Analytical Performance Report

OC-SENSOR PLEDIA

- OC-FCa Reagent

Calprotectin in faeces

**EIKEN CHEMICAL CO., LTD.**

2020.10

Calibration curve

	Theoretical FCa concentration (μg/g)	DA Value	Back Fit Value (μg/g)	
Std.1	0	6	0	
Std.2	85	92	89	105%
Std.3	340	487	347	102%
Std.4	850	1,672	869	102%
Std.5	1,700	3,251	1,708	100%
Std.6	2,720	4,243	2,834	104%
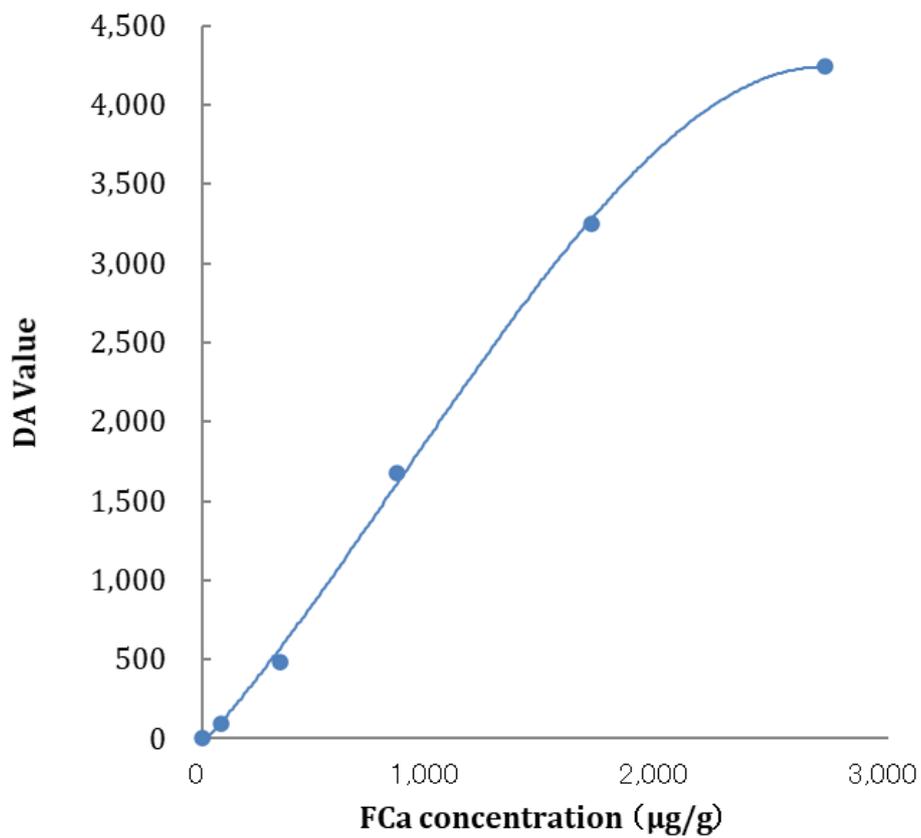
Intra-day reproducibility

（Measured Value: μg/g）

	Sample 1	Sample 2	Sample 3
1	182	524	1,345
2	174	529	1,369
3	167	516	1,362
4	170	523	1,342
5	166	531	1,359
6	169	532	1,405
7	171	533	1,374
8	171	528	1,393
9	172	533	1,399
10	172	538	1,404
11	162	525	1,385
12	162	533	1,371
13	166	531	1,357
14	161	521	1,367
15	167	538	1,391
16	165	538	1,374
17	169	543	1,386
18	169	544	1,387
19	168	537	1,391
20	169	543	1,380
Mean	169	532	1,377
S.D.	4.7	7.7	18.2
CV（%）	2.8%	1.4%	1.3%
Range	21	28	63
MAX.	182	544	1,405
MIN.	161	516	1,342

* Samples are calprotectin solution.

Inter-day reproducibility

(μg/g)

| Measurement day	1	2	3	4	5
Sample 1	174	177	176	178	179
Sample 2	515	517	516	521	519
Sample 3	1,369	1,389	1,383	1,384	1,381
Measurement day	6	7	8	9	10
Sample 1	178	180	178	179	177
Sample 2	516	518	519	521	521
Sample 3	1,379	1,380	1,384	1,378	1,392
Measurement day	11	12	13	14	15
Sample 1	179	179	181	180	180
Sample 2	516	521	519	519	519
Sample 3	1,379	1,395	1,389	1,386	1,391
Measurement day	16	17	18	19	20
Sample 1	180	181	180	181	179
Sample 2	517	520	518	521	521
Sample 3	1,391	1,392	1,393	1,392	1,395

* Samples are calprotectin solution.
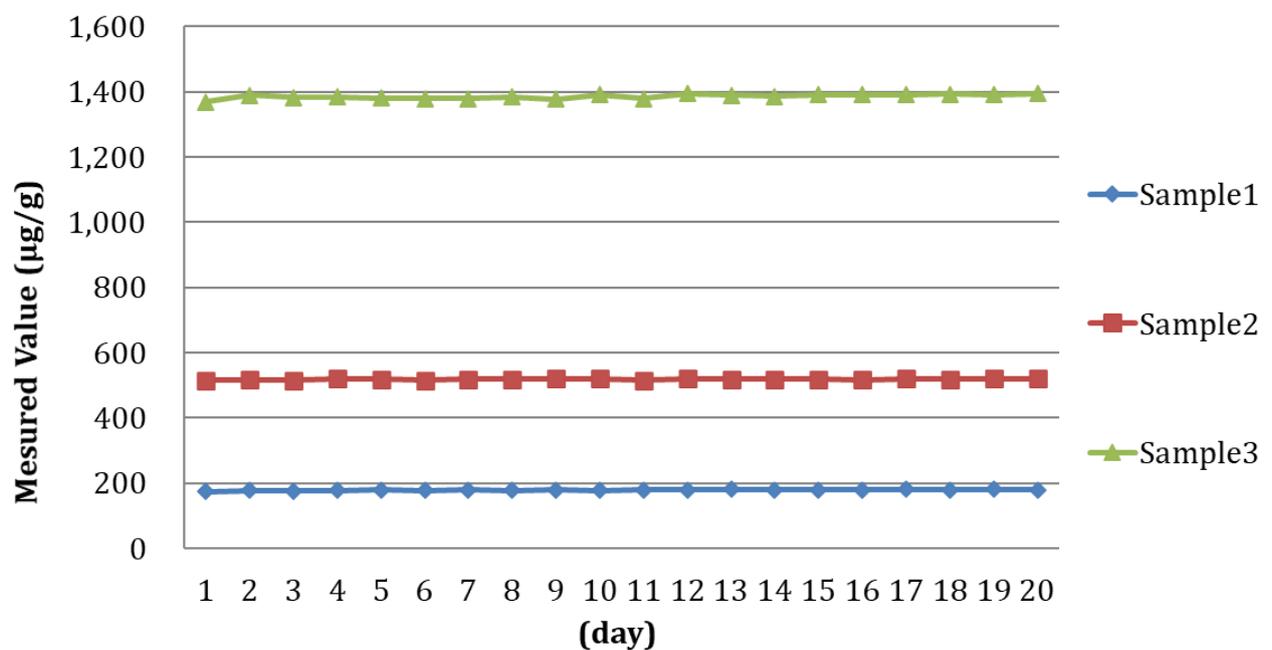
Dilution linearity

(μg/g)

Dilution Ratio	Low concentration sample	High concentration sample
1/10	89	277
2/10	164	550
3/10	249	819
4/10	335	1,054
5/10	426	1,303
6/10	517	1,585
7/10	615	1,858
8/10	700	2,107
9/10	772	2,401
10/10	857	2,621

* Samples are calprotectin solution.
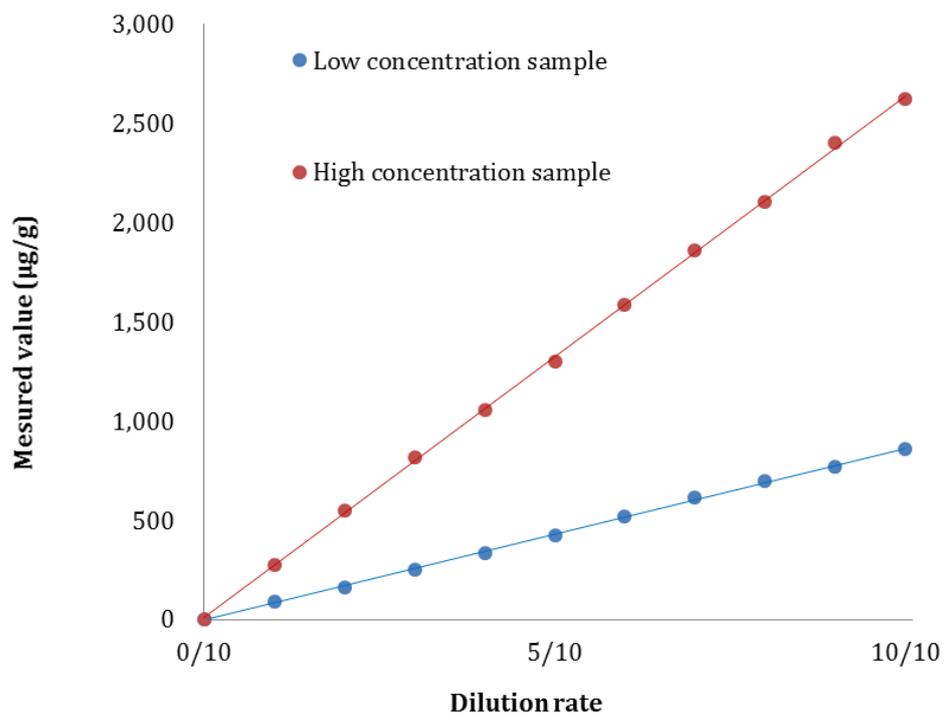
FCa detection limit – 2.6SD method

Theoretical Concentration μg/g	0	17	26	34
DA value	7	26	33	41
	8	28	37	43
	8	25	32	38
	6	22	36	45
	3	26	34	43
	6	27	37	42
	9	23	31	43
	-5	30	34	44
	5	26	34	40
	4	26	36	42
N	10	10	10	10
Mean(M)	5.1	25.9	34.4	42.1
S.D.	4.01	2.28	2.07	2.02
M-2.6SD	-5.33	19.96	29.03	36.84
M+2.6SD	15.53	31.84	39.77	47.36
CV（％）	78.7%	8.8%	6%	4.8%
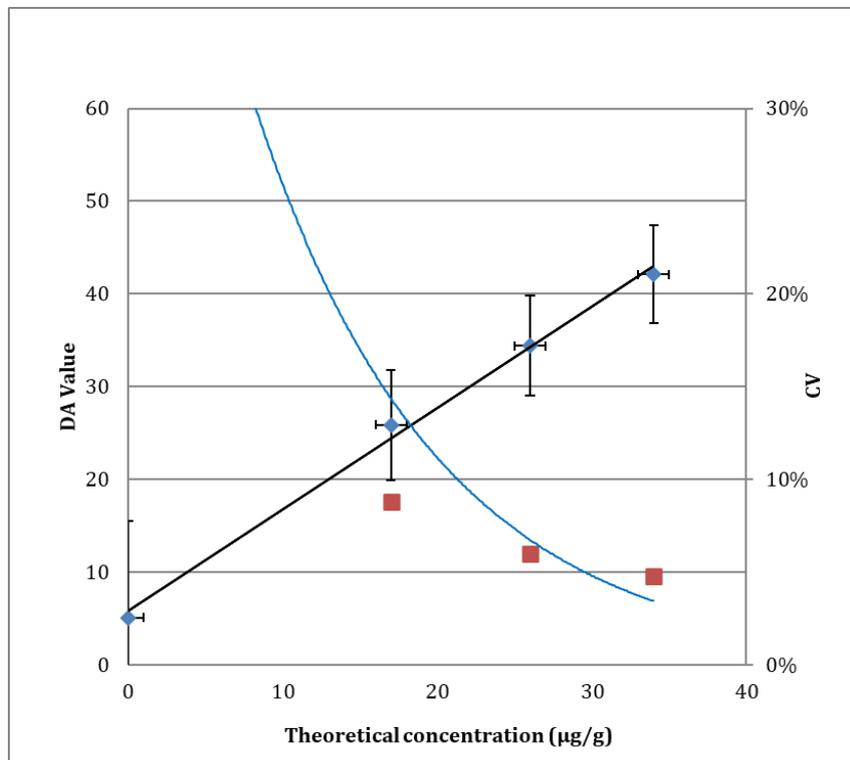
Limit of Detection; LOD：17μg/g

Hook Effect

| Theoretical Concentration （μg/g）	DA value	Measured value （μg/g） 〔 OR/PRC flag 〕
0	2	-
85	106	-
340	516	-
850	1,645	-
1,700	3,305	-
2,720	4,153	-
5,600	4,774	OR
11,200	4,643	OR
22,400	4,300	PRC
44,800	4,179	PRC
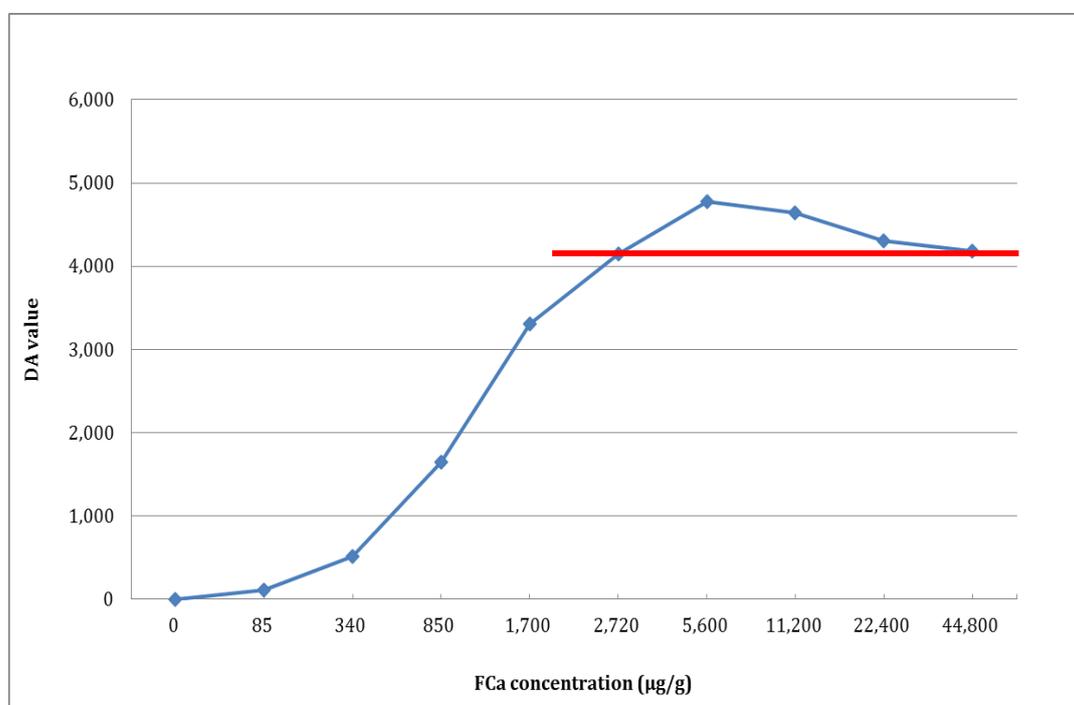
*Comments of "OR" or "PRC" are displayed for values exceeding the calibration point, Std6 (concentration 2720 μg/g). Samples with exceeded 50,000ug/g of calprotectin concentration may have results with measurement range because of hook effect.

Method Comparison with other products

➢ Correlation with Other product A, FEIA method

$y = 0.926x + 0.47$
$r = 0.929$
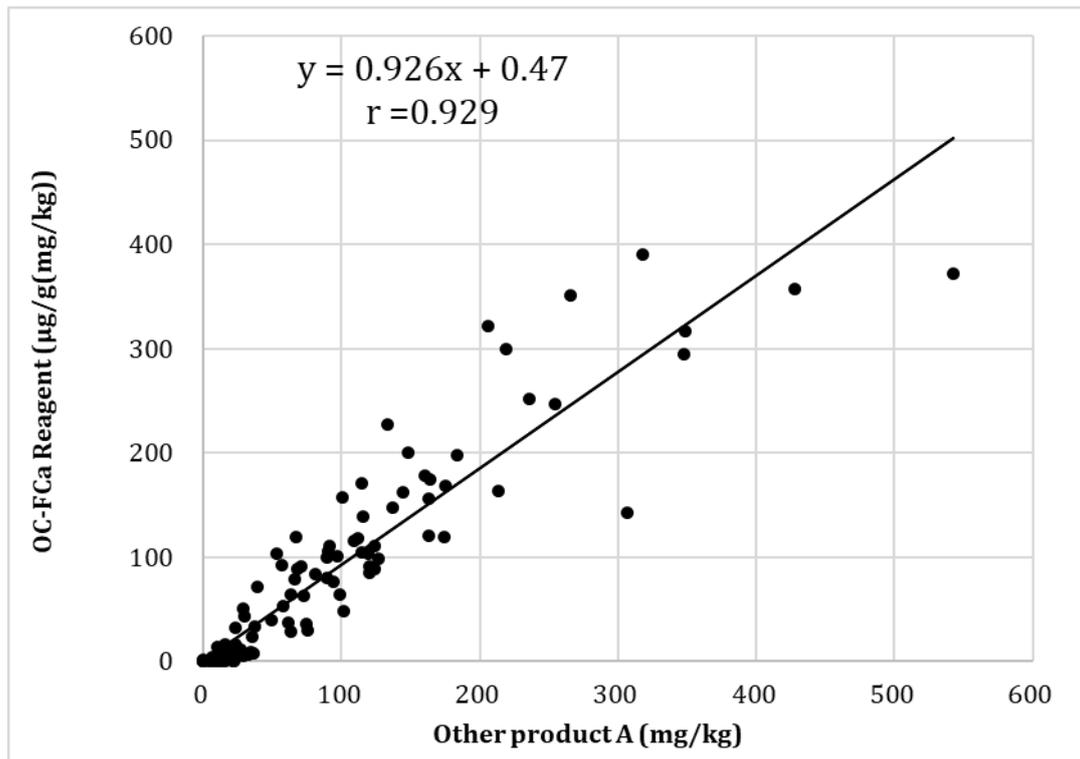
Cut-off value: 50 μg/g
: Distinguishing IBD from functional intestinal disorders

		Other product A		
		Positive	Negative	Total
OC-FCa	Positive	108	2	110
Reagent	Negative	5	62	67
	Total	113	64	177

Positive result consistency: 95.6%

Negative result consistency: 96.9%

Overall result consistency: 96.0%

Cut-off value: 300 μg/g

: Monitoring UC disease activity

		Other product A		
		Positive	Negative	Total
OC-FCa Reagent	Positive	58	4	62
	Negative	2	113	115
	Total	60	117	177

Positive result consistency: 96.7%

Negative result consistency: 96.6%

Overall result consistency: 96.6%

➢ Correlation with Other product B, ELISA method
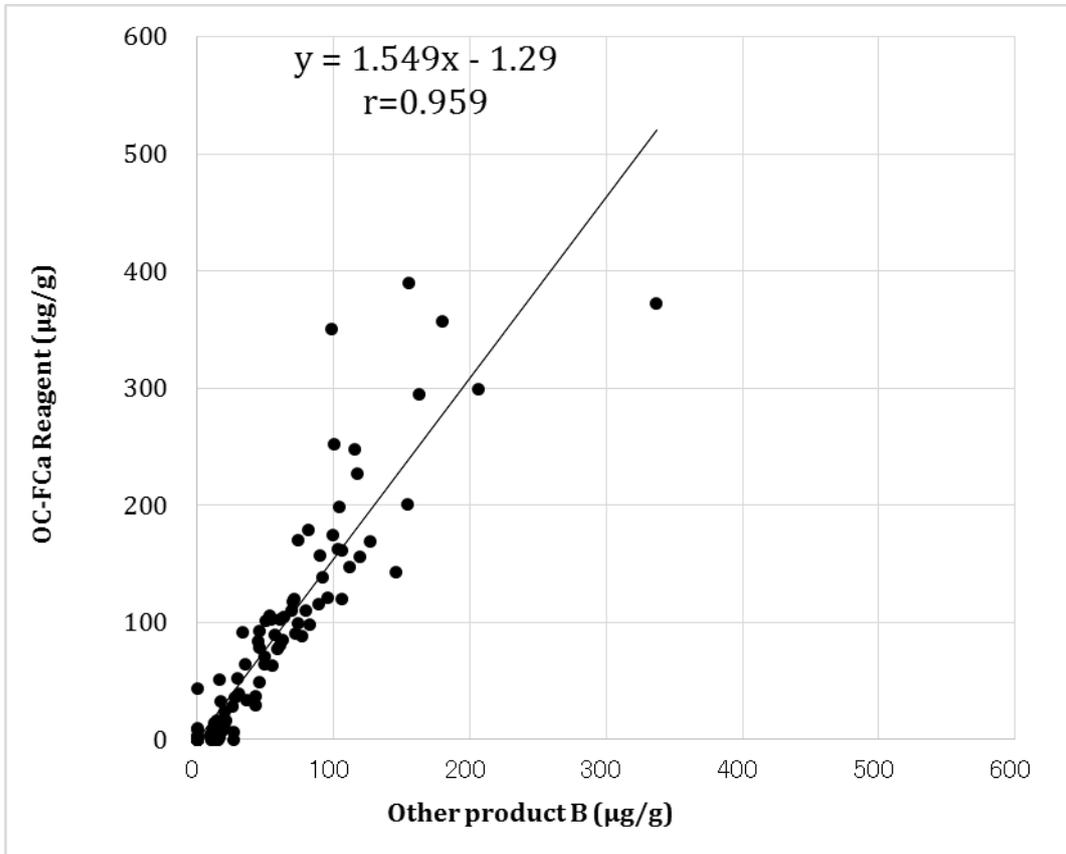
Cut-off value:

240 μg/g (Other product B), 300 μg/g (OC-FCa Reagent）

		Other product B		
		Positive	Negative	Total
OC-FCa	Positive	46	13	59
Reagent	Negative	0	112	112
	Total	46	125	171

Positive result consistency: 100 .0%

Negative result consistency: 89.6%
Overall result consistency: 92.4%

Carry over

No.	Cell No.	Sample	Mesured Value (μg/g)
①	1	High concentration specimen 50,000μg/g	PRC
	2	Buffer	0
	3	Buffer	0
	4	Buffer	0
	5	High concentration specimen 50,000μg/g	PRC
	6	Buffer	0
	7	Buffer	0
	8	Buffer	0
	9	High concentration specimen 50,000μg/g	PRC
	10	Buffer	0
	11	Buffer	0
	12	Buffer	0
②	1	High concentration specimen 25,000μg/g	OR
	2	Buffer	0
	3	Buffer	0
	4	Buffer	0
	5	High concentration specimen 25,000μg/g	OR
	6	Buffer	0
	7	Buffer	0
	8	Buffer	0
	9	High concentration specimen 25,000μg/g	OR
	10	Buffer	0
	11	Buffer	0
	12	Buffer	0
③	1	High concentration specimen 12,500μg/g	OR
	2	Buffer	0
	3	Buffer	0
	4	Buffer	0
	5	High concentration specimen 12,500μg/g	OR
	6	Buffer	0
	7	Buffer	0
	8	Buffer	0
	9	High concentration specimen 12,500μg/g	OR
	10	Buffer	1
	11	Buffer	0
	12	Buffer	0

Revision history

Issue date	Revisions
July 2020	First edition issued
October 2020	Correlation with Other product A, FEIA method in the section of Method Comparison with other products. Modified the correlation data to "400 μg/g or less" instead of "350 μg/g or less".