients had the IBDoc performed by the IBD nurse on an iPod Touch 5th Generation in clinic and eight patients were trained by the nurse to do the IBDoc test themselves at home using a variety of approved phones.

The IBDoc kit contains everything necessary for a patient to complete a single calprotectin test. Access is required to an approved smart phone by the patient, and they need to download the CalApp® free from iTunes or Google Play store and allow access for the App to the camera. The IBDoc gives a rapid quantitative result between 30 - 1000µg/g in an individually customisable traffic light system which is available immediately for both the patient and the clinic to view.



## Discussion

The IBDoc results are higher than those from the send away service; this could be due to a number of reasons:

- The freshness of samples will have a big influence on the result. When using the IBDoc any calprotectin in the sample is immediately stabilised in the extraction buffer. However samples tested by the ELISA send away service are transported from the patient to the hospital where they are stored at 2-8C before transporting to the testing laboratory and stored for batch testing. Even when stored at 2-8C there will be degradation of the calprotectin in the sample.
- The assays used in the study are from two different manufacturers and variation of results between manufacturers is well documented. Comparing the two has helped us to understand the new results and will allow us to interpret future results effectively.
- Individuality of calprotectin results was noted by one study [2] not just between individuals but between samples taken at different times of day from the same person.

A small survey of the patients who did the test at home was also conducted, and the seven patients that responded found the test easy to use and thought it had improved their access to treatment.

## Results

Fifteen tests were completed for both the IBDoc and the CALPRO ELISA and the results are shown in Figure 1 correlated against the patient reported symptoms:

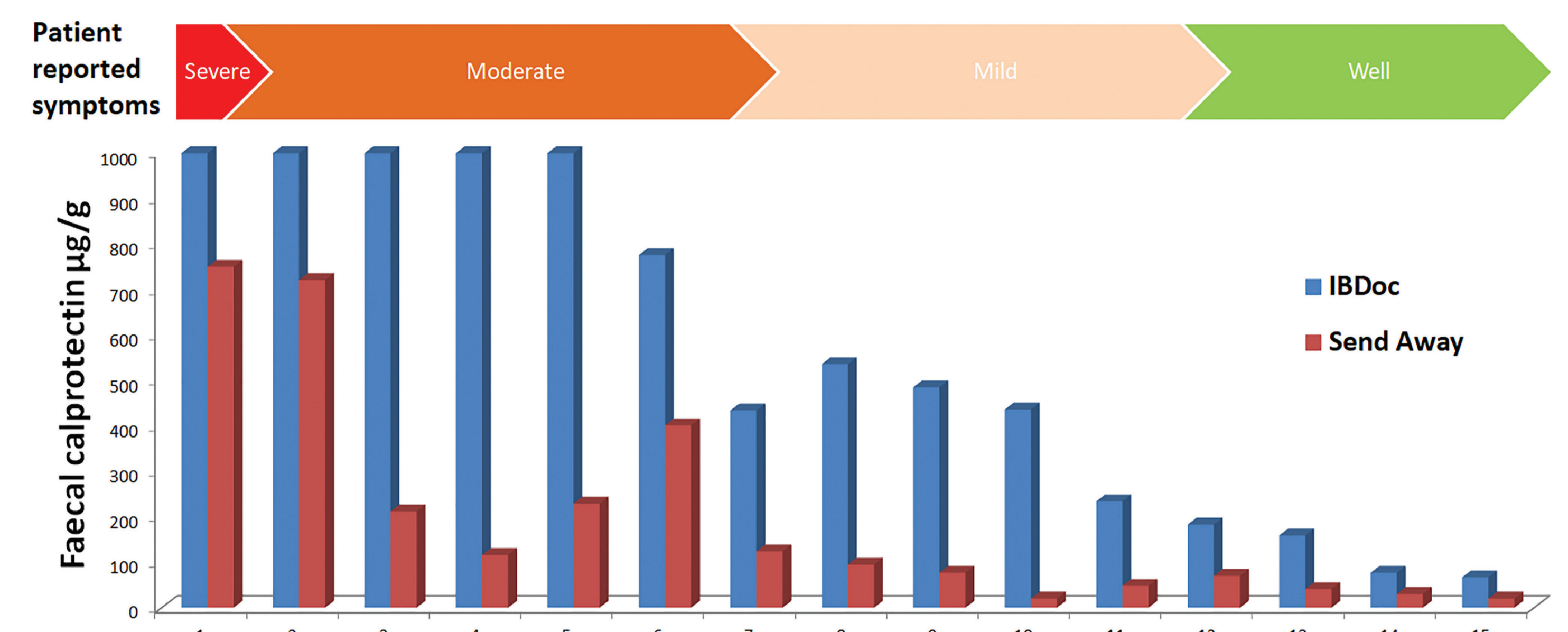


Figure 1: IBDoc and send away ELISA result with patient reported symptoms.

It can be seen that the IBDoc results are always higher than the send away ELISA result.

IBDoc Result µg/g	Send away Result µg/g	Disease Type	Patient reported symptoms	Outcome
>1000	750	UC	Severe	Escalated to Infliximab
>1000	721	CD	Moderate	Started Azathioprine
>1000	212	CD	Moderate	Started Adalimumab
>1000	116	CD	Moderate	Escalated to Adalimumab
434	124	CD	Mild	Symptoms resolved
>1000	229	CD	Moderate	Escalated to Adalimumab
485	77	CD	Moderate	Escalated to Adalimumab

Figure 2: Summary of results with IBDoc tests completed by the IBD nurse in clinic

IBDoc Result µg/g	Send away Result µg/g	Disease Type	Patient reported symptoms	Outcome
77	30	UC	Well	No change
436	20	UC	Mild	Restarted Azathioprine/Allopurinol
159	41	CD	Well	Watch and wait
67	20	CD	Well	No change
234	48	UC	Mild	Started Mesalazine
536	95	UC	Mild	Started Mesalazine
183	70	CD	Mild	No change
776	401	CD	Moderate	Escalated Adalimumab dose

Figure 3: Summary of results with IBDoc tests completed by patients at home

The results in Figure 2 show that even during this small evaluation at least one hospital admission was avoided, as a fast-track of treatment to Infliximab occurred. Following on from this evaluation, approval from the local Medical Devices Board was gained and IBDoc has been introduced for routine calprotectin testing. It is being rolled out to the entire cohort of 1300 patients, both as a self-test if the patient is appropriate or as a Point-of-care test.

## Conclusions

The BÜHLMANN IBDoc® adds value to patient care; it enhances the patient's journey allowing quick treatment decisions to be made saving at least one hospital admission during this small trial of the product. Patients reported that they felt their care was enhanced because of it. Using this test with remote monitoring software may save the need for face to face follow up.

## References:

1. Ghosh, N. and Premchand, P., (2015), A UK cost of care model for inflammatory bowel disease. *BMJ Publishing, Frontline Gastroenterology*, 169-174, 6(3), <http://fg.bmj.com/content/6/3/169.abstract>, 2017-11-27
2. Lasso, A., Stotzer, P.O., Öhman, L., Isaksson, S., Sapnara, M. and Strid, H. (2014), The intraindividual variability of faecal calprotectin: a prospective study in patients with active ulcerative colitis. *Journal of Crohn's and Colitis*, 26-32, 9(1)