

Evaluation of Usability and Performance of Home Fecal Sampling Using a Dedicated Device

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BACKGROUND

Calprotectin is an important biomarker for the diagnosis and follow-up of inflammatory bowel disease (IBD).

The first steps of the analysis involve collecting and extracting the samples. Sample extraction, which is routinely performed in a lab, is tedious and time-consuming work and could benefit from an altered workflow. This can be achieved by allowing patients to perform the sample collection at home with the required amount of sample directly into the extraction buffer. However, this requires clear instructions for the user and that the home fecal collection device shows conformity to the original weighing method. In addition, the collected sample needs to maintain stability during transportation.

Here, we explore the feasibility of letting patients perform the sampling themselves using the Easy Extract® kit accompanied by a quick-guide.

MATERIAL & METHODS

A usability study was conducted according to FDA guidelines on usability engineering. Twenty-four participants without prior knowledge of the product or procedure received an Easy Extract® kit, a simulated human fecal sample, and a quick-guide to perform the home sampling.

Matched participant-observer questionnaires were assessed to determine their usability. Separate performance studies of Easy Extract® included consistent sample uptake, agreement with the weighing method, and stability testing (at room temperature, after transportation, and after freeze-thaw cycles).

All samples were analyzed with CalproLab ELISA (CALP0170) to determine fecal calprotectin (fCal) concentration. Appropriate statistical methods were used to quantify and visualize the results.

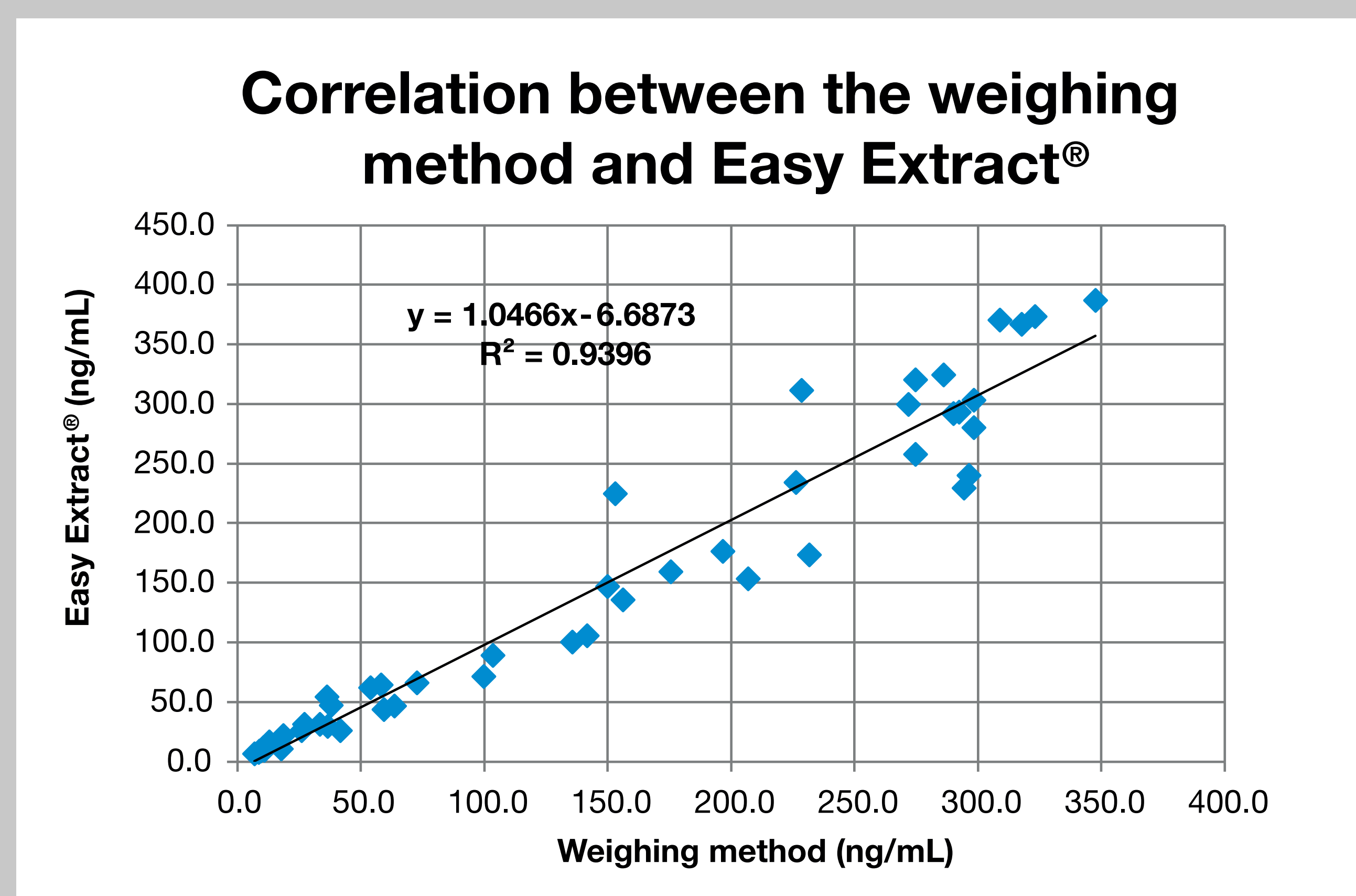


Figure 1. Correlation between Easy Extract® and the original weighing method. Samples across a wide measuring range have been extracted using both methods and analyzed using CalproLab ELISA (CALP0170). The results demonstrate an excellent correlation between the two methods (R^2 -value=0,9396).

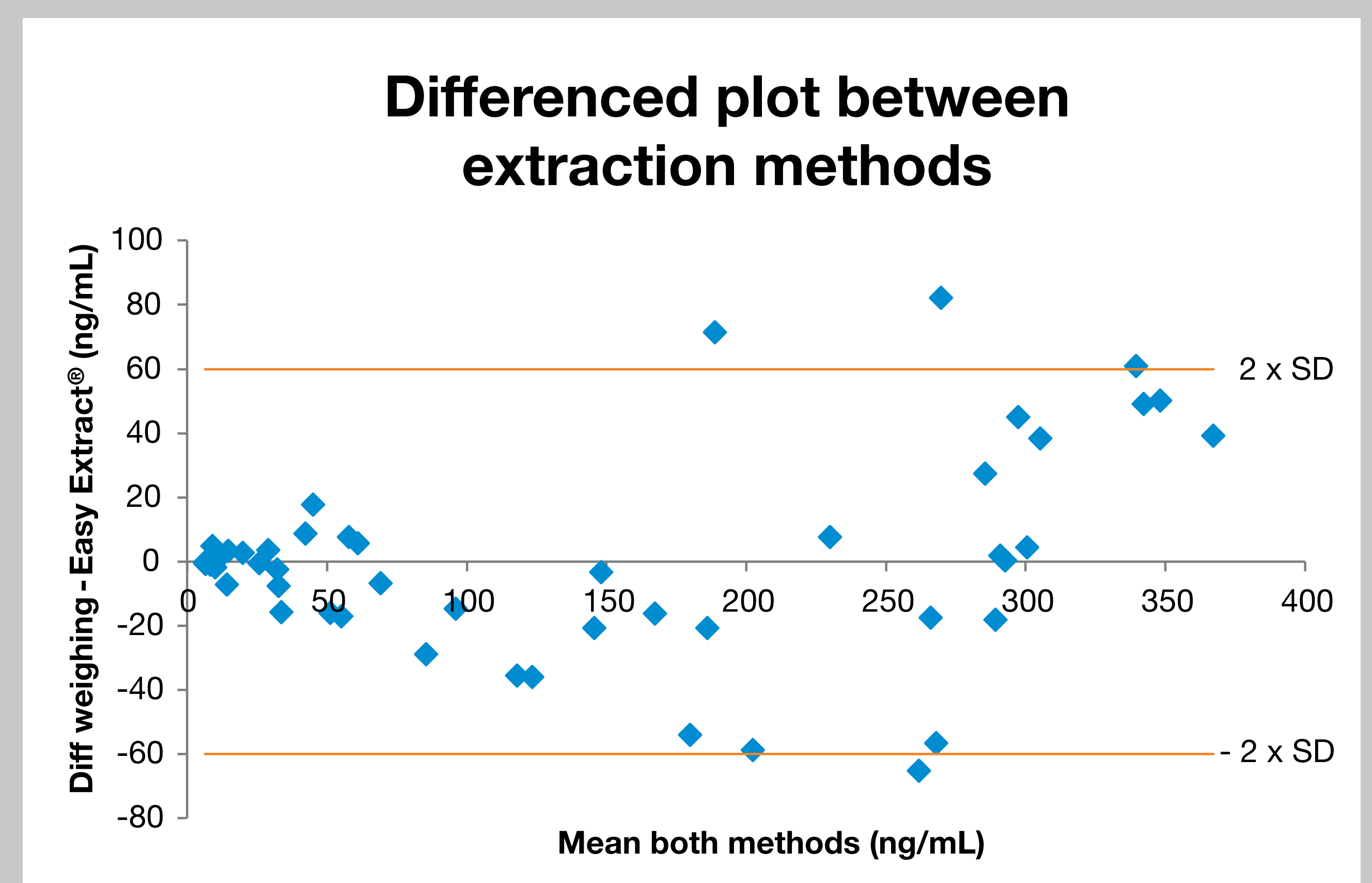


Figure 2. Bland-Altman plot with the difference between the extraction methods plotted against the mean values of both methods. Mean difference=0,27 ng/mL, 46 out of 50 values are within ± 2 standard deviations. These results demonstrate excellent agreement between the two methods.

RESULTS

All participants in the usability study completed sampling successfully. Easy Extract® and the quick guide got an average rating of 4.8 on a scale of 1-5 (where 1 is difficult and 5 is easy).

In-house performance studies show that the average sample weight collected 29.2 mg with a CV of 2.7%. It also showed that the extracts remained stable during transport at RT for 5 days with no changes after repeated freeze-thaw cycles. Easy Extract® shows excellent agreement with the established weighing method as seen in figures 1 and 2.

* The authors have no potential conflict of interest to disclose.

CONCLUSIONS

Easy Extract® and the quick guide enabled participants to sample accurately without prior experience with the device. Additionally, Easy Extract® allows for consistent weight and agrees with the original weighing method. Furthermore, fCal stability is maintained at RT for 5 days and repeated freeze-thawing cycles.

Taken together, these results demonstrate that Easy Extract® is a useful tool for patient home sampling of fCal.