P0334 Performance Testing of a Smartphone-based Patient Monitoring System measuring Calprotectin: Laboratory vs Lay Users

J. Weber1, P. Spies2, M.-E. Ueberschlag1, C. Reinhard1, S. Kräuchi1, Th. Jermahn1
1BÜHLMANN Laboratories AG, Schoenbuch, Switzerland
2University of Applied Life Sciences, Muttenz, Switzerland

BACKGROUND & OBJECTIVE

Inflammatory Bowel Disease (IBD) is a chronic inflammation of the gut comprising active inflammation, remission and flares. The disease course can be followed by biomarkers such as calprotectin which is measured in patients’ stool samples. Most studies have shown that a threshold around 250 µg/g correlates well with mucosal healing. Hence, one of the therapy goals is to achieve calprotectin values below 250 µg/g and to keep them below this level. We have developed a system, called IBDoc®, which allows the patient to regularly perform calprotectin tests at home and to check whether the low calprotectin level is under control (Fig. 1A). The objective of this study was to validate the IBDoc® home testing system by lay users vs. professional laboratory personnel and to compare its quantitative performance with routine laboratory-based methods.

METHODS

Quantitative result and its presentation by a traffic-light system

The IBDoc® test system (Fig. 1A) produces a quantitative test result between 30 and 1000 µg of calprotectin/g of stool which covers the clinically relevant range of this biomarker. The result is also presented by a traffic-light system (Fig. 1B), set by the treating physician, in which the green light represents a NORMAL result (<100 µg/g), the yellow light a MODERATE and grey zone result (100-300 µg/g), and the red light a HIGH result (>300 µg/g) by default.

RESULTS

Validation of the key components of the IBDoc test

The CALEX® Valve stool collection and extraction (Fig. 1A, steps B & C), the running and measuring of the TC with a smartphone (Fig. 1A, steps D & E) as compared to the Quantum Blue® reader (by professionals) and the combination of CALEX® Valve extraction and TC measurement with smartphone (Fig. 1A, steps B to F) were performed by 31 lay users and by 2 laboratory professionals. The entire IBDoc® test (Fig. 1A, steps B to F) done by lay users was also compared with a conventional stool weighing method and extraction with a vortexing machine combined with a routine, standard ICAL® ELISA (BÜHLMANN, Switzerland) in a second, independent professional laboratory. All statistical analyses are presented in Table 1.

IBDoc® performed by lay users vs laboratory professionals

Twenty-six stool samples in total were analyzed by 31 lay users and 2 laboratory professionals both using the IBDoc® home test. The quantitative results of the lay users were correlated to the results of the professionals showing a slope of 0.99 by Passing-Bablok fit (Fig. 2A), and a bias of -1.5% and R² of 0.945 by Bland-Altman difference plot (Fig. 2B). The total within-bias agreement (TA) of performing the IBDoc® between lay users and laboratory professionals was 96.8% (Fig. 3; blue shaded fields) with 0% false positive (red instead of green traffic-light) and 0% false negative rates (green instead of red traffic-light).

CONCLUSIONS

• IBDoc® is the first complete and validated (CE-IVD) test system which allows the IBDoc patient to monitor and follow his inflammatory status by measuring the IBDoc biomarker, fecal calprotectin, using his/her own smartphone. It is the first self testing device of its kind.

• There is no difference in the qualitative test results generated by lay users as compared to the results of laboratory professionals.

• The performance of the smartphone-based IBDoc® home testing system is comparable to professional, laboratory-based methods.