THE WAY TO TOTAL AUTOMATION OF CALPROTECTIN MEASUREMENT IN FAECES WITH BÜHLMANN fCAL® TURBO

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BACKGROUND

Calprotectin, an important marker to detect and monitor inflammatory processes in the gastrointestinal tract, has been well established during the last few years. As a consequence the amount of Calprotectin determinations in the laboratory has increased rapidly. Calprotectin has to be extracted from faeal specimens. Due to the nature and inherent inhomogeneity of this specimen the work load in the laboratory increased over time and reduction of hands-on-time is needed by simplification and automation. In our laboratory we evaluated the user-friendly CALEX® Cap Extraction device to speed up and streamline the cumbersome and labour-intensive extraction procedure. As a second step we established and validated the new turbidometric test ICAL turbo on our Roche Cobas® c501 analyzer. The ICAL turbo allows random-access sample handling with a time to result of 12 min and with a measuring range of 20 – 8,000 µg/g. The time saving on hands-on-time was 70% and the total turn-around-time decreased to 20 minutes. The combination of the CALEX® Cap extraction device together with the new turbidimetric assay ICAL turbo (PETIA; particle enhanced turbidimetric immuno assay) is a paradigm-shift to total automation of Calprotectin quantification in faeces. Moreover the CALEX® Cap, with its unique stability of 3 days at room temperature, would allow extraction by the patient at home increasing efficacy even more.

CONCLUSIONS

The preparation of stool specimens for Calprotectin determination with CALEX® and the analysis with the new ICAL turbo on the Cobas® c501 module (Roche Diagnostics) is practically a fully automated testing procedure. As the consequence this setup can be handled as a routine- and random-access procedure. The hands-on-time reduces to a few minutes only and the time to result is close to 12 minutes. Calprotectin shows with 3 days at room temperature a fair stability in the buffer solution of the extraction device CALEX®. Therefore, faeces collection and transfer into the CALEX® might be easily done at home.

RESULTS

Method Comparison Extraction – CALEX® Cap device

Measuring of the two extracted solutions with the Roche faecal sample preparation kit cup and CALEX® on the Euroimmun Analyzer 1 system. The correlation was y = 0.80 x + 0.00; r = 0.88396. However, the discrimination at the cut-off of 50 µg/g showed no difference between the two methods (Fig 1).

Method Comparison ICAL ELISA vs. ICAL turbo

The faeces specimens got extracted with the CALEX® device. The Calprotectin in the buffer solution was measured on both systems Euroimmun Analyzer 1 with the ICAL ELISA reagent and on the Cobas® c501 module with the ICAL turbo (PETIA) reagent. The correlation was y = x – 0.004; r = 0.9708. For the ICAL turbo reagent measured on the c501 we calculated for the 50 µg/g specimen a 1s of 2.78 µg/g and a coefficient of variation of 5.4% and for the 200 µg/g specimen a 1s of 14.03 µg/g and a coefficient of variation of 6.3% (Fig 2).

References:
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