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Validation of faecal calprotectin determination with the DSX System.

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Objective

Calprotectin is a marker for intestinal inflammation that allows for a non-invasive screening for inflammatory bowel disease (Crohn's disease and ulcerative colitis) that differentiates it from functional disorders [1, 2].

The measurement procedure by ELISA (Bühlmann fCAL, Palex) with the DSX System analyser (Dynex technologies) is evaluated. This method uses a monoclonal detection antibody and has a greater range of linearity: the upper limit of detection increases to 1800 µg/g, compared to 500 µg/g using the previous method (ELISA Calprest, Eurospital, Alere).

Methods

The precision was studied by checking the results of a patient sample with a pathological result for intra-assay precision, and by checking the controls against the assigned values for inter-assay precision. The quality requirements (coefficient of variation expressed in percentage) were set by the supplier (CV% ≤4 for intra-assay precision; CV% ≤15 for inter-assay precision)[3].

The results were compared with the above method via repetitions of 44 samples and a study of the differences using a Bland & Altman plot (MedCalc® program).

Table 1. Initial study of precision in the new analysers.

Calprotectin	Specimen	Average value (µg/g)	Experimental CV%	Quality requirements of insert (CV %)
Intra-assay precision	Low Sample	68.7	2.81	<4
	Pathological Sample	325.0	2.56	<4
Inter-assay precision	Low Control	105.2	1.26	<15
	High Control	388.9	1.11	<15

Table 2. Tracking of precision (CV%) during 2016.

January		February		March*		April		May		June*		July	
Low Control	High Control	Low Control	High Control	Low Control	High Control	Low Control	High Control	Low Control	High Control	Low Control	High Control	Low Control	High Control
0.86	0.60	1.62	0.78	7.90	5.13	1.73	0.73	2.72	1.20	8.31	3.81	0.91	1.15

* Two different batches explains the increase of CV%. It meets the quality requirement.

Results

The analysers met the established quality requirements for precision in the initial study (Table 1) and during the follow-up period (Table 2).

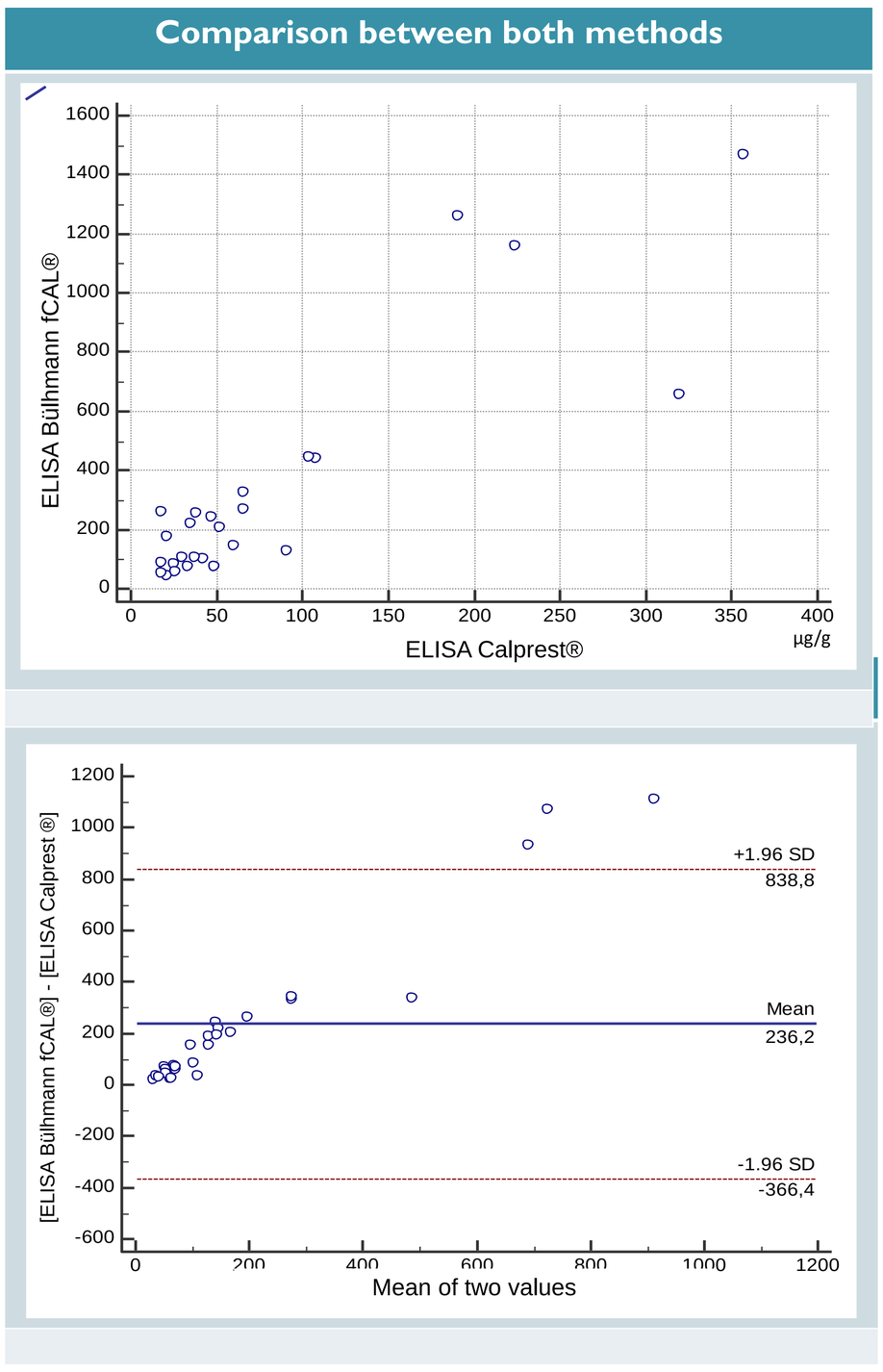
The new method provides higher values compared to the previous method, mainly for values greater than 200 µg/g (Table 3 and Figure 1). One reason can be the range of linearity of the old method (15,6 to 500 µg/g), in which values between 200 and 500 µg/g were located near the saturation zone. The new method has a linearity range between 30 and 1800 µg/g and uses a secondary monoclonal antibody. Samples do not have to be diluted because the upper limit of linearity is sufficient to track patient progress or status, and higher values have no clinical relevance.

Table 3. Results classified by ranges using each method.

(µg/g)		ELISA Bühlmann DSX System			Total
		<50*	50-200**	>200***	
ELISA Calprest	<50	11	14	4	29
	50-200	0	2	7	9
	>200	0	0	6	6
	Total	11	16	17	44

* Indicate no inflammation of the intestinal tract.
** May suggest mild organic disorder or inflammatory bowel disease in remission phase.
*** Indicates organic disorder active inflammation of the intestinal tract. We recommend monitoring specialist and conducting additional tests (the cutoff point f or children under 4 years is between 100 and 2 50 µg/g, whereas positive values from >250 µg/g).

Figure 1. Regression line and Bland & Altman plot (study of the differences).



Conclusions

The new method, having a greater range of linearity, allows for better classification of results: a larger number of results are classified in the categories of 50-200µg/g and >200µg/g. In these, additional studies are recommended to confirm an inflammatory bowel disease, thereby decreasing the number of undiagnosed cases, which is advisable for a screening technique.

Referencias

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