

Comparability Test Report

AFIAS IL-6

AFIAS PCT Plus

AFIAS CRP

Boditech Med R&D center

Boditech Med Marketing team

AFIAS IL-6

1. The purpose of test

Compare the correlation between the control equipment and AFIAS IL-6 measurement values.

2. Test material

- Reagent:

Item	Lot No. / EXP		
AFIAS IL-6	Lot1	ILOXA01G	2020.04.05
	Lot2	ILOXA02G	2020.04.07
	Lot3	ILOXA03G	2020.04.08

- Device

Company		Product name
Boditech Med		AFIAS-6
Reference	Device	Roche Cobas e411
	Reagent	Elecsys IL-6

- Sample

- Spiked sample (n=100)
- Pooled Normal Human Serum (Innovative research, Cat n/o. ISER, Lot no. 20585)
- Control: NIBSC, WHO 1st International Standard for IL-6 (89/548)

3. Test date: 2020.06.22 ~ 2020.06.25

4. Test Result

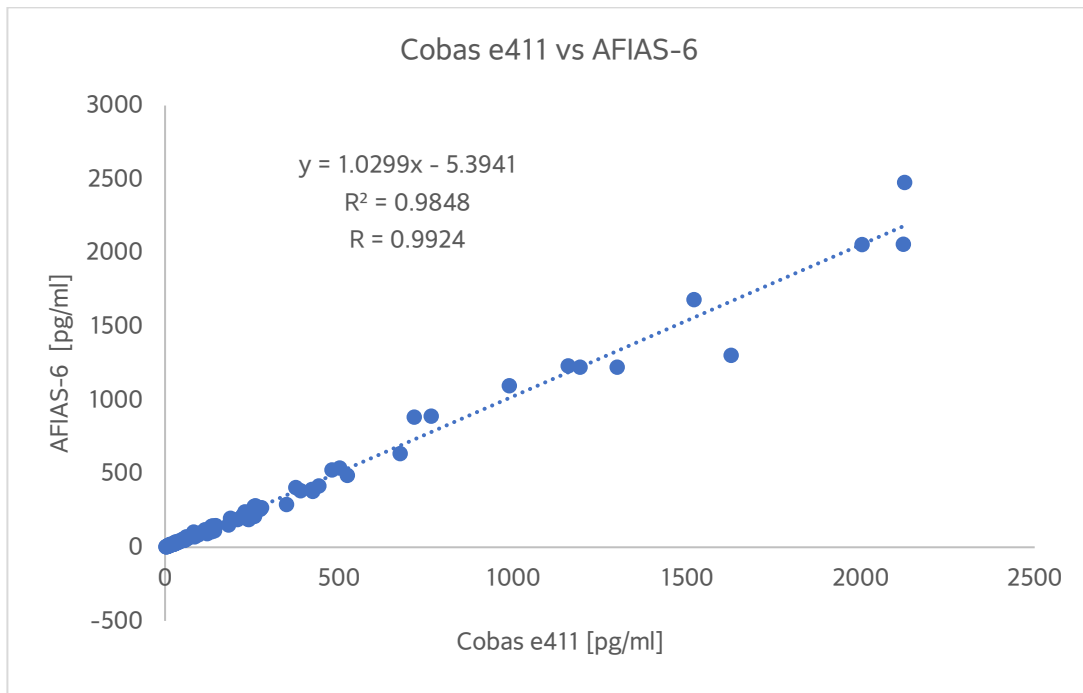
No.	Expected value [pg/ml]	Cobas e411 [pg/ml]	AFIAS-6 [pg/ml]	AFIAS-1 [pg/ml]
1	476.19	442.29	418.20	386.10
2	238.10	238.75	192.35	248.81
3	119.05	114.56	118.61	127.50
4	59.52	65.41	63.48	51.30
5	29.76	30.77	32.16	31.69
6	14.88	14.27	15.33	14.42
7	7.44	6.51	7.86	6.06
8	3.72	2.98	3.78	3.38

9	1666.67	1520.63	1683.82	1728.92
10	833.33	765.83	891.01	708.39
11	416.67	425.28	380.00	425.78
12	208.33	188.19	198.66	203.33
13	104.17	106.76	101.99	103.94
14	52.08	52.18	55.90	55.16
15	26.04	26.11	24.10	22.52
16	13.02	10.57	14.22	13.74
17	1071.43	989.79	1097.78	988.17
18	535.71	501.81	538.74	528.74
19	267.86	256.45	277.98	271.13
20	133.93	133.96	128.32	141.63
21	66.96	62.03	62.71	57.08
22	33.48	29.90	28.09	32.66
23	16.74	16.32	16.38	13.77
24	8.37	7.00	9.07	7.62
25	1428.57	1193.06	1223.74	1309.19
26	714.29	675.97	636.19	645.36
27	357.14	349.51	291.35	299.18
28	178.57	182.75	152.26	152.42
29	89.29	85.10	72.52	91.37
30	44.64	38.40	40.73	43.02
31	22.32	21.85	23.14	24.50
32	1190.48	1159.20	1232.77	1022.61
33	595.24	480.25	527.16	610.21
34	297.62	260.66	282.17	275.01
35	148.81	134.18	144.43	151.39
36	74.40	69.20	67.54	75.48
37	37.20	37.34	35.45	32.15
38	18.60	15.44	15.64	16.06
39	892.86	716.65	885.46	842.79
40	446.43	422.19	394.43	409.69
41	223.21	241.10	189.09	189.36
42	111.61	121.19	93.45	94.36
43	55.80	51.20	51.64	60.50
44	27.90	28.04	29.41	22.46
45	13.95	11.56	12.86	11.50
46	158.73	133.65	138.29	158.34
47	79.37	79.26	83.92	84.02
48	39.68	34.98	34.67	42.63
49	19.84	17.78	19.13	19.64
50	9.92	10.00	9.62	8.12
51	4.96	4.05	4.98	4.73
52	555.56	524.24	489.64	478.38
53	277.78	240.42	233.55	253.57
54	138.89	142.09	113.43	129.90
55	69.44	61.76	71.95	70.08
56	34.72	30.26	36.06	29.16
57	17.36	16.62	17.71	15.53

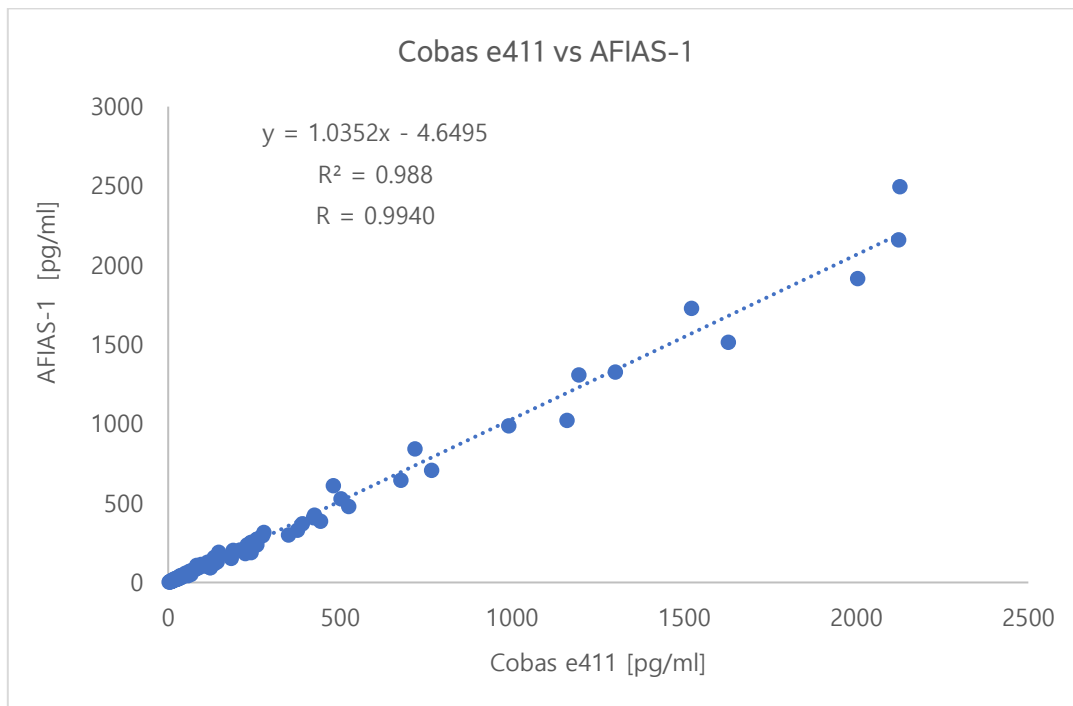
58	178.57	146.34	146.91	190.11
59	89.29	87.98	93.47	93.48
60	44.64	44.81	43.86	45.63
61	22.32	21.50	20.85	24.39
62	11.16	9.31	9.86	12.03
63	238.10	257.77	211.06	237.44
64	297.62	277.95	270.01	316.49
65	148.81	137.45	146.29	145.82
66	29.76	28.46	29.16	24.11
67	14.88	14.09	12.06	12.50
68	396.83	376.01	405.62	331.02
69	297.62	274.18	258.88	294.79
70	198.41	208.3	189.7	205.0
71	99.21	82.5	104.0	108.7
72	49.60	53.7	49.7	47.2
73	24.80	24.5	22.3	20.4
74	12.40	11.9	11.2	13.2
75	223.21	229.4	242.3	237.3
76	111.61	122.3	97.5	94.1
77	55.80	45.7	47.0	50.7
78	27.90	30.2	26.6	27.2
79	13.95	13.2	14.5	11.2
80	39.68	41.1	36.7	35.0
81	19.84	16.24	20.75	20.81
82	9.92	10.00	10.41	10.11
83	4.96	4.18	5.22	5.34
84	7.44	7.36	7.66	7.19
85	416.67	389.82	384.84	369.55
86	208.33	223.63	214.39	183.72
87	104.17	95.65	83.99	113.17
88	52.08	57.04	47.73	44.19
89	26.04	27.60	22.91	23.46
90	13.02	10.52	14.29	12.68
91	133.93	134.51	107.65	119.88
92	66.96	63.21	58.80	71.20
93	33.48	29.32	27.11	34.32
94	16.74	16.31	16.66	15.91
95	8.37	8.32	8.44	7.60
96	2380.95	2126.38	2479.43	2495.19
97	2142.86	2003.68	2057.64	1916.87
98	2023.81	2122.37	2059.33	2160.50
99	1517.86	1627.77	1303.69	1514.24
100	1250.00	1299.61	1224.31	1326.93

5. Comparability analysis

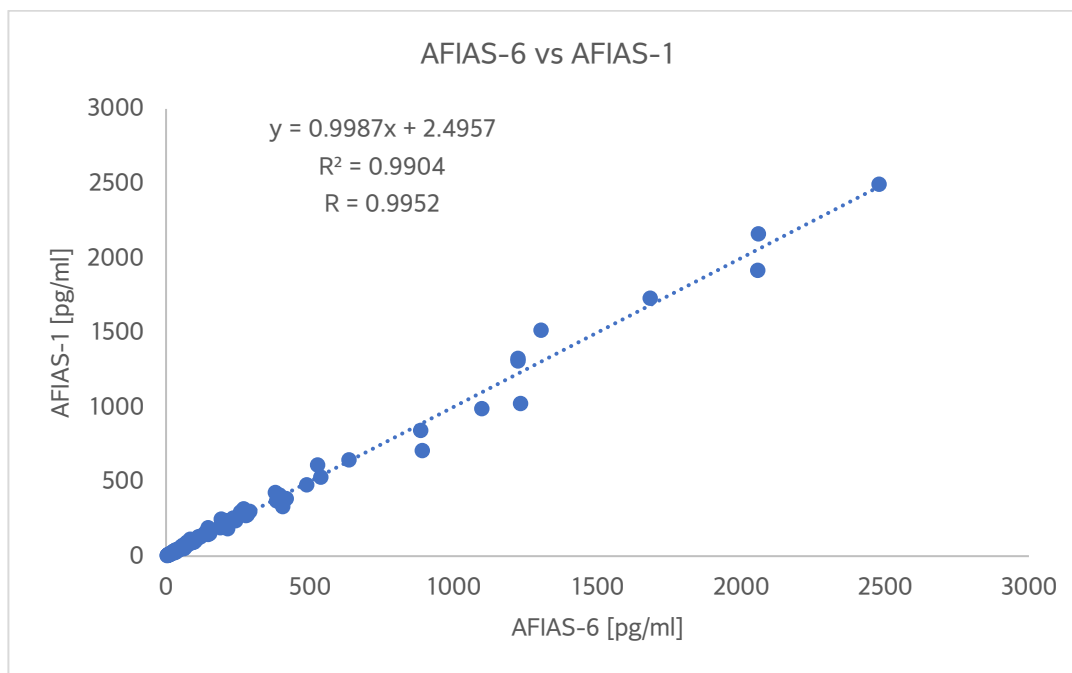
1) Reference vs AFIAS-6



2) Reference vs AFIAS-1



3) AFIAS-6 vs AFIAS-1



Device	Cobas e411	R
AFIAS-6	$y = 1.0299x - 5.3941$	0.9924
AFIAS-1	$y = 1.0352x - 4.6495$	0.9940

6. Conclusion

- As a result of the correlation between the control equipment and the equipment using AFIAS IL-6 (AFIAS-6, AFIAS-1), the correlation coefficient R was 0.9924 and 0.9940, respectively, confirming that the criterion ($R > 0.9$) was satisfied. .
- In addition, as a result of comparing the correlation between the measured values of the AFIAS IL-6 reagent in AFIAS-6 and AFIAS-1, it was confirmed that the correlation coefficient R was 0.9952, which satisfies the criterion.
- Therefore, it was confirmed that AFIAS IL-6 has a correlation with the control equipment, and it can be used for both AFIAS-6 and AFIAS-1.

AFIAS PCT Plus

1. The purpose of test

Compare the correlation between the control equipment and AFIAS PCT Plus measurement values.

2. Test material

- Reagent:

Item	Lot No. / EXP	
AFIAS PCT Plus	PPNBA01G	2018.01.10

- Device

Company	Product name	
Boditech Med	AFIAS-6	
	AFIAS-1	
Reference	Device	Roche Cobas e411
	Reagent	Elecsys BRAHMS PCT
Reference2	Device	BioMerieux mini VIDAS
	Reagent	Vidas BRAHMS PCT

- Sample

- Horse serum spiked PCT

1	Recombinant PCT
2	Horse serum

3. Test date : 2017.03.20 ~ 2017.03.21

4. Test Result

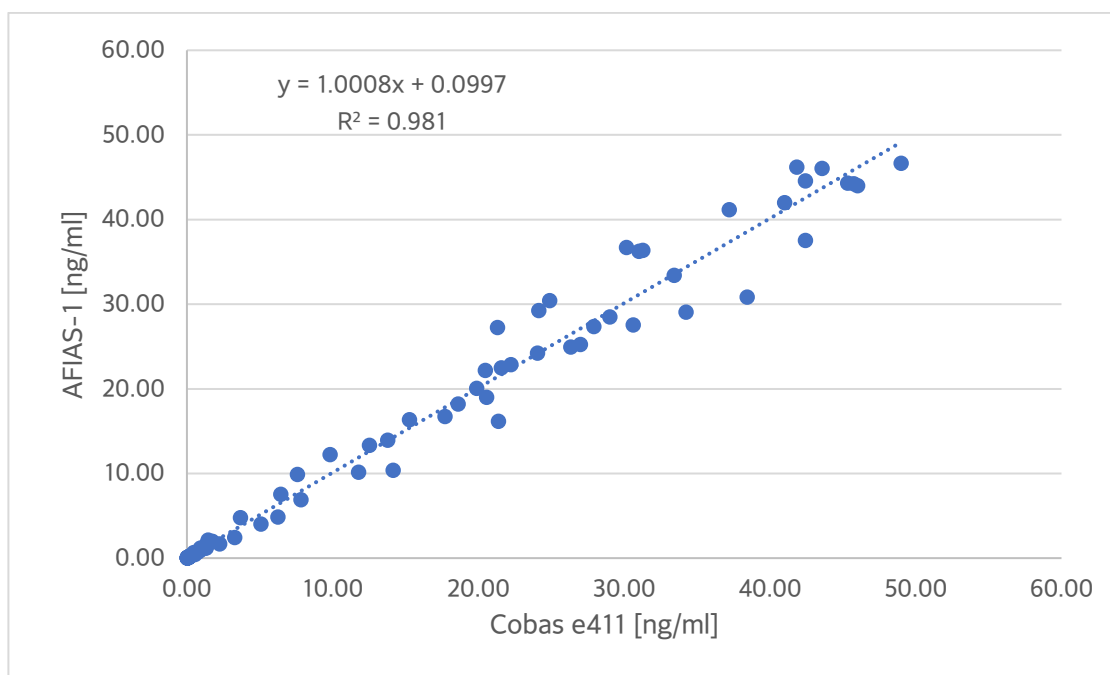
No.	Expected Value [ng/mL]	Cobas e411 [ng/ml]	VIDAS [ng/ml]	AFIAS-1 [ng/ml]	AFIAS-6 [ng/ml]
1	0.025	0.02	0.02	0.02	0.02
2	0.03	0.03	0.02	0.03	0.03
3	0.035	0.03	0.03	0.03	0.03
4	0.04	0.04	0.02	0.03	0.03
5	0.045	0.05	0.05	0.02	0.04
6	0.05	0.03	0.05	0.03	0.03
7	0.055	0.03	0.05	0.05	0.04
8	0.06	0.06	0.05	0.05	0.05
9	0.065	0.06	0.07	0.04	0.06
10	0.07	0.06	0.06	0.07	0.07
11	0.075	0.06	0.04	0.04	0.05
12	0.08	0.06	0.07	0.06	0.05
13	0.085	0.07	0.05	0.07	0.06
14	0.09	0.08	0.06	0.10	0.05
15	0.095	0.09	0.09	0.09	0.05
16	0.1	0.11	0.11	0.09	0.11
17	0.105	0.09	0.08	0.12	0.10
18	0.11	0.13	0.13	0.10	0.09
19	0.115	0.11	0.13	0.10	0.11
20	0.12	0.12	0.11	0.11	0.10
21	0.125	0.11	0.10	0.10	0.15
22	0.13	0.14	0.12	0.14	0.16
23	0.135	0.12	0.12	0.11	0.12
24	0.14	0.15	0.12	0.12	0.16
25	0.145	0.16	0.12	0.15	0.15
26	0.15	0.16	0.13	0.17	0.14
27	0.155	0.14	0.17	0.18	0.14
28	0.16	0.19	0.17	0.19	0.14
29	0.165	0.14	0.14	0.16	0.18
30	0.17	0.16	0.20	0.18	0.20
31	0.175	0.19	0.18	0.17	0.20
32	0.18	0.15	0.20	0.15	0.17
33	0.185	0.19	0.19	0.20	0.17
34	0.19	0.18	0.19	0.16	0.18
35	0.195	0.20	0.18	0.19	0.18
36	0.2	0.19	0.18	0.20	0.19
37	0.3	0.32	0.34	0.32	0.29
38	0.4	0.35	0.39	0.36	0.34

39	0.5	0.55	0.48	0.44	0.55
40	0.6	0.48	0.62	0.64	0.60
41	0.7	0.78	0.82	0.73	0.81
42	0.8	0.91	0.76	0.95	0.96
43	0.9	0.87	1.03	0.91	1.01
44	1	0.93	0.83	1.18	0.89
45	1.1	1.12	1.12	1.11	0.94
46	1.2	1.33	0.97	1.17	1.21
47	1.3	1.07	1.13	1.15	1.44
48	1.4	1.18	1.54	1.16	1.33
49	1.5	1.39	1.36	1.64	1.53
50	1.6	1.36	1.37	1.62	1.69
51	1.7	1.75	1.40	1.94	1.44
52	1.8	1.45	1.99	2.11	1.47
53	1.9	1.75	1.77	1.97	1.83
54	2	2.25	1.83	1.68	1.73
55	3	3.29	3.11	2.42	2.71
56	4	3.68	4.27	4.76	4.69
57	5	5.08	5.02	4.01	5.75
58	6	6.25	6.34	4.86	6.52
59	7	6.44	6.04	7.53	6.10
60	8	7.82	9.29	6.88	8.01
61	9	7.59	8.46	9.90	9.98
62	10	11.77	11.86	10.14	11.96
63	11	9.83	12.16	12.22	13.00
64	12	14.15	14.04	10.39	12.87
65	13	13.78	13.30	13.91	15.17
66	14	12.53	15.49	13.32	15.60
67	15	15.29	15.10	16.34	14.82
68	16	18.61	18.19	18.20	14.26
69	17	17.72	14.29	16.74	16.84
70	18	21.38	17.11	16.16	20.36
71	19	19.88	20.72	20.06	15.60
72	20	20.56	16.96	18.99	21.43
73	21	20.48	19.59	22.16	19.34
74	22	21.58	21.34	22.50	23.00
75	23	22.24	21.41	22.87	19.84
76	24	26.34	23.57	24.93	23.49
77	25	24.05	26.69	24.22	27.21
78	26	21.31	25.73	27.26	27.16
79	27	27.00	24.75	25.23	29.69
80	28	24.16	25.45	29.23	27.49

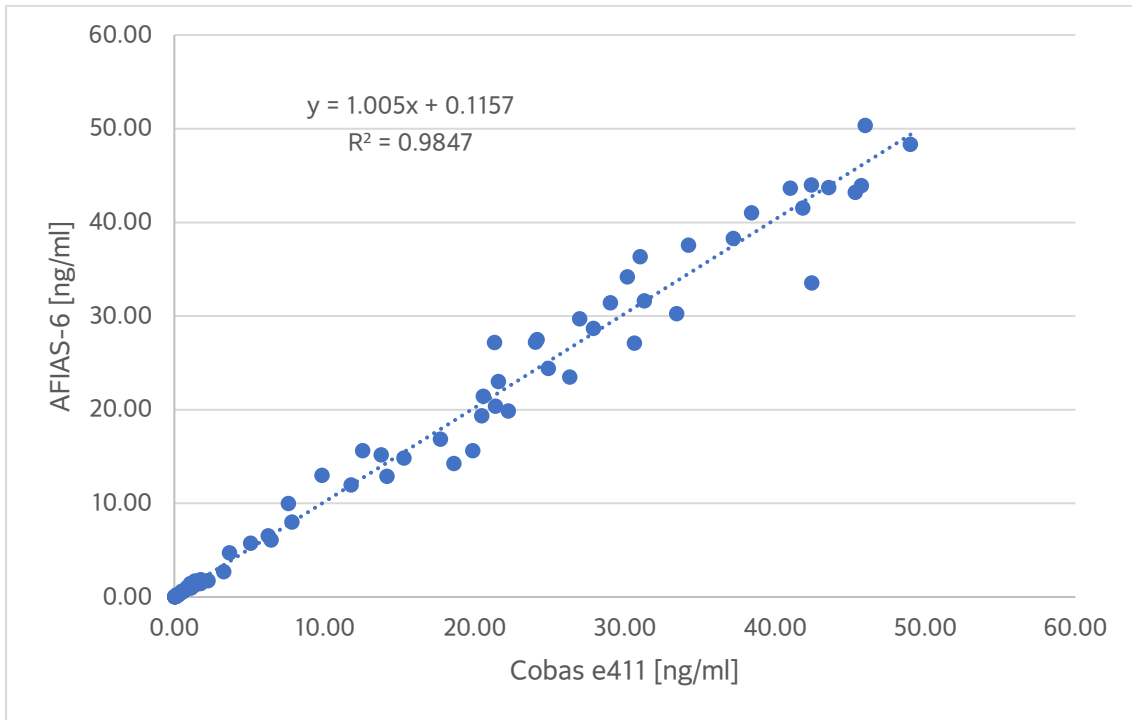
81	29	24.89	30.71	30.43	24.40
82	30	30.64	32.73	27.56	27.10
83	31	33.45	26.81	33.40	30.24
84	32	27.91	27.80	27.36	28.67
85	33	29.03	31.73	28.48	31.40
86	34	31.03	33.09	36.23	36.33
87	35	30.17	28.01	36.71	34.16
88	36	34.25	31.71	29.06	37.57
89	37	31.29	35.86	36.34	31.62
90	38	38.43	30.65	30.85	41.01
91	39	42.45	33.59	37.53	33.54
92	40	37.21	39.89	41.15	38.27
93	41	41.02	42.76	42.00	43.64
94	42	42.43	38.19	44.57	43.99
95	43	41.85	43.65	46.18	41.54
96	44	45.33	39.79	44.30	43.19
97	45	49.02	47.87	46.64	48.33
98	46	46.01	50.29	44.00	50.33
99	47	43.58	50.37	46.04	43.71
100	48	45.75	51.15	44.24	43.90

5. Comparability analysis

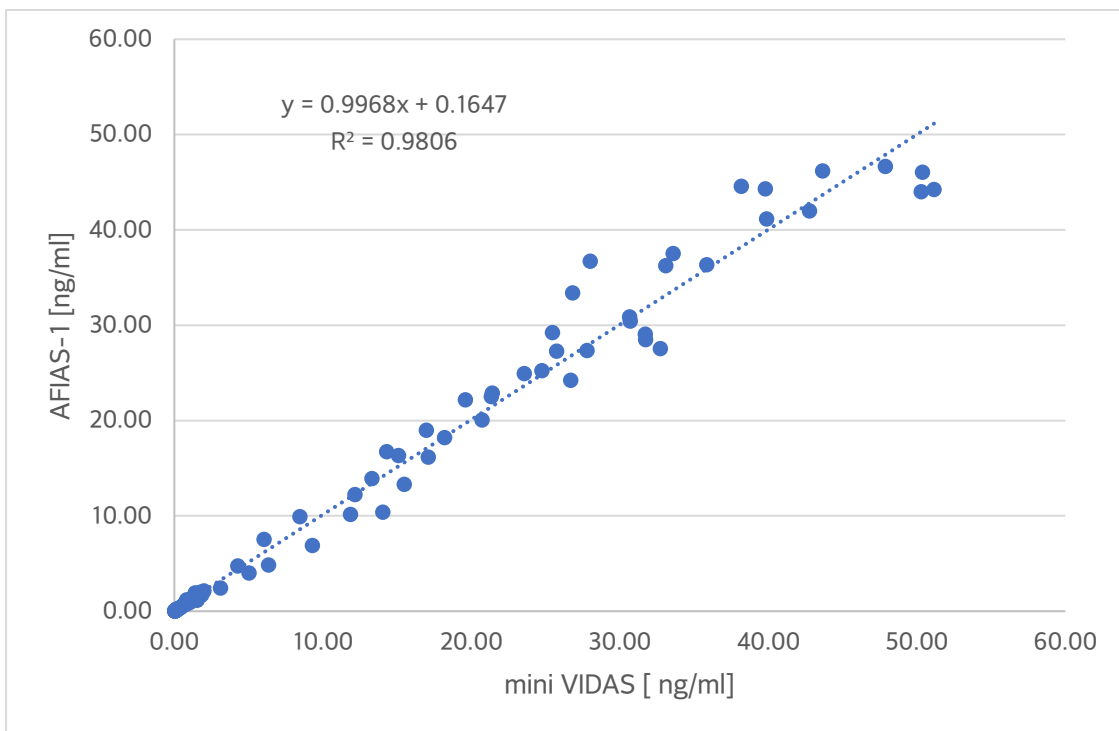
1) Reference vs AFIAS-1



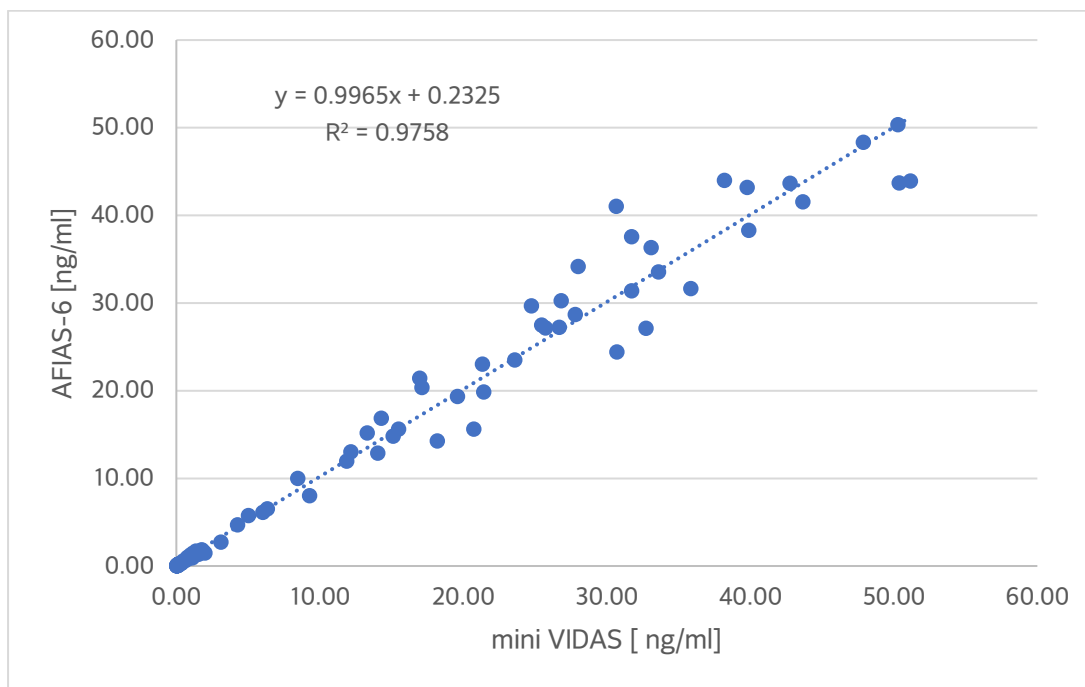
2) Reference vs AFIAS-6



3) Reference2 vs AFIAS-1



4) Reference2 vs AFIAS-6



Device	regression	correlation coefficient (R2)
Cobas e411 vs AFIAS-1	$y = 1.0008x + 0.0997$	$R^2 = 0.981$
Cobas e411 vs AFIAS-6	$y = 1.005x + 0.1157$	$R^2 = 0.9847$
Mini VIDAS vs AFIAS-1	$y = 0.9968x + 0.1647$	$R^2 = 0.9806$
Mini VIDAS vs AFIAS-6	$y = 0.9965x + 0.2325$	$R^2 = 0.9758$

6. Conclusion

- As a result of comparative testing using the reference equipment and the company's equipment, it was confirmed that both linear regression and correlation coefficient (R) judgment criteria were satisfied. Therefore, it was confirmed that the correlation between each device was high.

AFIAS CRP

1. The purpose of test

Compare the correlation between the control equipment and AFIAS CRP measurement values.

2. Test material

- Reagent:

Item	Lot No.
AFIAS CRP	CRPEA57F

- Device

Company	Product name
Boditech Med	AFIAS-6
Reference	Device
	Hitachi 7020
	Reagent
	XM080

3. Test Result

No.	Expected Value[ng/mL]	Hitachi 7020 (mg/L)	AFIAS-6 (mg/L)
1	3.1	2.6	3.01
2	3.3	2.8	3.27
3	3.6	3.2	3.47
4	4.1	3.3	3.99
5	4.3	3.5	3.52
6	4.8	4.1	4.78
7	5.4	3	4.97
8	5.6	4.6	4.4
9	6	5	5.78
10	6.5	5.4	6.65
11	7.4	7.2	8.13
12	7.8	7.1	8.01
13	8.4	7	7.04
14	8.5	7.8	8.6
15	8.7	7.8	8.53
16	9.1	8.5	9.9
17	9.4	8.5	9.9
18	9.9	9.7	10.5
19	10.1	9.6	10.02
20	10.6	11	10.92

21	23.9	58.8	64.19
22	33.8	33.5	35.36
23	37.2	36.2	39.7
24	48.6	44.7	49.63
25	58.5	54.1	52.73
26	65.2	58.3	65.84
27	71.8	63.8	74.36
28	83.6	75.9	91.32
29	91	84.9	107.4
30	93.4	87.7	107.33
31	99.9	91.7	102
32	113.8	102.6	110.26
33	115.7	105.1	113.78
34	117.7	110.9	106.54
35	119.9	108.6	103.36
36	137.2	121.4	123.64
37	146.8	127.8	130.07
38	152.4	143.6	146.21
39	170.1	158.3	163.77
40	181.3	171.1	169.02
41	206.8	204.5	181.19
42	213.6	195.3	206.96
43	222.9	141.9	148.68
44	231	233.5	255.41
45	263.4	262.5	246.64
46	275.9	266.4	275.07
47	371.3	358.1	292.25

4. Comparability Analysis

