# 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]

OC-Auto Sampling Bottle 3

## 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)

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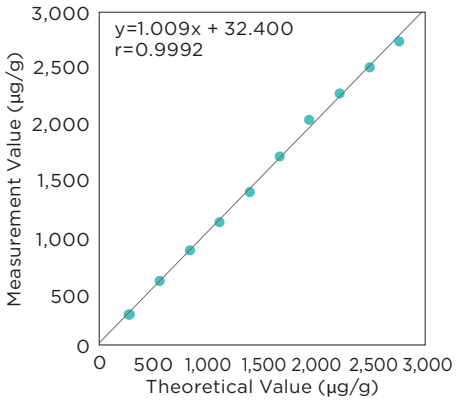
# MEASUREMENT OF FAECAL CALPROTECTIN

## ANALYTICAL PERFORMANCE

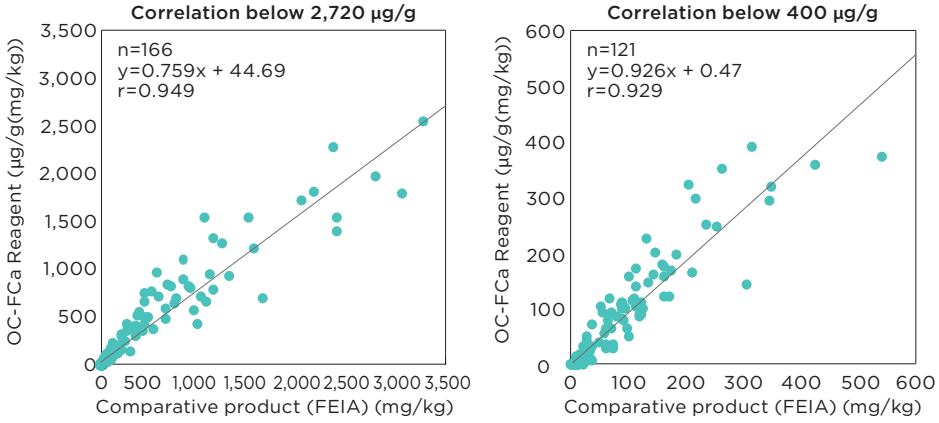
### Repeatability and Precision

| 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

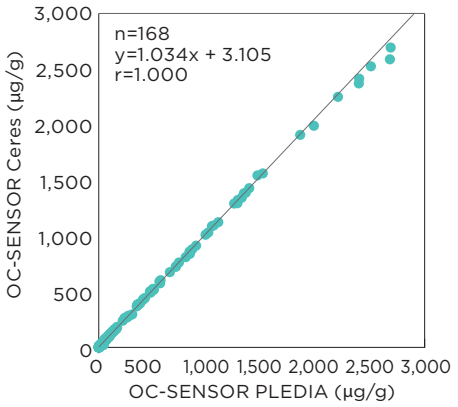



### COMPARISON BETWEEN OTHER PRODUCT (Comparative product (FEIA) vs OC-SENSOR PLEDIA) *Faecal sample




### 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<br>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<br>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


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 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/

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