HOME vs HOSPITAL-BASED ANALYSIS OF STOOL CALPROTECTIN
COMPARISON OF TWO DIAGNOSTIC METHODS FOR MONITORING INFLAMMATORY BOWEL DISEASE
A. Heida, M. Knol, A.C. Muller Kobold, G. Dijkstra, P.F. van Rheezen
IBD Center, University Medical Center Groningen, The Netherlands

BACKGROUND AND AIM
Fecal calprotectin measurements are increasingly used to monitor patients with inflammatory bowel diseases. Recently a home-used lateral flow-based rapid test for the analysis of stool calprotectin was launched. It comes together with an application (IBDoc®, BÜHLMANN Laboratories AG, Switzerland) that turns an ordinary smartphone camera into a reader for quantitative measurements. We compared the new IBDoc® method with the established enzyme-linked immuno sorbent assay (ELISA) to assess the agreement between the two.

METHODS
Eligible teenagers and adults, who had a smartphone validated for the IBDoc® app, received an instruction manual to perform the calprotectin stool test at home (Figure 1). The residual of the stool specimen was sent to the hospital for ELISA measurement (BÜHLMANN Laboratories AG). We assessed agreement by Bland-Altman plot and evaluated concordance between our clinically relevant calprotectin ranges (<250, 250-500, >500 μg/g). Predefined acceptable limits of agreement were ±100 μg/g in the lower range of calprotectin and ±200 μg/g in the higher range.

CONCLUSION
We found sufficient agreement between IBDoc® home test and hospital-based ELISA in the lower ranges of calprotectin to use this new test for disease monitoring. We suggest that ELISA confirmation of positive IBDoc® findings is done before therapy adjustment is considered. We expect that misclassification will reduce when patients receive face-to-face training of an expert before the first IBDoc® measurement.

RESULTS

Figure 2: Bland-Altman plot showing difference against mean

We analyzed 152 paired samples. We found 81% agreement (100 of 124 samples) in the lower range of calprotectin and 64% (18 of 28 samples) in the higher range (Figure 2).

The concordance between methods is presented in Figure 3. 108 of 152 test pairs (71%) were concordant. Two of six discordant test pairs, depicted in the right lower corner of the graph, were caused by one participant who did not observe the advised incubation time.

Figure 3: Scatterplot showing concordance between IBDoc® against ELISA results

Disclosure
This project was supported by BÜHLMANN Laboratories AG, producer of both the IBDoc® method and the ELISA assay used in this study. BÜHLMANN did not have a role in the design, execution, analyses, and interpretation of the data, or in the decision to submit the results.

a.heida01@umcg.nl