

OC-FCa Reagent

For
OC-SENSOR PLEDIA
OC-SENSOR Ceres

MEASUREMENT OF
FAECAL CALPROTECTIN



OC-FCa Control LV1
OC-FCa Control LV2
OC-FCa Control LV3



OC-FCa Calibrator



OC-FCa Reagent

OC-FCa Reagent FEATURES

- The same OC-Auto Sampling Bottle 3 and OC-SENSOR series can be used as for the Faecal Immunochemical Test (FIT).
- Wide measurement range up to 2,720 µg/g
- OC-Auto Sampling Bottle 3 can be stored at 1 - 30°C before specimen collection.

WHAT IS FAECAL CALPROTECTIN?

Calprotectin is an inflammatory protein abundantly present in neutrophils.¹ The amount of calprotectin in faeces increases accompanied with intestinal mucosal inflammation.²

USE OF CALPROTECTIN

Measuring the amount of calprotectin in faeces can be used for disease monitoring of inflammatory bowel disease (IBD; e.g. ulcerative colitis, Crohn's disease) patients and distinguishing IBD from functional intestinal disorders (e.g. Irritable bowel syndrome).³⁻⁵

PRINCIPLE

Latex agglutination immunoturbidimetry

MEASUREMENT RANGE

Up to 2,720 µg/g

■ OC-SENSOR PLEDIA

Limit of Detection (LOD): 9 µg/g

Limit of quantification (LOQ): 23 µg/g

■ OC-SENSOR Ceres

Limit of Detection (LOD): 5 µg/g

Limit of quantification (LOQ): 22 µg/g

ANALYSERS

OC-SENSOR PLEDIA (Left)
OC-SENSOR Ceres (Right)



OC-Auto Sampling Bottle 3



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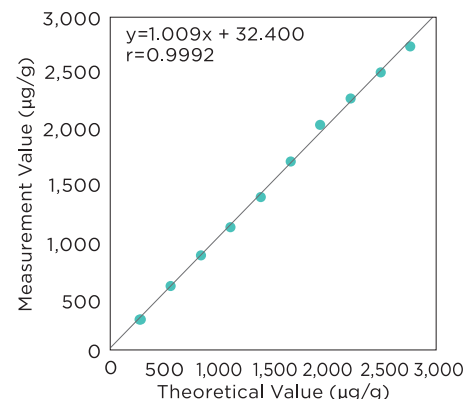
MEASUREMENT OF FAECAL CALPROTECTIN

ANALYTICAL PERFORMANCE

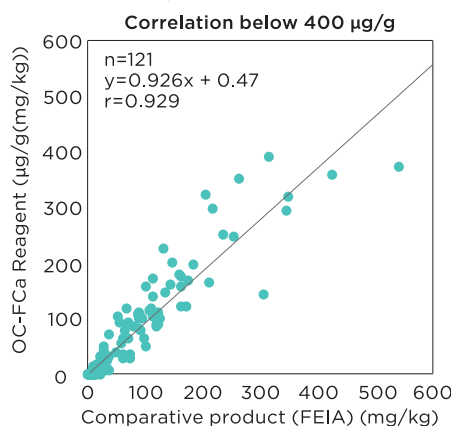
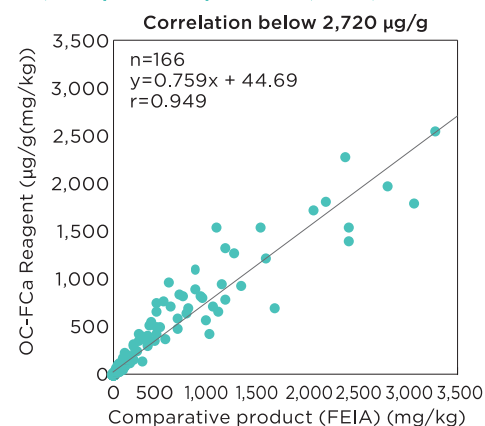
Repeatability and Precision

Samples	Mean (µg/g)	Repeatability		Between-Run		Between-Day		Precision	
		SD	CV	SD	CV	SD	CV	SD	CV
Control LV1	252.7	2.8	1.1%	2.2	0.9%	2.9	1.2%	4.6	1.8%
Control LV2	496.0	4.1	0.8%	2.3	0.5%	4.4	0.9%	6.5	1.3%
Faecal Sample 1	53.0	3.0	5.6%	1.5	2.8%	0.7	1.4%	3.4	6.4%
Faecal Sample 2	284.3	2.6	0.9%	1.3	0.4%	2.7	0.9%	3.9	1.4%

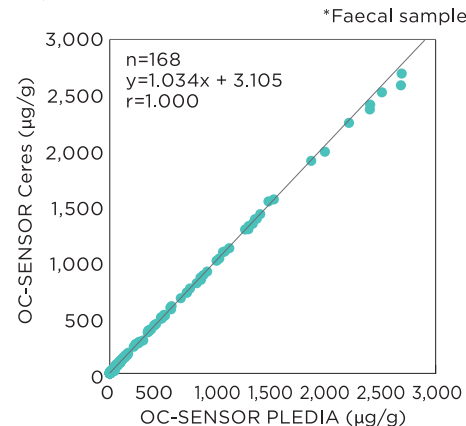
DILUTION LINEARITY *Calprotectin solution



COMPARISON BETWEEN OTHER PRODUCT (Comparative product (FEIA) vs OC-SENSOR PLEDIA) *Faecal sample



COMPARISON BETWEEN ANALYSERS (OC-SENSOR PLEDIA vs OC-SENSOR Ceres) *Faecal sample



Agreement at each cut-off value

Cut-off value	Positive agreement	Negative agreement	Overall agreement
50 µg/g ⁶ (Distinguishing IBD from functional intestinal disorders)	95.6% (108/113)	96.9% (62/64)	96.0% (170/177)
300 µg/g ⁶ (Monitoring UC disease activity)	96.7% (58/60)	96.6% (113/117)	96.6% (171/177)

PRODUCT SERIES AND STORAGE

Ready-to-Use: Reagents, Calibrator, Control and Sample Diluent

Product Name	Product Code	Contents	Storage	Compatible Analyser
OC-FCa Reagent	V-PH11	Latex 8mL x 2 Buffer 15mL x 2	2-10°C	OC-SENSOR PLEDIA
OC-SENSOR Sample Diluent	V-PH19	45mL x 3	2-8°C	
OC-FCa Reagent	V-PH09	Latex 8mL x 2 Buffer 15mL x 2	2-10°C	OC-SENSOR Ceres
OC-SENSOR Sample Diluent	V-PH08	20mL x 2	2-8°C	
OC-FCa Calibrator	V-PH12	1mL x 6	2-8°C	OC-SENSOR PLEDIA and OC-SENSOR Ceres
OC-FCa Control LV1	V-PH13	5mL x 2	2-8°C	
OC-FCa Control LV2	V-PH14	5mL x 2	2-8°C	
OC-FCa Control LV3	V-PH15	5mL x 2	2-8°C	
OC-Auto Sampling Bottle 3	V-PZ25	100 bottles	1-30°C	
OC-Auto Sampling Bottle 3 (without barcode)	V-PZ26	100 bottles	1-30°C	

*Please check the IFU (instructions for use) carefully before use of this product.

*Reference

- Dale I et al. Purification and partial characterization of a highly immunogenic human leukocyte protein, the LI antigen. *Eur J Biochem*. 1983;134(1):1-6.
- Roseth AG et al. Assessment of the neutrophil dominating protein calprotectin in feces. A methodologic study. *Scand J Gastroenterology*. 1992;27(9):793-798.
- Tibble et al. A simple method for assessing intestinal inflammation in Crohn's disease. *Gut*. 2000;47(4):506-513.
- Tibble JA, et al. Use of surrogate markers of inflammation and Rome criteria to distinguish organic from nonorganic intestinal disease. *Gastroenterology*. 2002;123(2):450-460.
- Schoepfer AM, et al. Discriminating IBD from IBS: comparison of the test performance of fecal markers, blood leukocytes, CRP, and IBD antibodies. *Inflamm Bowel Dis*. 2008;14(1):32-39.
- K. Matsuoka et al. Clinical utility of fecal calprotectin in Japanese patients *Japanese Journal of Medicine and Pharmaceutical Science*. 2017;74(6):717-726.

https://www.eiken.co.jp/en/ourfields/gastroenterology/fecal_calprotectin/



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