

Analytical Performance Report

OC-SENSOR PLEDIA

- OC-SENSOR DIANA Latex Reagent
- OC-SENSOR DIANA Buffer

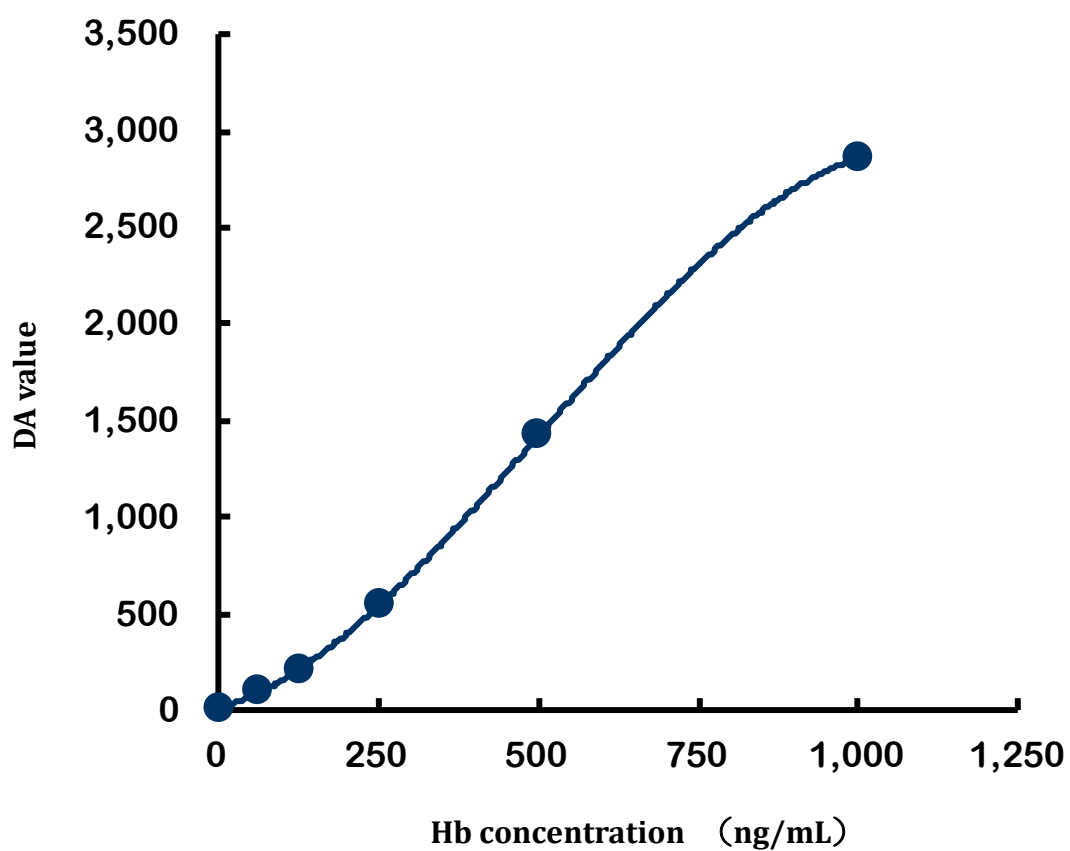
Haemoglobin in faeces; FIT



2020.6

Calibration curve

	Theoretical Hb concentration (ng/mL)	DA value	Back Fit value (ng/mL)	
Std.1	0	8	0	
Std.2	62.5	94	63	101.0%
Std.3	125	206	122	97.4%
Std.4	250	542	254	101.7%
Std.5	500	1,420	497	99.4%
Std.6	1,000	2,860	1,001	100.1%

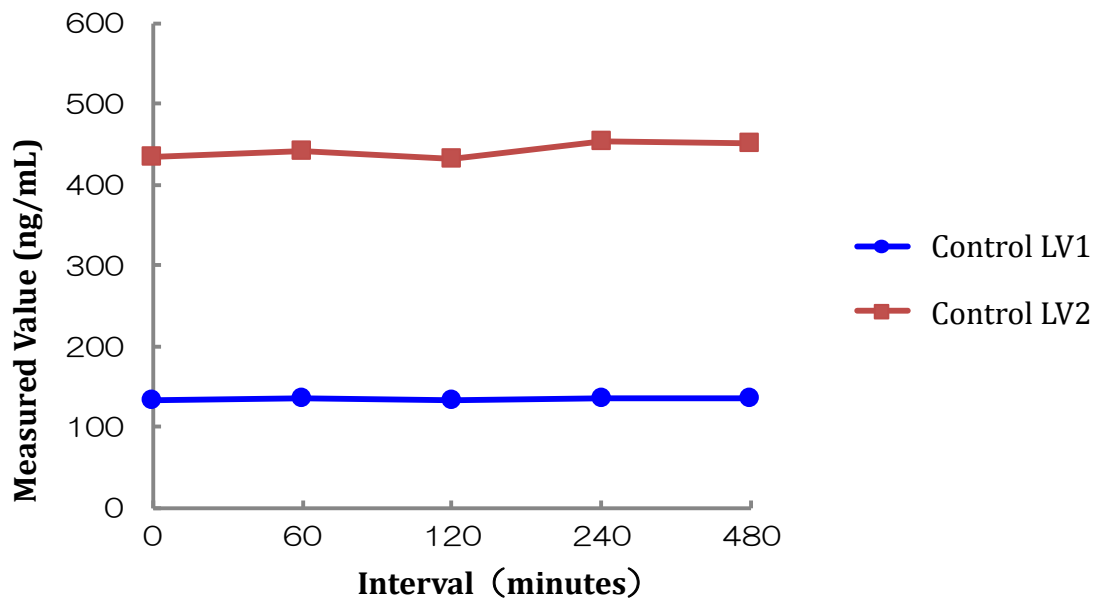


Intra-day reproducibility

	(ng/mL)	
	Control LV1	Control LV2
1	130	446
2	131	451
3	132	456
4	133	447
5	135	447
6	135	445
7	133	450
8	134	440
9	135	446
10	135	447
11	134	441
12	134	443
13	133	454
14	131	457
15	132	453
16	131	452
17	131	454
18	136	458
19	136	459
20	133	459
Mean	133	450
S.D.	1.82	5.94
CV (%)	1.37%	1.32%
Range	6	19
MAX.	136	459
MIN.	130	440

Reproducibility within a day

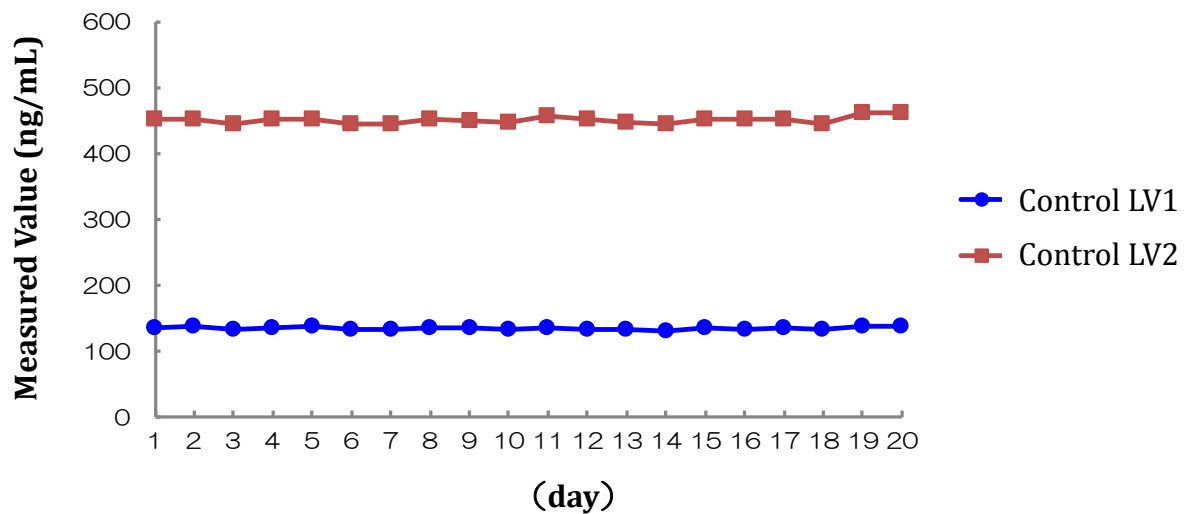
Interval (min)	0	60	120	240	480
Control LV1	133	136	134	136	135
Control LV2	435	441	431	453	451



Inter-day reproducibility

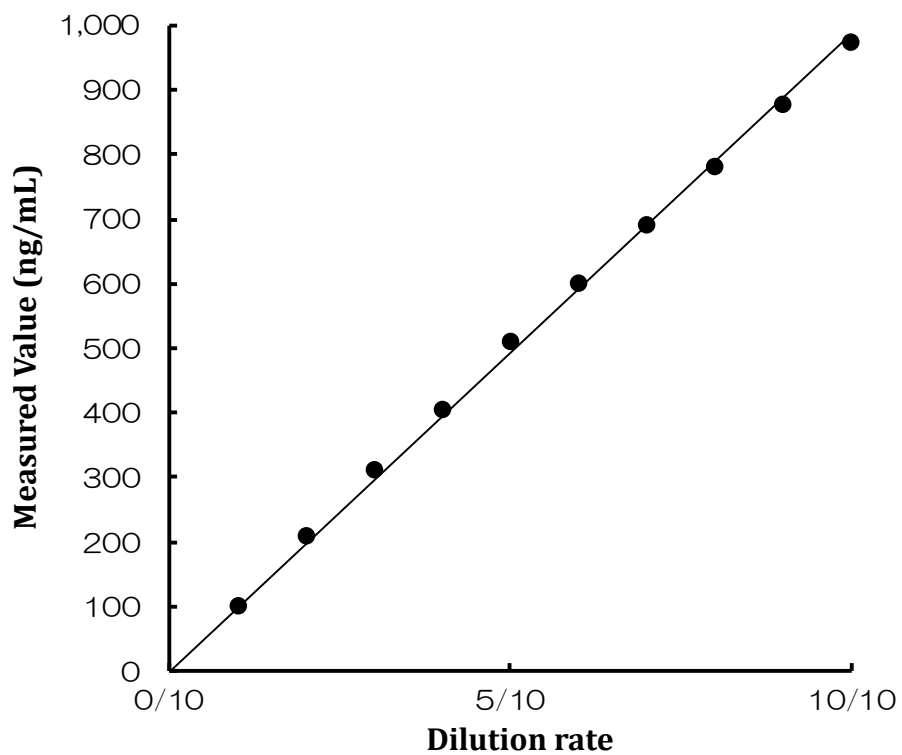
(ng/mL)

Measurement day	1	2	3	4	5
Control LV1	135	137	133	135	137
Control LV2	452	453	445	452	453
Measurement day	6	7	8	9	10
Control LV1	133	132	135	134	132
Control LV2	445	445	452	450	448
Measurement day	11	12	13	14	15
Control LV1	136	134	134	132	135
Control LV2	456	452	448	445	453
Measurement day	16	17	18	19	20
Control LV1	134	135	134	139	138
Control LV2	453	453	444	463	461



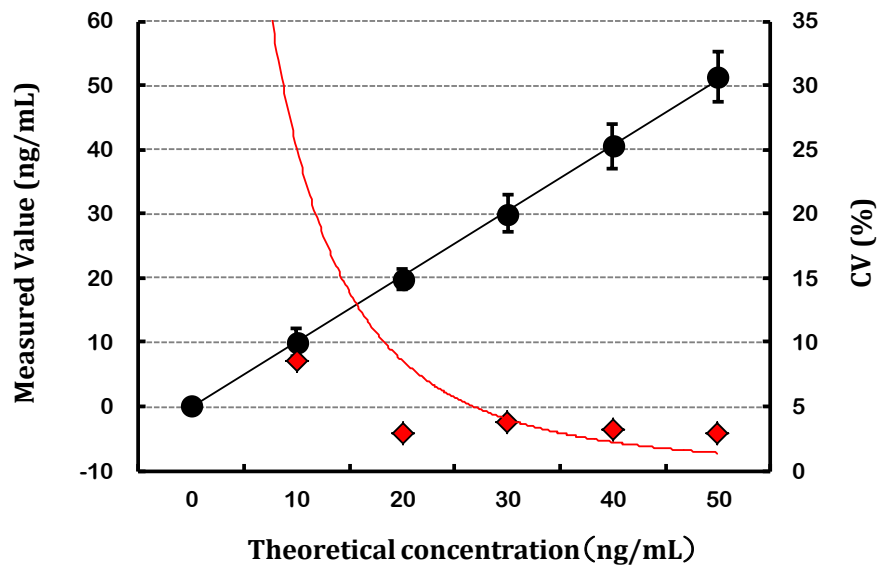
Dilution linearity

Dilution rate	Measured value (ng/mL)
1/10	101
2/10	208
3/10	313
4/10	406
5/10	510
6/10	601
7/10	690
8/10	782
9/10	879
10/10	975



Hb detection limit – 2.6SD method

		(ng/mL)					
Theoretical concentration	0	10	20	30	40	50	
Measured value	0	11	19	31	43	50	
	0	10	19	30	41	53	
	0	10	20	31	42	52	
	0	10	20	31	40	52	
	0	9	19	31	39	53	
	1	9	20	31	40	52	
	0	11	20	31	40	52	
	0	10	20	31	38	51	
	0	9	20	29	39	51	
	0	9	21	31	42	53	
	0	9	20	29	40	49	
	0	11	20	29	40	52	
	0	9	20	28	40	51	
	0	10	21	29	41	54	
	0	11	20	28	40	50	
	0	11	20	30	42	49	
	0	11	20	29	43	51	
	0	10	20	31	40	51	
	0	9	19	29	41	48	
	0	11	19	31	40	52	
N	20	20	20	20	20	20	
Mean	0.1	10.0	19.9	30.0	40.6	51.3	
S.D.	0.22	0.86	0.59	1.12	1.32	1.53	
CV (%)	447.21	8.58	2.96	3.75	3.25	2.97	

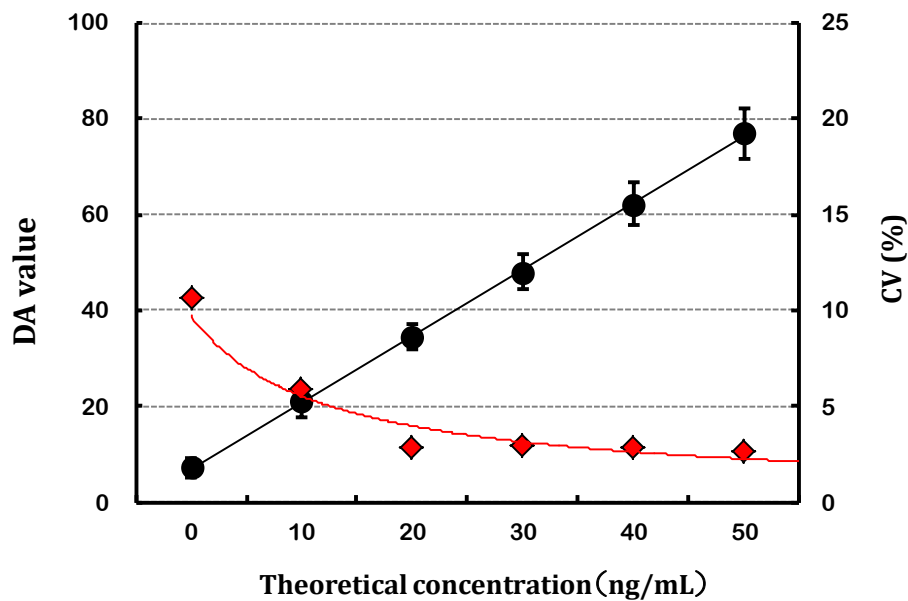


Hb detection limit : 10ng/mL

Hb acceptable limit : 10ng/mL

Hb detection limit – 2.6SD method

Theoretical concentration	0	10	20	30	40	50
DA value	7	22	33	49	66	75
	7	21	33	48	63	79
	8	21	34	49	64	78
	8	21	35	50	61	78
	8	20	33	50	60	79
	9	19	35	49	62	78
	7	22	35	49	62	78
	7	21	35	49	59	77
	7	19	35	47	60	76
	8	19	36	50	64	79
	6	20	35	47	61	74
	7	23	34	47	62	78
	7	20	35	45	61	77
	6	21	36	47	63	81
	7	22	34	46	62	75
	7	23	35	48	64	74
	8	22	35	47	65	76
	6	21	34	49	62	77
	7	20	33	47	63	73
	7	22	33	49	62	78
N	20	20	20	20	20	20
Mean	7.2	21.0	34.4	48.1	62.3	77.0
S.D.	0.77	1.23	0.99	1.41	1.75	2.03
CV (%)	10.66	5.89	2.89	2.93	2.81	2.63

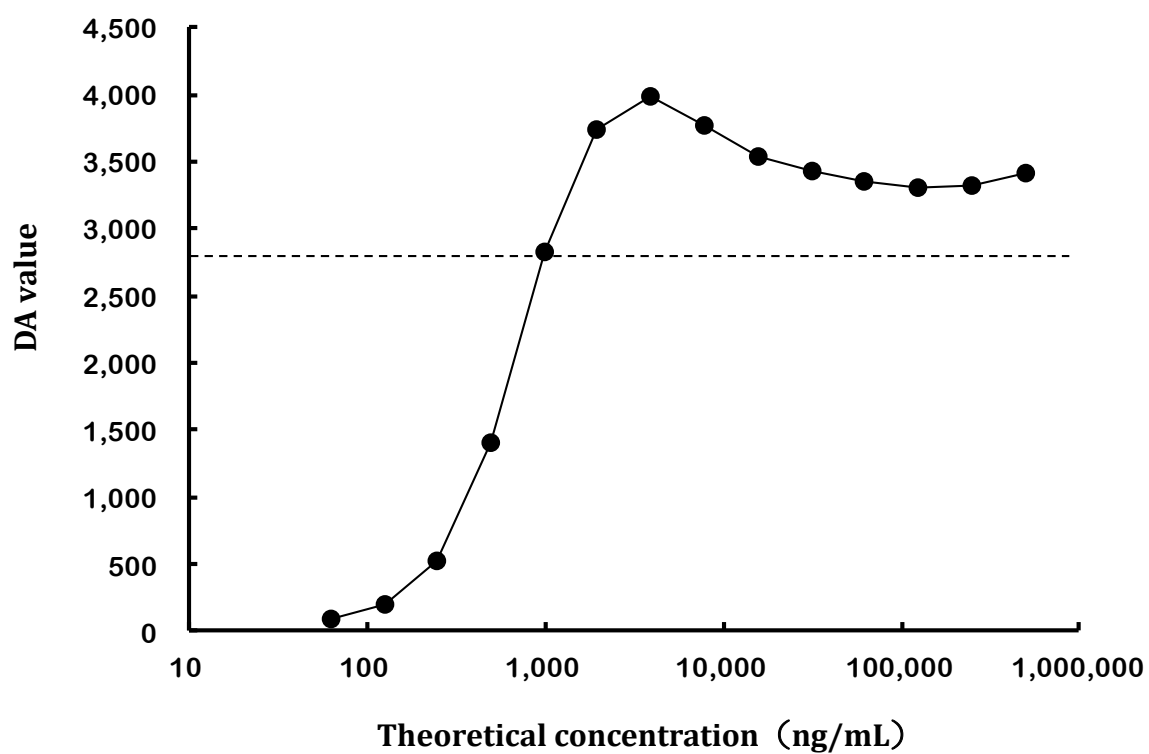


Hb detection limit : 10ng/mL

Hb acceptable limit : 10ng/mL

Hook Effect

Theoretical concentration (ng/mL)	DA value	Measured value (ng/mL) [OR/PRC flag]
0	6	0
62.5	89	63
125	201	124
250	523	253
500	1,403	499
1,000	2,830	1,001
1,953	3,740	OR
3,906	3,996	OR
7,813	3,777	OR
15,625	3,543	OR
31,250	3,427	OR
62,500	3,362	OR
125,000	3,310	OR
250,000	3,325	OR
500,000	3,415	OR



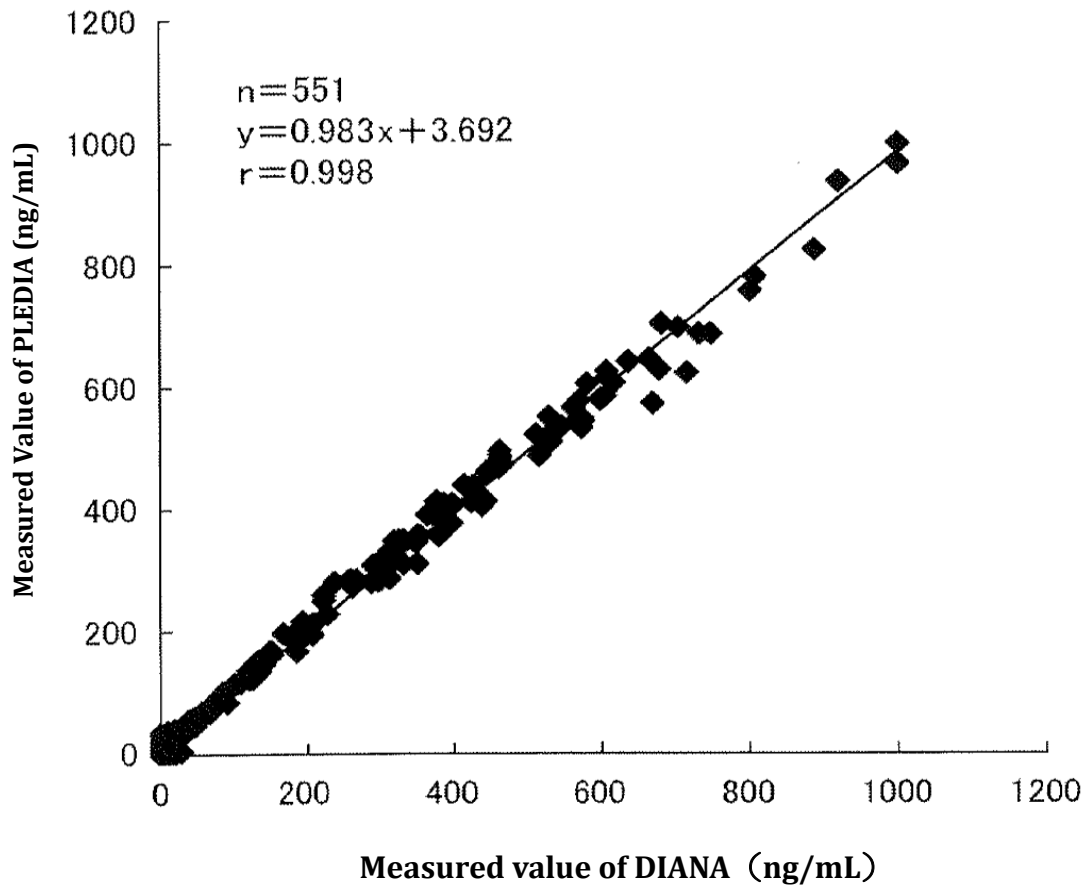
Recovery test

Ratio of 9:1 (sample : added Hb)

Sample No.	Added sample (ng/mL)	Measured value (ng/mL)	Theoretical concentration (ng/mL)	Recovery (%)
Specimen A 82ng/mL	0	82	—	—
	109	199	191	104.2
	210	298	292	102.1
	316	399	398	100.3
Specimen B 188ng/mL	0	188	—	—
	109	288	297	97.0
	210	385	398	96.7
	316	486	504	96.4
Specimen C 274ng/mL	0	274	—	—
	109	372	383	97.1
	210	470	484	97.1
	316	562	590	95.3

Correlation with DIANA

(External evaluation)



TAKU KUSAKA*, et al. : Basic Measurement Performance Evaluation of Fecal Occult Blood Analyzer OC Sensor PLEDIA.

The Journal of Clinical Laboratory Instruments and Reagents, 2014, vol.37 (5), 643-648

* Tokai University Hospital

Carry over

No.	Cell No.	Sample	Mesured Value (ng/mL)	Carry over percentage
①	1	High concentration specimen 500,000ng/mL	OR	
	2	Buffer	4	0.0008%
	3	Buffer	2	0.0004%
	4	Buffer	3	0.0006%
	5	High concentration specimen 500,000ng/mL	OR	
	6	Buffer	2	0.0004%
	7	Buffer	0	0.0000%
	8	Buffer	1	0.0002%
	9	High concentration specimen 500,000ng/mL	OR	
	10	Buffer	2	0.0004%
	AVG		0	0.0004%
②	1	High concentration specimen 250,000ng/mL	OR	
	2	Buffer	0	0.0000%
	3	Buffer	0	0.0000%
	4	Buffer	0	0.0000%
	5	High concentration specimen 250,000ng/mL	OR	
	6	Buffer	0	0.0000%
	7	Buffer	1	0.0004%
	8	Buffer	2	0.0008%
	9	High concentration specimen 250,000ng/mL	OR	
	10	Buffer	1	0.0004%
	AVG	Buffer	0	0.0002%
③	1	High concentration specimen 125,000ng/mL	OR	
	2	Buffer	0	0.0008%
	3	Buffer	0	0.0000%
	4	Buffer	0	0.0000%
	5	High concentration specimen 125,000ng/mL	OR	
	6	Buffer	0	0.0008%
	7	Buffer	0	0.0000%
	8	Buffer	0	0.0000%
	9	High concentration specimen 125,000ng/mL	OR	
	10	Buffer	1	0.0000%
	AVG	Buffer	0	0.0002%
Tortal AVG		Buffer	0	0.0003%