

RIDASCREEN® Calprotectin

Marker of inflammation in inflammatory bowel disease

- Differentiation of inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS)
- Monitoring of response to treatment in IBD-therapy
- Early diagnosis of relapse
- 1-point calibration and standard curve in one single kit
- Calibrator and controls ready to use
- Cut-off: 50 mg/kg

Information on Calprotectin

Calprotectin, a calcium-binding protein produced in cells such as neutrophils, is released during inflammation.

Fecal calprotectin serves as a biomarker of gastrointestinal inflammation and neoplasia. In the presence of an inflammatory bowel disease, neutrophils influx into the intestinal lumen and release calprotectin, which is excreted in the feces. Consequently, the fecal calprotectin concentration can be used as a measure of the number of neutrophils in the bowel lumen and as an indicator of the severity of intestinal inflammation. Clinically, the special relevance of fecal calprotectin measurement lies in its capacity for the reliable diagnosis of inflammatory bowel disease. In many cases, inflammatory bowel disease produces symptoms that are very difficult to

distinguish from those of irritable bowel syndrome. Fecal calprotectin measurement provides a reliable indication of the presence of inflammatory bowel disease. Through the use of this biomarker, many patients with irritable bowel syndrome can therefore be spared unnecessary colonoscopy. In a number of publications, fecal calprotectin concentrations have been shown to be strongly correlated with histological and endoscopic parameters of disease activity in patients with chronic inflammatory bowel disease. Therefore, measurement of fecal calprotectin provides a means of objectively assessing the response to treatment of inflammatory bowel disease and for monitoring these patients during clinical remission to enable the early detection and treatment of relapses of irritable bowel syndrome.

RIDASCREEN® Calprotectin as marker of inflammation in inflammatory bowel disease

- For reliable differentiation between inflammatory bowel disease and irritable bowel syndrome
- For early detection of flares of inflammatory bowel disease
- To objectively document the severity of inflammation
- For monitoring of response to treatment in IBD-therapy

Performance characteristics

Intra-assay variation coefficient

The intra-assay variation coefficient was determined in a single run using 4 references in 40 replicates each. From the OD-values of these measurements calprotectin concentrations have been determined.

The mean value (MV), standard deviation (SD) and coefficient of variation (CV) were calculated for each sample.

	1-Point Calibration			Standard Curve		
	MV (mg/kg)	SD (mg/kg)	CV (%)	MV (mg/kg)	SD (mg/kg)	CV (%)
Reference A	53.77	2.88	5.36	56.62	2.99	5.28
Reference B	96.58	5.49	5.69	102.35	6.33	6.19
Reference C	136.52	5.59	4.09	130.51	5.18	3.97
Reference D	246.65	14.06	5.70	267.58	14.96	5.59

Inter-assay variation coefficient

The inter-assay variation coefficient was determined in duplicate in 20 runs (2 runs a day) using four references by three technicians. From the OD-values of these measurements calprotectin

concentrations have been determined. The mean value (MV), standard deviation (SD) and coefficient of variation (CV) were calculated for each sample.

	1-Point Calibration			Standard Curve		
	MV (mg/kg)	SD (mg/kg)	CV (%)	MV (mg/kg)	SD (mg/kg)	CV (%)
Reference A	55.92	4.13	7.38	57.79	3.88	6.72
Reference B	106.41	7.28	6.84	112.31	8.19	7.29
Reference C	129.18	7.48	5.79	138.55	7.40	5.34
Reference D	259.24	27.50	10.61	285.81	21.55	7.54

Extraction precision

Extraction precision was determined in duplicate in 10 runs (5 days, 2 runs a day) at different days by two technicians with 3 stool samples (concentrations > 50 mg/kg). The samples have been extracted before each run and diluted

as recommended. From the OD-values of these measurements calprotectin concentrations have been determined. The mean value (MV), standard deviation (SD) and coefficient of variation (CV) were calculated for each sample.

	1-Point Calibration			Standard Curve		
	MV (mg/kg)	SD (mg/kg)	CV (%)	MV (mg/kg)	SD (mg/kg)	CV (%)
Sample A	63.98	5.05	7.89	67.41	5.06	7.50
Sample B	114.06	10.32	9.05	123.05	10.73	8.72
Sample C	263.71	33.14	12.57	284.91	22.26	7.81

Linearity

Four samples with increased calprotectin concentrations were extracted 1:50 according to the instructions of use. The extracts were first diluted 1:50 in Diluent 3 and then serially diluted in

Diluent 3. The dilutions were done in triplicates and according to the instruction of use. The deviation between the expected and observed concentrations were determined.

Sample	Dilution	1-Point Calibration			Standard Curve		
		Observed (mg/kg)	Expected (mg/kg)	O/E (%)	Observed (mg/kg)	Expected (mg/kg)	O/E (%)
1	1:20000	406.78			399.87		
	1:40000	186.29	186.29	100	193.54	193.54	100
	1:80000	96.28	93.15	103	97.80	96.77	101
	1:160000	49.79	46.57	107	51.71	48.39	107
	1:320000	21.19	23.29	91	28.30	24.19	117
	Mean			100		106	
2	Mean			102		103	
3	Mean			104		104	
4	Mean			104		105	
Mean				103		105	

References:

Tibble JA et al. A simple method for assessing intestinal inflammation in Crohn's disease. *Gut* 2000; 47: 506-513.

Tibble JA et al. Surrogate markers of intestinal inflammation are predictive of relapse in patients with inflammatory bowel disease. *Gastroenterology* 2000; 119: 15-22.

Johne B et al. Functional and clinical aspects of the myelomonocyte protein calprotectin. *J Clin Pathol Mol Pathol* 1997; 50: 113-123.

van Rhenen PF et al. Faecal calprotectin for screening of patients with suspected inflammatory bowel disease: a diagnostic meta-analysis. *BMJ* 2010; 341:c3369.

R-Biopharm Gastroenterology – diagnostics at a glance

Product	Description	Tests	Matrix	Art. No.
Enzyme immunoassays				
RIDASCREEN® Haemoglobin	Enzyme immunoassay for the detection of haemoglobin	96	Stool	G09030
RIDASCREEN® Haemo-/Haptoglobin Complex	Enzyme immunoassay for the detection of haemoglobin/haptoglobin complex	96	Stool	G09031
RIDASCREEN® α_1 -Antitrypsin	Enzyme immunoassay for the detection of α_1 -Antitrypsin	96	Stool	G09034
RIDASCREEN® sIgA	Enzyme immunoassay for the detection of secretoric IgA	96	Stool	G09035
RIDASCREEN® Calprotectin	Enzyme immunoassay for the detection of calprotectin	96	Stool	G09036
Pancreatic Elastase ELISA	Enzyme immunoassay for the detection of pancreatic elastase	96	Stool	G09038
Pancreatic Elastase ELISA (SK15)	Enzyme immunoassay for the detection of pancreatic elastase; additional standard (SK15)	96	Stool	G09040
Pankrin® ELISA	Enzyme immunoassay for the detection of pancreatic elastase and other pancreatic enzymes	96	Serum	G09039
Accessories for RIDASCREEN®				
New RIDA®TUBE Haemoglobin	For collection and preparation of stool samples <ul style="list-style-type: none"> only use with RIDASCREEN® Haemoglobin G09030 and RIDASCREEN® Haemo-/Haptoglobin Complex G09031 	50		GZ3012
New RIDA®TUBE Calprotectin	For collection and preparation of stool samples <ul style="list-style-type: none"> only use with RIDASCREEN® Calprotectin G09036 	50		GZ3016
RIDASCREEN® Stuhlröhrchen	For collection and preparation of stool samples <ul style="list-style-type: none"> unfilled; to use after internal validation 	48		GZ3003
Stool Preparation Set	For collection and preparation of stool samples <ul style="list-style-type: none"> only use with Pancreatic Elastase ELISA G09038 and G09040 	45		GZ3008

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