

# ASSESSMENT OF A REMOTE CALPROTECTIN MONITORING TOOL IN IBD:

## A Comparative Agreement Analysis of a Classical Lab-Based Assay and a Mobile Phone-Based Quantitative Patient Self-Test

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### INTRODUCTION

Several treatment guidelines and published clinical consensus studies recommend using fecal Calprotectin as a monitoring tool for IBD. Available analysis methods range from well-established laboratory analysis methods to more recently developed rapid methods for remote monitoring and point of care.

Since there is no international reference for calprotectin, an established agreement between different assay platforms is needed to use them interchangeably. Ideally the assays from the same manufacturers should measure fecal calprotectin equally, although this is not always the case.

This study compares fecal calprotectin measurements obtained from two different assay platforms, both from the same manufacturer.

### AIMS & METHODS

131 fecal samples from IBD patients were measured using CalproLab® ELISA ALP (CALPO170) and CalproSmart® self-test for remote monitoring of IBD.

All fecal samples were extracted and analysed in parallel according to the kit-specific instructions given by the manufacturer, requiring individual sample collection and extraction methods for both assays.

64 samples covered the linear range for the assays and were included in the method comparison analysis.

### RESULTS

When comparing the two analysis methods, the slope and intercept values of 0,92 and 4,44 mg/kg respectively suggest that there is no significant difference between the two methods within their common linear range. This includes all relevant clinical cut-off values for the two methods. Furthermore, the relative difference between the two assays ranges from -1,9% to -6,8% at selected calprotectin values.

Table 1.  
The relative difference between CalproSmart® and CalproLab® ELISA at selected calprotectin values.

Calprotectin values [mg/kg]	Relative difference
77	-1,9%
100	-3,2%
200	-5,5%
250	-5,9%
500	-6,8%

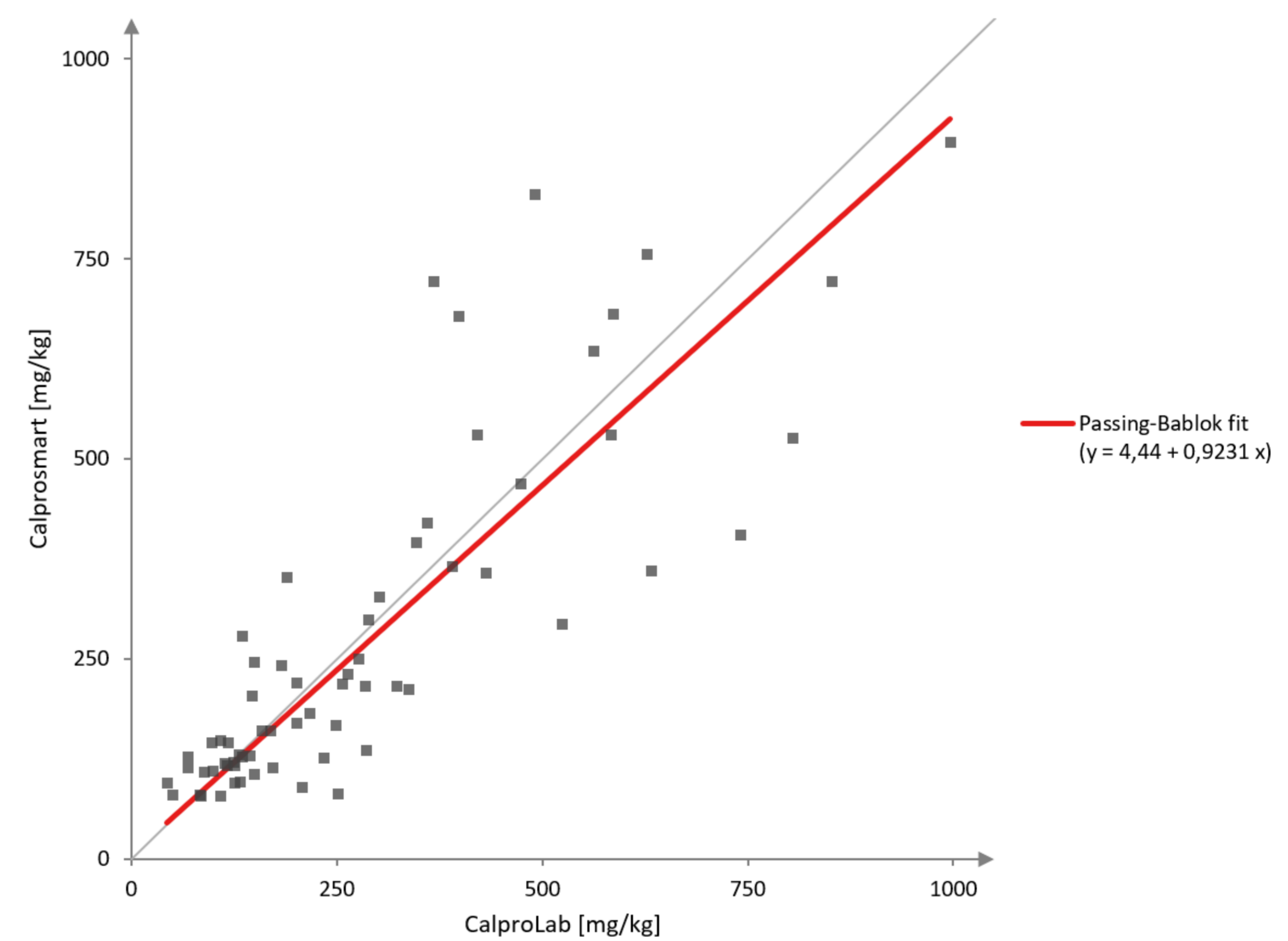


Figure 1.  
The figure shows a method comparison plot between CalproLab® and CalproSmart®. The intercept of 4,44 mg/kg and the slope of 0,92 suggest that there is no significant difference between the two methods.

### CONCLUSIONS

The CalproSmart® and CalproLab® ELISA platforms measure fecal calprotectin levels equally, indicating that they can be used interchangeably without affecting the reliability of the results.

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All authors are employees at Calpro AS. Experiments performed at Calpro R&D lab.

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