

VALIDATION OF FECAL CALPROTECTIN ON THE DRG:HYBRID-XL ANALYSER

Christian Lauf¹, Javier Arroyo-Gómez¹, Matthias Herkert¹ and Cyril Geacintov²

¹ DRG Instruments GmbH Frauenbergstr. 18 D-35039, Marburg, Germany

² DRG International, Inc. 841 Mountain Avenue, Springfield, NJ 07081, USA

Introduction

Calprotectin is a calcium-binding protein secreted predominantly by neutrophils and monocytes. Fecal calprotectin is a marker for acute inflammation in general and for neoplastic and inflammatory gastrointestinal diseases. It has been shown that fecal calprotectin tests allow clear differentiation between patients with inflammatory bowel disease (acute Morbus Crohn's disease and ulcerative colitis) and irritable bowel syndrome. Elevated levels of calprotectin are a much better predictor of relapse of inflammatory bowel disease than standard inflammatory markers. This can save costs for extensive and unnecessary colonoscopic examinations. Comparing this marker with standard fecal occult blood screening in colorectal cancer clearly demonstrates the diagnostic advantages of the fecal calprotectin test.

OBJECTIVE:
VALIDATION OF FECAL CALPROTECTIN ON THE DRG:HYBRID-XL ANALYSER



Assay Characteristics

Specificity:	Human Calprotectin
Sample Type:	Stool
Sensitivity:	LoB: 2.86 µg/g; LoD: 8.14 µg/g LoQ: 17.22 µg/g
Sample Volume:	5 µl
Dynamic Range:	8.14 – 1500 µg/g
Total assay time:	1 hour
Cross-Reactivity:	No cross reactivity with Lysozyme, PMN Elastase, Myeloperoxidase, Lactoferrin

Spike Recovery	1	2	3	4
Concentration (µg/g)	196.5	426.5	622.5	986.5
Average Recovery (%)	106.3	111.2	120.6	96.3
Range of Recovery (%)	from 96.3	100.3	94.0	81.3
	to 118.4	137.0	141.3	108.6

Linearity	1	2	3	4
Sample	1	2	3	4
Concentration (µg/g)	514.5	578.5	870	1200.0
Average Recovery (%)	141.8	110.9	99.9	123.6
Range of Recovery (%)	from 106.7	79.2	90.3	86.5
	to 106.7	79.2	90.3	86.5

Reference Range	Healthy Donors	Bowel Disease
Population	41	61
n	41	61
Range (µg/g)	12.4 - 48.3	51.0 - > 1500
Mean (µg/g)	27.0	524

Intra-Assay Precision

Sample	n	Mean (µg/g)
1	80	30.21
2	80	77.99
3	80	562.84
4	80	942.46

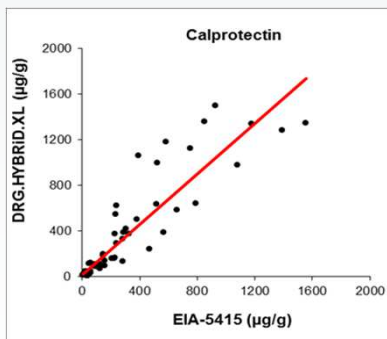
Intra-Assay Precision

Sample	n	Mean (µg/g)
1	40	30.21
2	40	77.99
3	40	562.84
4	40	942.46

Interpretation of Results

- The median value in healthy adults is about 25 µg/g.
- Samples with a calprotectin concentration < 50 µg/g are regarded as negative.
- Samples with a calprotectin concentration from 50 µg/g - 200 µg/g are regarded as borderline positive. We recommend repeating the measurement at a later time point in order to confirm the result.
- Samples with a calprotectin concentration > 200 µg/g are regarded as positive.

Method Comparison



Conclusions

- The DRG:HYBRID-XL is the first fully automated system for the quantification of Calprotectin in stool samples.
- The calprotectin Elisa allows clear differentiation between healthy patients and patients with bowel disease like Crohn's disease and ulcerative colitis.
- The fecal calprotectin test shows diagnostic advantages over standard fecal occult blood screening in colorectal cancer and is a much better predictor of relapse.
- Benefits of the new assay are ready-to-use reagents, fully automated sample preparation and assay procedure, and a short total assay time of 1 hour

Literature

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