OC-SENSOR io

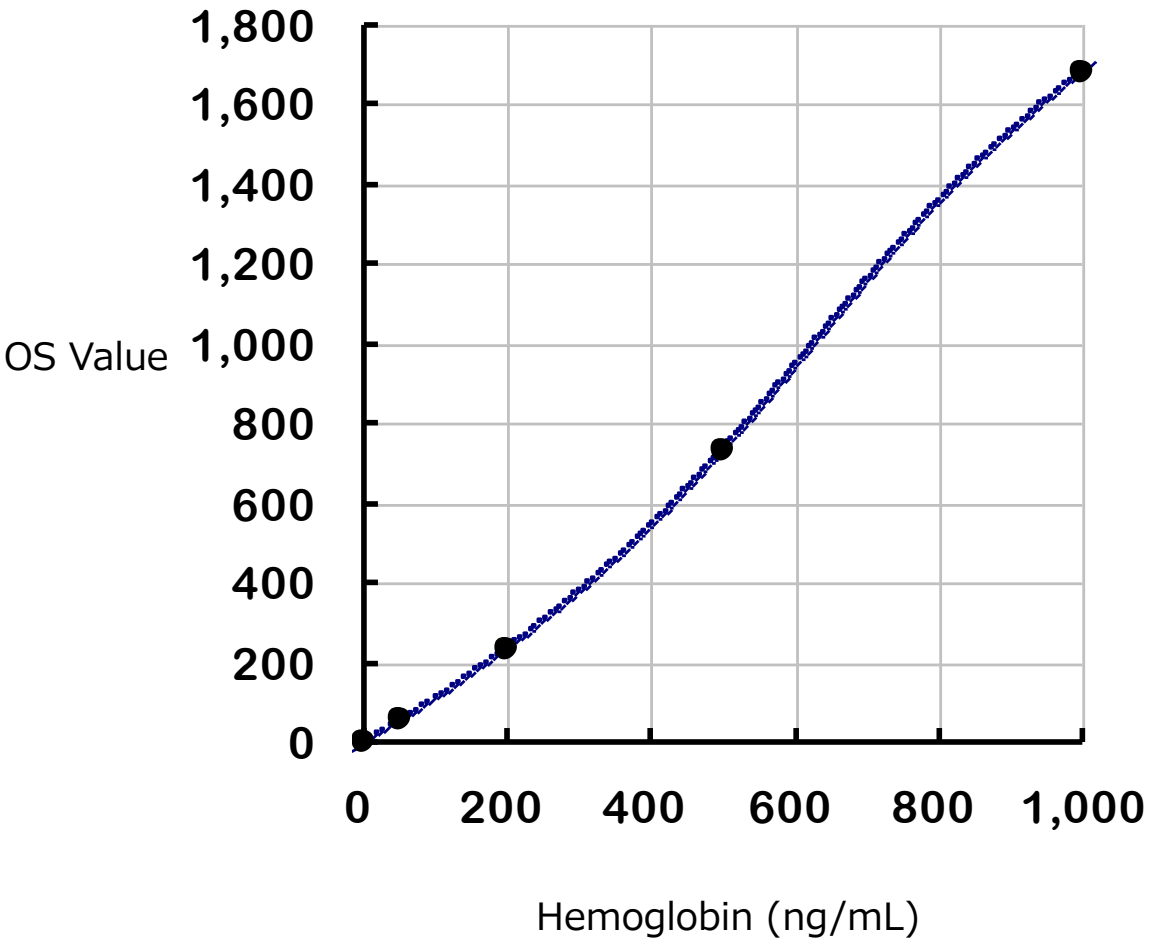
Analytical Performance Report

Eiken Chemical Co., Ltd.

2009,01

Calibration

	Concentration (ng/mL)	DA Value	Back Fit	
Std.1	0	-4	0	
Std.2	50	54	50	100.0%
Std.3	200	235	200	100.0%
Std.4	500	734	500	100.0%
Std.5	1,000	1,683	1,000	100.0%

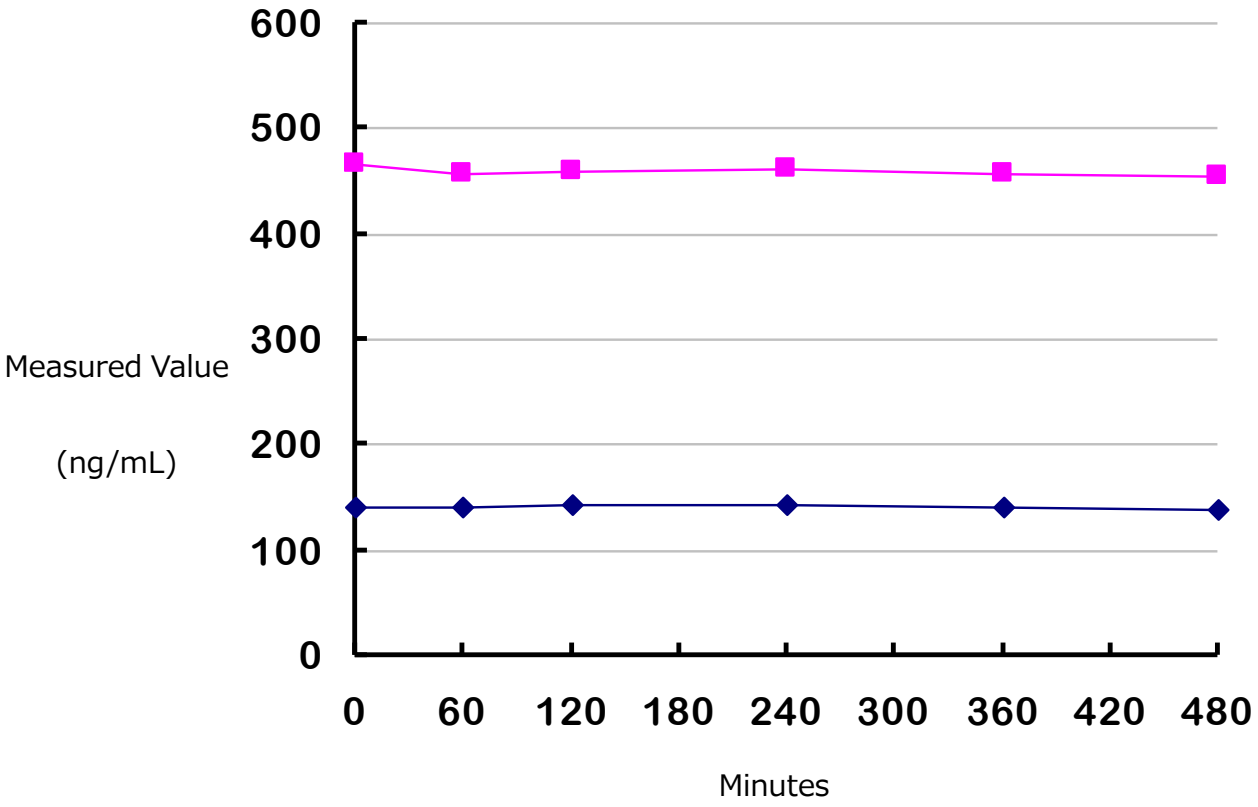


Reproducibility

	Sample 1	Sample 2	Sample 3
1	52	138	449
2	52	138	456
3	51	139	459
4	55	137	461
5	50	139	456
6	51	138	454
7	54	137	458
8	51	137	454
9	52	136	456
10	51	136	458
11	53	133	457
12	52	141	465
13	52	137	461
14	51	134	455
15	51	136	458
16	52	134	461
17	51	133	454
18	52	134	465
19	53	135	459
20	51	136	461
Mean	51.9	136.4	457.9
S.D.	1.2	2.1	3.9
C.V. (%)	2.28%	1.57%	0.85%
Range	5	8	16
MAX.	54	141	465
MIN.	50	133	449

Reproducibility within a day

Minutes	0	60	120	240	360	480
Control L	141	140	143	142	141	139
Control H	467	458	458	461	458	454



Inter/Intra-day reproducibility

Calibrated Every Day

50 ng/mL	1st	2nd	3rd	Average
Day 1	53	52	53	52.7
Day 2	48	48	53	49.7
Day 3	48	46	55	49.7
Day 4	53	51	57	53.7
Day 5	51	47	53	50.3
Day 6	52	54	53	53.0
Day 7	50	50	53	51.0
Day 8	50	46	50	48.7
Day 9	46	48	54	49.3
Day 10	50	54	55	53.0
Day 11	49	51	50	50.0
Day 12	56	59	56	57.0
Day 13	52	52	56	53.3
Day 14	55	54	57	55.3
Day 15	45	44	48	45.7
Day 16	49	48	51	49.3
Day 17	52	50	55	52.3
Day 18	54	51	55	53.3
Day 19	46	45	54	48.3
Day 20	53	53	50	52.0
Day 21	54	54	54	54.0

Analysis of Variance Table

Variation factor	Variation	DOF	Variant	Observed Variance Ratio	P-Value	F-Boundary
Intra Group	424.41	20	21.22	3.191	0.001	1.826
Inter Group	279.33	42	6.65			
Summary	703.75	62				

Intra Day Accuracy	2.20	CV(%)	4.29
Interday Accuracy	2.58	CV(%)	5.02
Accuracy Total	3.39	CV(%)	6.60

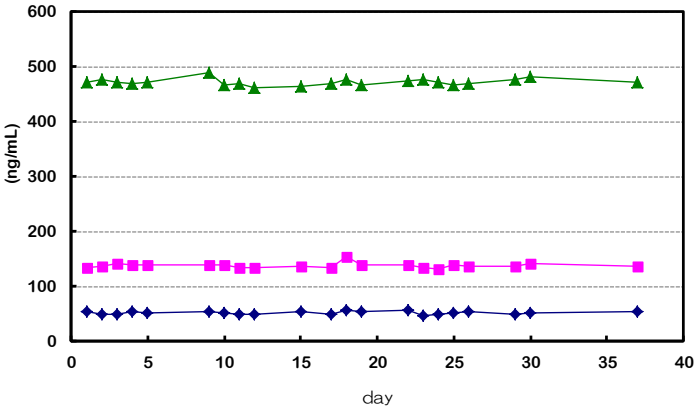
Control L	1st	2nd	3rd	Average
Day 1	135	136	134	135.0
Day 2	139	135	138	137.3
Day 3	143	140	142	141.7
Day 4	139	138	138	138.3
Day 5	141	139	140	140.0
Day 6	141	139	138	139.3
Day 7	142	138	140	140.0
Day 8	136	133	132	133.7
Day 9	136	132	132	133.3
Day 10	137	136	134	135.7
Day 11	136	134	133	134.3
Day 12	156	154	151	153.7
Day 13	142	139	135	138.7
Day 14	140	141	139	140.0
Day 15	134	133	133	133.3
Day 16	133	133	131	132.3
Day 17	141	139	139	139.7
Day 18	137	137	137	137.0
Day 19	136	136	137	136.3
Day 20	141	140	142	141.0
Day 21	138	136	138	137.3

Analysis of Variance Table

Variation factor	Variation	DOF	Variant	Observed Variance Ratio	P-Value	F-Boundary
Intra Group	1,236.00	20	61.80	23.596	0.000	1.826
Inter Group	110.00	42	2.62			
Summary	1,346.00	62				

Intra Day Accuracy	4.44	CV(%)	3.22
Interday Accuracy	1.62	CV(%)	1.17
Accuracy Total	4.73	CV(%)	3.42

Control H	1st	2nd	3rd	Average
Day 1	485	468	461	471.3
Day 2	478	474	474	475.3
Day 3	473	472	471	472.0
Day 4	472	468	469	469.7
Day 5	471	472	471	471.3
Day 6	489	489	486	488.0
Day 7	465	470	463	466.0
Day 8	474	462	467	467.7
Day 9	459	461	463	461.0
Day 10	465	467	463	465.0
Day 11	463	478	467	469.3
Day 12	476	473	477	475.3
Day 13	464	466	469	466.3
Day 14	471	478	475	474.7
Day 15	488	470	473	477.0
Day 16	471	470	474	471.7
Day 17	467	466	466	466.3
Day 18	470	468	465	467.7
Day 19	478	478	472	476.0
Day 20	483	480	480	481.0
Day 21	467	475	471	471.0



Analysis of Variance Table

Variation factor	Variation	DOF	Variant	Observed Variance Ratio	P-Value	F-Boundary
Intra Group	2,179.08	20	108.95	5.177	0.000	1.826
Inter Group	884.00	42	21.05			
Summary	3,063.08	62				

Intra Day Accuracy	5.41	CV(%)	1.15
Interday Accuracy	4.59	CV(%)	0.97
Accuracy Total	7.10	CV(%)	1.50

Inter/Intra-day reproducibility

Calibrated only on the 1st day

50 ng/mL	1st	2nd	3rd	Average
Day 1	53	52	53	52.7
Day 2	50	50	55	51.7
Day 3	51	48	57	52.0
Day 4	51	49	54	51.3
Day 5	51	46	53	50.0
Day 6	48	50	49	49.0
Day 7	49	49	52	50.0
Day 8	49	45	49	47.7
Day 9	43	45	52	46.7
Day 10	45	49	50	48.0
Day 11	47	49	48	48.0
Day 12	48	50	48	48.7
Day 13	46	46	50	47.3
Day 14	46	45	48	46.3
Day 15	45	44	48	45.7
Day 16	45	44	48	45.7
Day 17	47	45	50	47.3
Day 18	49	46	50	48.3
Day 19	42	41	49	44.0
Day 20	46	46	44	45.3
Day 21	46	46	46	46.0

Analysis of Variance Table

Variation factor	Variation	DOF	Variant	Observed Variance Ratio	P-Value	F-Boundary
Intra Group	344.41	20	17.22	2.633	0.004	1.826
Inter Group	274.67	42	6.54			
Summary	619.08	62				

Intra Day Accuracy	1.89	CV(%)	3.91
Interday Accuracy	2.56	CV(%)	5.30
Accuracy Total	3.18	CV(%)	6.58

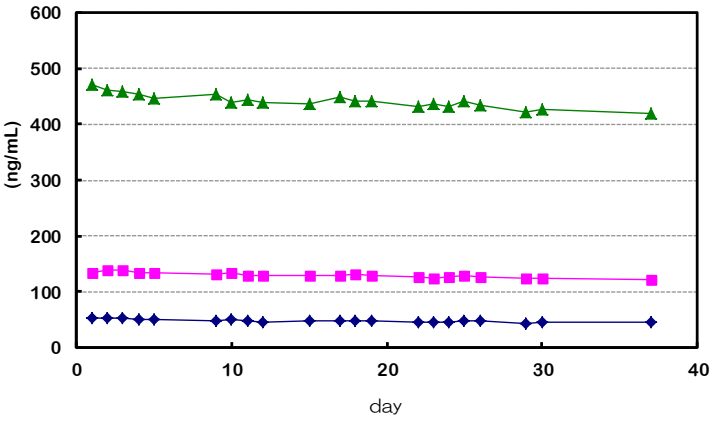
Control L	1st	2nd	3rd	Average
Day 1	135	136	134	135.0
Day 2	142	138	140	140.0
Day 3	140	138	139	139.0
Day 4	135	134	135	134.7
Day 5	136	134	135	135.0
Day 6	132	130	129	130.3
Day 7	135	131	133	133.0
Day 8	131	128	127	128.7
Day 9	131	127	127	128.3
Day 10	129	128	127	128.0
Day 11	130	128	127	128.3
Day 12	134	131	129	131.3
Day 13	131	129	125	128.3
Day 14	127	128	127	127.3
Day 15	124	123	123	123.3
Day 16	127	127	125	126.3
Day 17	131	128	128	129.0
Day 18	127	127	127	127.0
Day 19	123	123	124	123.3
Day 20	123	123	125	123.7
Day 21	123	121	123	122.3

Analysis of Variance Table

Variation factor	Variation	DOF	Variant	Observed Variance Ratio	P-Value	F-Boundary
Intra Group	1,479.94	20	74.00	30.873	0.000	1.826
Inter Group	100.67	42	2.40			
Summary	1,580.60	62				

Intra Day Accuracy	4.89	CV(%)	3.76
Interday Accuracy	1.55	CV(%)	1.19
Accuracy Total	5.12	CV(%)	3.94

Control H	1st	2nd	3rd	Average
Day 1	485	468	461	471.3
Day 2	463	460	460	461.0
Day 3	459	458	457	458.0
Day 4	456	452	454	454.0
Day 5	446	447	446	446.3
Day 6	455	455	452	454.0
Day 7	439	444	437	440.0
Day 8	449	437	442	442.7
Day 9	437	439	441	439.0
Day 10	437	439	435	437.0
Day 11	442	456	446	448.0
Day 12	442	439	443	441.3
Day 13	439	442	445	442.0
Day 14	429	435	432	432.0
Day 15	448	431	433	437.3
Day 16	431	430	433	431.3
Day 17	441	440	440	440.3
Day 18	435	434	431	433.3
Day 19	424	424	419	422.3
Day 20	428	426	425	426.3
Day 21	417	424	420	420.3



Analysis of Variance Table

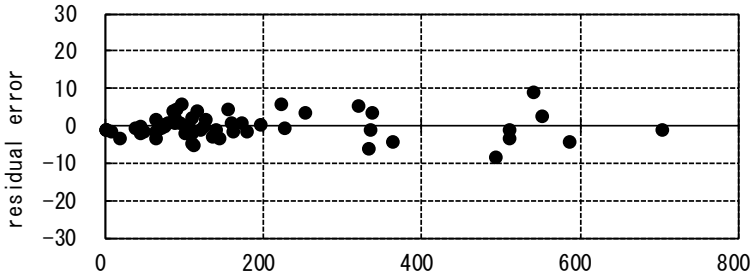
Variation factor	Variation	DOF	Variant	Observed Variance Ratio	P-Value	F-Boundary
Intra Group	9,820.38	20	491.02	25.048	0.000	1.826
Inter Group	823.33	42	19.60			
Summary	10,643.71	62				

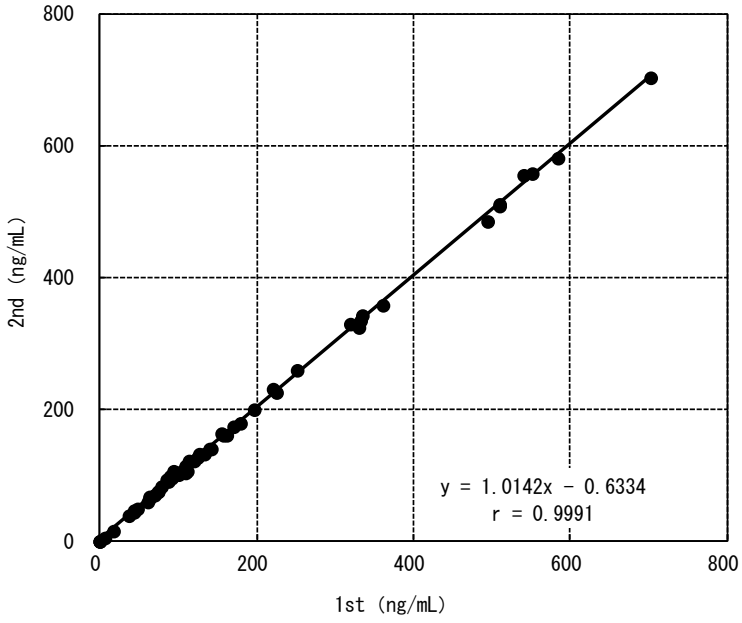
Intra Day Accuracy	12.54	CV(%)	2.83
Interday Accuracy	4.43	CV(%)	1.00
Accuracy Total	13.29	CV(%)	3.00

Accuracy validation – From stool samples

No.	1st	2nd	residual error
1	142	139	−3.37
2	63	63	−1.26
3	251	259	3.88
4	73	75	0.54
5	158	161	1.01
6	224	226	−0.25
7	702	704	−0.86
8	509	507	−3.01
9	87	90	1.05
10	178	178	−1.37
11	87	92	2.25
12	124	126	0.19
13	5	5	−1.41
14	92	95	1.01
15	509	510	−0.70
16	104	106	0.33
17	18	15	−3.31
18	335	343	3.62
19	221	231	5.95
20	134	131	−2.75
21	139	139	−1.07
22	108	113	2.06
23	63	67	1.83
24	94	104	5.74
25	44	45	0.07
26	84	92	4.07
27	540	555	9.18
28	89	97	4.62
29	100	99	−2.02
30	126	131	1.89
31	319	329	5.34
32	154	162	4.39
33	78	81	1.11
34	0	0	−1.10
35	108	103	−4.41
36	170	173	0.88
37	110	105	−5.01
38	74	75	−0.08
39	69	69	−0.66
40	333	334	−0.83
41	585	581	−4.19
42	0	0	−1.10
43	109	108	−2.05
44	161	161	−1.23
45	196	199	0.60
46	114	122	4.33
47	61	59	−3.11
48	331	325	−5.81
49	47	47	−1.22
50	361	358	−3.96
51	120	120	−0.94
52	493	484	−8.13
53	44	43	−1.89
54	0	0	−1.10
55	37	38	−0.62
56	551	558	2.90

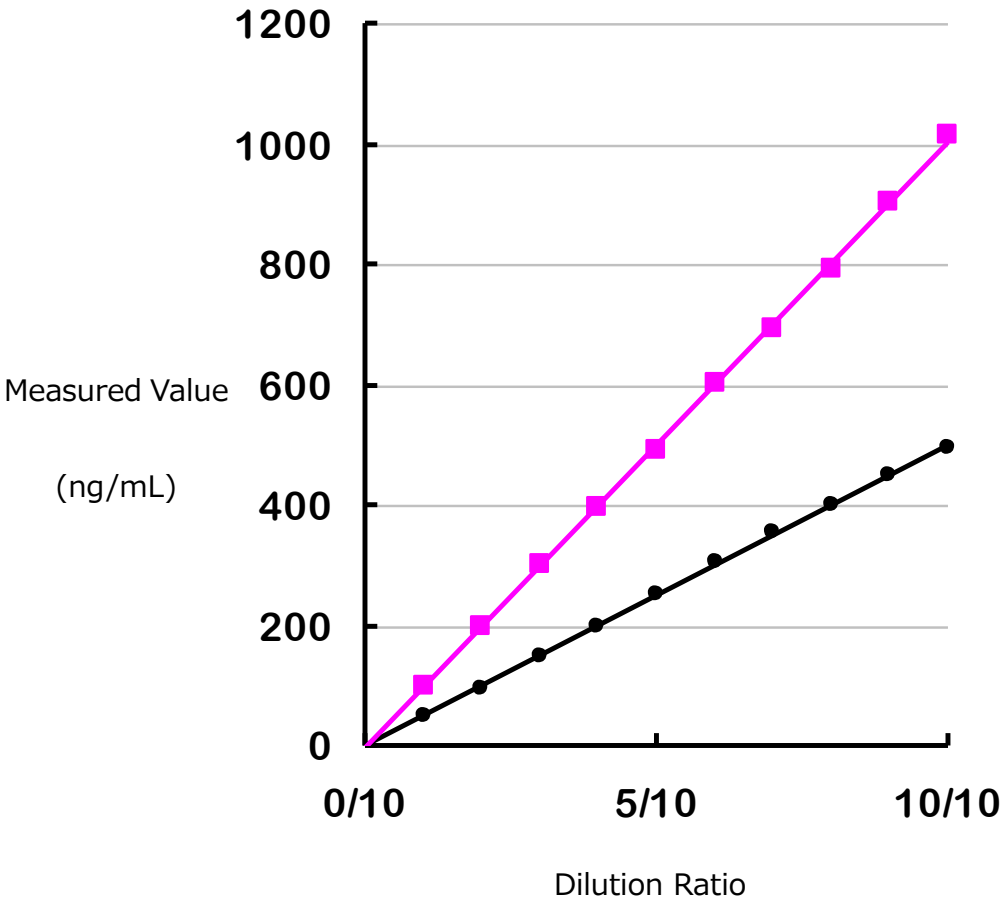
X error valiance	Vx =	1
Y error valiance	Vy =	1
error valiance rate	λ =	1
number of data	n =	56
X mean	Xmean =	179.05
Y mean	Ymean =	180.89
mean difference	dbar =	1.83
X valiation	Sxx =	1569594.12
Y valiation	Syy =	1574275.93
X, Y covariation	Sxy =	1571362.02
slope	b' =	1.001
intercept	a' =	1.564
perpendicular slope	b'' =	−0.999
correlation coefficient	r =	1.000
std deviation of estimation	Syx =	3.25
std deviation of difference	SDdif =	4.56
expected std deviation	σ ^ =	3.45





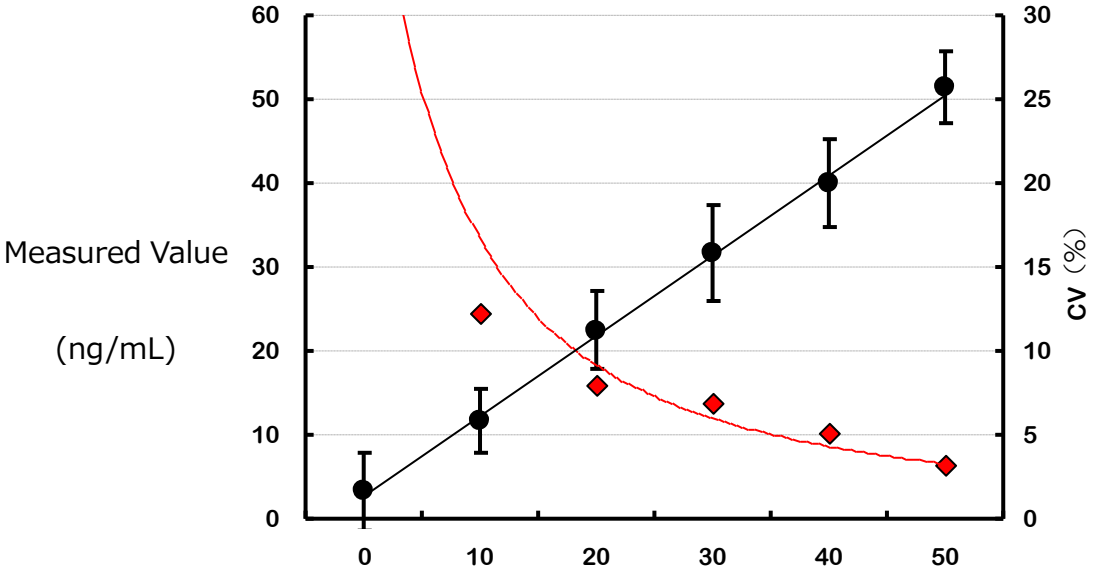
Proportionality

Dilution Ratio	Sample 1	Sample 2
1/10	50	99
2/10	96	197
3/10	150	301
4/10	198	396
5/10	251	490
6/10	303	600
7/10	356	691
8/10	400	791
9/10	449	901
10/10	496	1013



Sensitivity using calculated figures – 2.6ＳＤ

Theoretical Value	0	10	20	30	40	50
Measured Value	2	9	21	35	37	51
	3	13	24	29	38	53
	4	12	22	31	39	51
	5	11	20	35	39	54
	7	11	22	35	41	55
	4	11	22	33	40	53
	6	12	22	34	39	51
	3	12	21	35	37	52
	1	10	20	32	38	50
	0	8	19	29	37	49
	2	11	22	31	44	50
	3	12	24	30	41	50
	3	14	25	31	38	49
	3	11	24	28	42	51
	4	13	24	31	43	51
	5	13	22	31	39	50
	6	14	22	34	44	51
	3	10	23	30	40	51
	5	12	24	31	41	50
	0	11	21	34	39	49
N	20	20	20	20	20	20
Mean	3.2	11.7	22.4	31.7	40.0	51.4
SD	1.78	1.44	1.79	2.18	2.05	1.64
CV	55.2	12.3	8.0	6.9	5.1	3.2

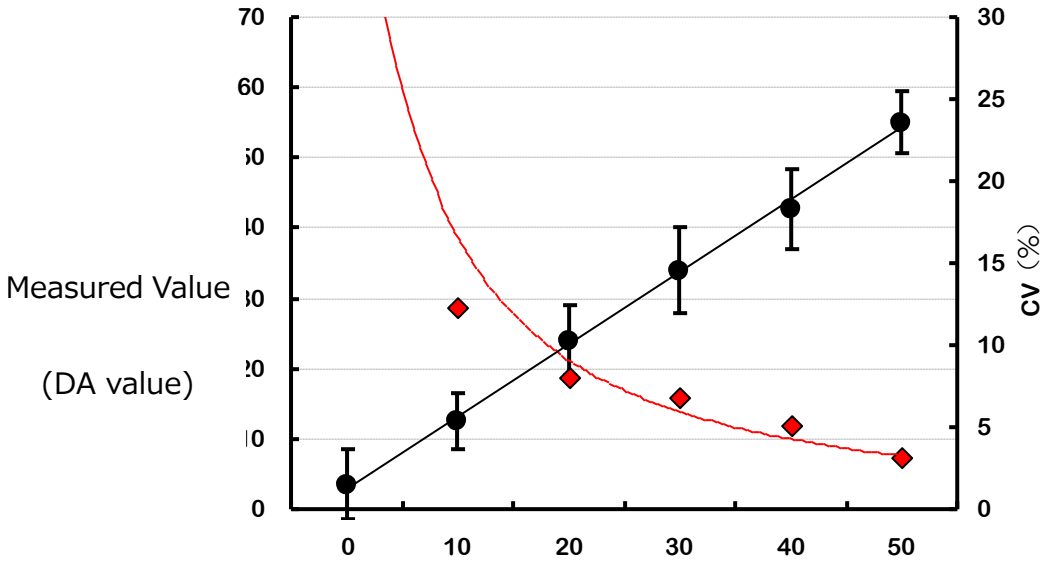


LOD : 10ng/mL

Acceptable Limit : 20ng/mL

Sensitivity using absorbance (DA) – 2.6ＳＤ

Theoretical Value	0	10	20	30	40	50
DA Value	2	10	22	37	40	55
	3	14	26	31	41	57
	4	13	24	33	42	55
	5	12	21	37	42	58
	7	12	24	37	44	59
	4	12	24	35	43	57
	6	13	24	36	42	55
	3	13	23	38	40	56
	1	11	21	34	41	54
	0	9	20	31	40	53
	2	12	24	33	47	54
	3	13	26	32	44	54
	3	15	27	33	41	53
	3	12	26	30	45	55
	4	14	26	33	46	55
	5	14	24	33	42	54
	6	15	24	36	47	55
	3	11	25	32	43	55
	5	13	26	33	44	54
	0	12	23	36	42	52
N	20	20	20	20	20	20
Mean	3.5	12.5	24.0	34.0	42.8	55.0
SD	1.90	1.54	1.92	2.34	2.19	1.72
CV	55.2	12.3	8.0	6.9	5.1	3.1

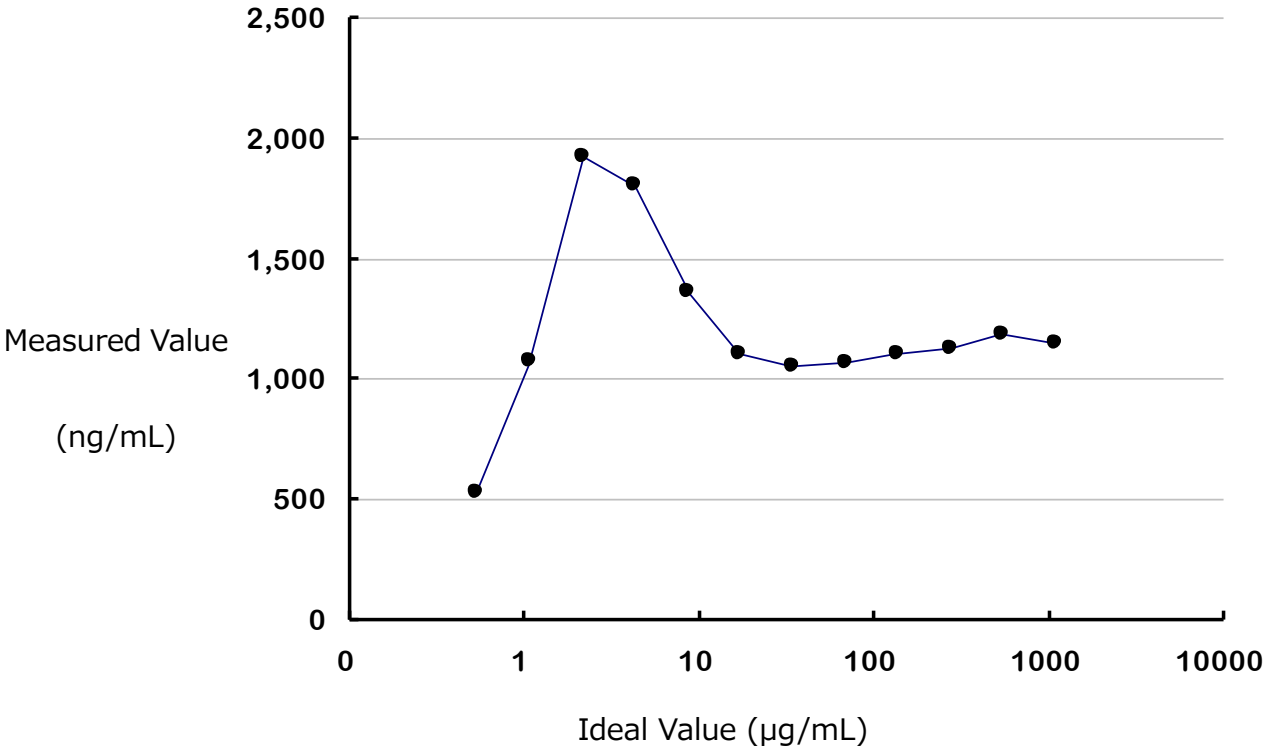


LOD : 10ng/mL

Acceptable limit : 20ng/mL

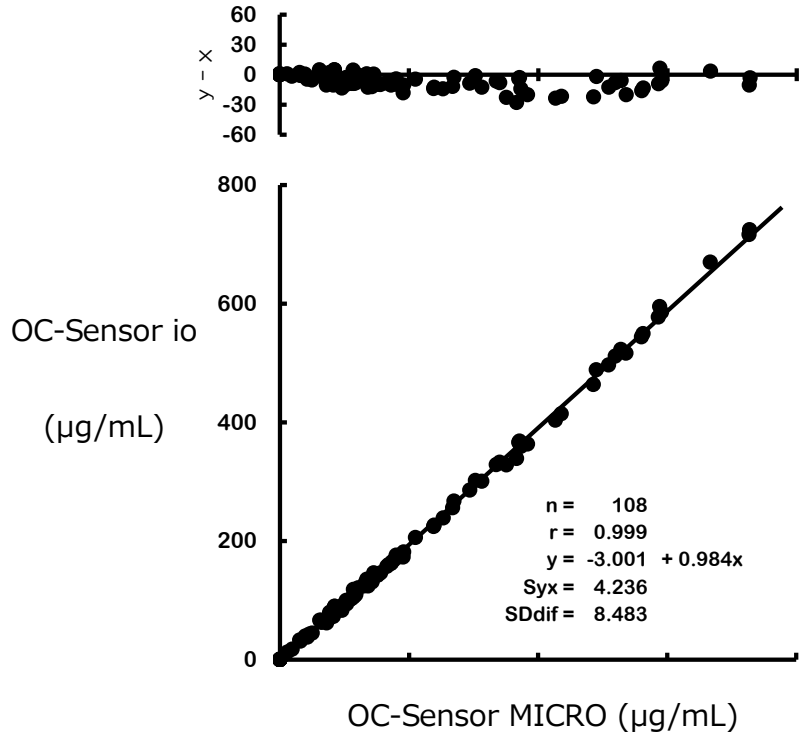
Excess antigen calculation

Theoretical Hb Conc (ng/mL)	OS value	Measured value (ng/mL)	Over Range flag
530	772	529	
1,060	1,772	1,073	OR
2,120	2,529	1,924	OR
4,240	2,452	1,808	OR
8,480	2,096	1,361	OR
16,960	1,815	1,106	OR
33,920	1,749	1,056	OR
67,840	1,768	1,070	OR
135,680	1,816	1,107	OR
271,360	1,846	1,131	OR
542,720	1,910	1,184	OR
1,085,440	1,874	1,154	OR



Comparison between OC MICRO and OC io

	μ	io	y − x		μ	io	y − x		μ	io	y − x		μ	io	y − x
1	72	62	−10	28	253	239	−14	55	168	160	−9	82	373	359	−14
2	341	333	−8	29	88	85	−3	56	238	224	−14	83	335	329	−7
3	50	45	−5	30	79	78	−1	57	728	725	−3	84	173	163	−10
4	384	364	−20	31	486	464	−22	58	529	523	−6	85	87	83	−4
5	132	129	−3	32	0	0	0	59	92	86	−5	86	0	0	0
6	490	489	−2	33	303	302	−1	60	727	716	−10	87	135	132	−2
7	43	38	−5	34	87	82	−5	61	192	181	−11	88	175	166	−9
8	0	0	0	35	64	66	3	62	85	90	5	89	118	109	−8
9	39	40	0	36	427	404	−23	63	137	131	−6	90	116	112	−4
10	563	550	−13	37	667	670	3	64	0	1	1	91	81	81	0
11	83	73	−10	38	0	0	0	65	105	100	−5	92	73	69	−4
12	103	100	−3	39	270	267	−3	66	536	516	−20	93	351	328	−23
13	146	146	1	40	589	595	6	67	112	103	−9	94	592	585	−6
14	109	102	−8	41	294	286	−9	68	12	13	1	95	0	0	0
15	436	414	−22	42	509	497	−13	69	367	339	−28	96	114	108	−6
16	181	171	−10	43	115	106	−9	70	239	226	−13	97	180	176	−4
17	313	300	−12	44	77	79	2	71	143	131	−12	98	210	206	−4
18	173	162	−11	45	0	0	0	72	152	143	−9	99	121	121	0
19	78	75	−3	46	31	33	2	73	118	113	−5	100	156	146	−10
20	116	113	−3	47	371	369	−3	74	65	63	−2	101	32	31	−1
21	191	173	−18	48	83	86	3	75	97	90	−7	102	137	127	−9
22	96	83	−13	49	520	511	−8	76	46	43	−3	103	166	157	−8
23	146	142	−4	50	587	578	−9	77	100	94	−6	104	130	124	−6
24	0	0	0	51	135	136	1	78	560	544	−16	105	104	94	−10
25	62	66	5	52	64	65	1	79	85	90	5	106	141	132	−10
26	0	0	0	53	268	256	−12	80	114	118	4	107	137	124	−12
27	370	366	−4	54	77	74	−3	81	152	142	−10	108	19	17	−2



Carry over contamination

Auto dispense No.	Cell No.	Test Concentration	ng/mL	Carry Over Rate
①	1	High Hb 1,000, 000ng/mL	OR	
	2	Buffer	10	0.0020%
	3	Buffer	0	0.0000%
	4	High Hb 1,000, 000ng/mL	OR	
	5	Buffer	7	0.0014%
	6	Buffer	0	0.0000%
	7	High Hb 1,000, 000ng/mL	OR	
	8	Buffer	12	0.0024%
	9	Buffer	0	0.0000%
	AVG			0.0019%
②	1	High Hb 500, 000ng/mL	OR	
	2	Buffer	9	0.0036%
	3	Buffer	2	0.0008%
	4	High Hb 500, 000ng/mL	OR	
	5	Buffer	11	0.0044%
	6	Buffer	3	0.0012%
	7	High Hb 500, 000ng/mL	OR	
	8	Buffer	7	0.0028%
	9	Buffer	5	0.0020%
	AVG			0.0036%
AVG				0.0028%

Manual dispense No.	Cell No.	Test Concentration	ng/mL	Carry Over Rate
①	1	High Hb 1,000, 000ng/mL	OR	
	2	Buffer	0	0.0000%
	3	Buffer	0	0.0000%
	4	High Hb 1,000, 000ng/mL	OR	
	5	Buffer	0	0.0000%
	6	Buffer	0	0.0000%
	7	High Hb 1,000, 000ng/mL	OR	
	8	Buffer	0	0.0000%
	9	Buffer	0	0.0000%
	AVG			0.0000%
②	1	High Hb 500, 000ng/mL	OR	
	2	Buffer	0	0.0000%
	3	Buffer	0	0.0000%
	4	High Hb 500, 000ng/mL	OR	
	5	Buffer	0	0.0000%
	6	Buffer	0	0.0000%
	7	High Hb 500, 000ng/mL	OR	
	8	Buffer	0	0.0000%
	9	Buffer	0	0.0000%
	AVG			0.0000%
AVG				0.0000%