OC-FCa Reagent

For
OC-SENSOR R70
OC-SENSOR Ceres
OC-SENSOR PLEDIA

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 & 4 and OC-SENSOR series can be used for the Faecal Immunochemical Test (FIT).
- Wide measurement range up to 2,720 µg/g
- OC-Auto Sampling Bottle 3 & 4 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 with intestinal mucosal inflammation. [2]



OC-Auto Sampling Bottle 3 & 4

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.
The lower measurement limit varies depending on the analyser used. Please refer to the OC-FCa Reagent IFU for details.

ANALYSERS

OC-SENSOR R70 (Left)
OC-SENSOR Ceres (Right)
OC-SENSOR PLEDIA

EIKEN CHEMICAL CO., LTD.

MEASUREMENT OF FAECAL CALPROTECTIN

ANALYTICAL PERFORMANCE (IN-HOUSE DATA)

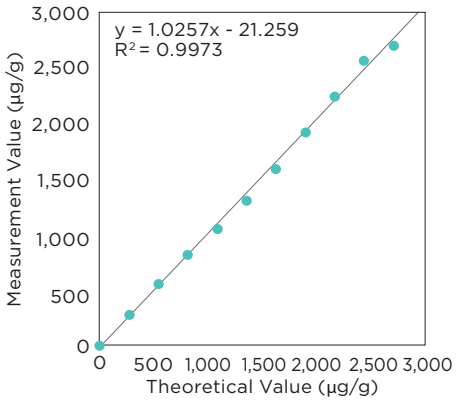
REPEATABILITY AND PRECISION (OC-SENSOR R70)

*Faecal samples collected with OC-Auto Sampling Bottle 4

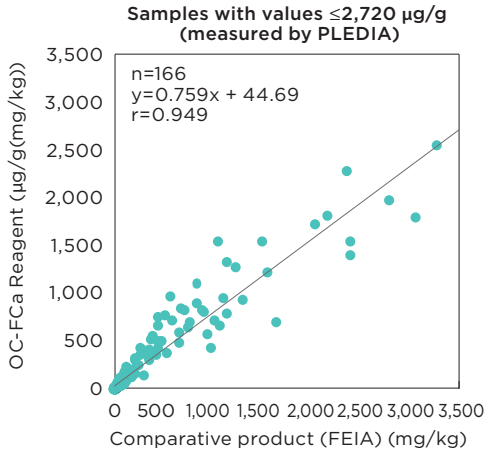
Samples	Mean (μg/g)	Repeatability		Between-Run		Between-Day		Precision	
		SD	CV	SD	CV	SD	CV	SD	CV
Control LV1	248.6	1.8	0.7%	3.0	1.2%	2.3	0.9%	3.3	1.4%
Control LV2	496.6	3.5	0.7%	5.8	1.2%	4.9	1.0%	6.8	1.4%
Faecal Sample 1	60.0	2.5	4.2%	1.7	2.8%	1.1	1.8%	2.7	4.4%
Faecal Sample 2	289.0	2.7	0.9%	2.0	0.7%	3.0	1.0%	3.7	1.3%

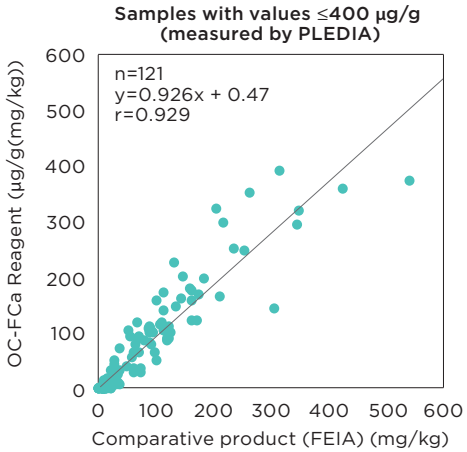
DILUTION LINEARITY (OC-SENSOR R70)

*Calprotectin solution



METHOD COMPARISON (Comparative product (FEIA) vs OC-SENSOR PLEDIA) *Faecal sample





AGREEMENT WITH COMPARATIVE PRODUCT (FEIA) 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)

*Cutoff values are provided for reference only, and each laboratory is recommended to establish its own cutoff values.

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-PH09	Latex 8 mL x 2 Buffer 15 mL x 2	2-10°C	OC-SENSOR R70 OC-SENSOR Ceres
OC-SENSOR Sample Diluent	V-PH08	20 mL x 2	2-8°C	
OC-FCa Reagent	V-PH11	Latex 8 mL x 2 Buffer 15 mL x 2	2-10°C	OC-SENSOR PLEDIA
OC-SENSOR Sample Diluent	V-PH19	45 mL x 3	2-8°C	
OC-FCa Calibrator	V-PH12	1 mL x 6	2-8°C	OC-SENSOR R70 OC-SENSOR Ceres OC-SENSOR PLEDIA
OC-FCa Control LV1	V-PH13	5 mL x 2	2-8°C	
OC-FCa Control LV2	V-PH14	5 mL x 2	2-8°C	
OC-FCa Control LV3	V-PH15	5 mL 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	
OC-Auto Sampling Bottle 4	VCPZ45	100 bottles	1–30°C	
OC-Auto Sampling Bottle 4 without barcode	VCPZ46	100 bottles	1–30°C	

*Please refer the IFU (instructions for use) carefully before use of this product.
*CE 0123 applies to OC-FCa Reagent, OC-FCa Calibrator, OC-FCa Controls and OC-SENSOR Sample Diluent only.
*Reference

1. Dale I et al. Purification and partial characterization of a highly immunogenic human leukocyte protein, the L1 antigen. *Eur J Biochem.* 1983;134(1):1-6.
2. Røseth AG et al. Assessment of the neutrophil dominating protein calprotectin in feces. A methodologic study. *Scand J Gastroenterology.* 1992;27(9):793-798.
3. Tibble J, et al. A simple method for assessing intestinal inflammation in Crohn's disease. *Gut.* 2000;47(4):506-513.
4. 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.
5. 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.
6. 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/

CE 0123 IVD

EIKEN CHEMICAL CO.,LTD.
4-6 Kanda Surugadai, Chiyoda-ku,
Tokyo, 101-0062 JAPAN

EU REP
Advena Ltd.
Tower Business Centre, 2nd Flr., Tower Street,
Swatar, BKR 4013 Malta

6185 DIB
October, 2026