

## 萬芳醫院 檢驗科

## Comparison評估總表

項次	檢驗項目	$R^2 \geq 0.95$	Bias%	允收標準TEa	測試結果
1	Cyfra 21-1	0.9907	7.59%	27.9%	Pass
2	Insulin	0.9995	-2.25%	25.0%	Pass
3	LH	0.9961	0.83%	27.9%	Pass
4	NSE	0.2619	41.82%	10.0%	Fail
5	SCC	0.9812	-2.79%	45.8%	Pass
6	TRAb	0.9744	-13.66%	30.0%	Pass
7	Anti-HBc	Agreement	100%	Agreement = 100%	Pass
		Pos Agreement	100%		Pass
		Neg Agreement	100%		Pass
8	Anti-HBc IgM	Agreement	100%	Agreement = 100%	Pass
		Pos Agreement	#DIV/0!		#DIV/0!
		Neg Agreement	100%		Pass
9	HAVAb IgM	Agreement	100%	Agreement = 100%	Pass
		Pos Agreement	#DIV/0!		#DIV/0!
		Neg Agreement	100%		Pass
10	HBeAg	Agreement	100%	Agreement = 100%	Pass
		Pos Agreement	100%		Pass
		Neg Agreement	100%		Pass

# Method Comparison

項目名稱：Cyfra 21-1

測試機台(Y)：Alinity i (green)

項目單位：ng/mL

測試機台編號：Ai26836

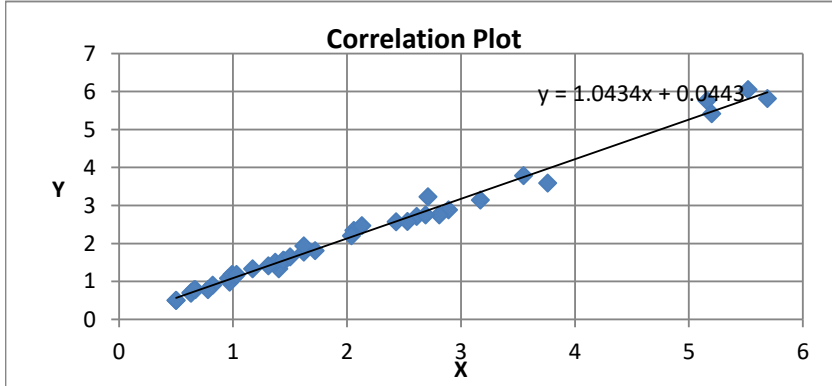
允收標準： $R^2 \geq 0.95$  <TEa 28%

原始機台(X)：Alinity i (red)

測試日期：2021/8/9

原始機台編號：Ai26836

測試結果：



N =	40
R2 =	0.9907
R2 $\geq$ 0.95	Pass

Y = a X + b	
Slope (a) =	1.0434
Intercept (b) =	0.0443

X Mean =	2.04
X Maximum =	5.69
X Minimum =	0.5
Y Mean =	2.18
Y Maximum =	6.05
Y Minimum =	0.5
Average Diff% =	7.59%

測試數據：

編號	檢體編號	X	Y	Diff
1	1	5.16	5.76	0.6
2	2	0.97	0.98	0.01
3	3	0.63	0.7	0.07
4	4	2.71	3.23	0.52
5	5	2.06	2.34	0.28
6	6	1.02	1.14	0.12
7	7	0.82	0.9	0.08
8	8	0.96	1.08	0.12
9	9	3.55	3.78	0.23
10	10	0.67	0.78	0.11
11	11	0.63	0.69	0.06
12	12	3.76	3.59	-0.17
13	13	1.40	1.33	-0.07
14	14	5.69	5.81	0.12
15	15	2.89	2.88	-0.01
16	16	3.17	3.14	-0.03
17	17	2.43	2.57	0.14
18	18	1.17	1.33	0.16
19	19	2.81	2.75	-0.06
20	20	0.66	0.78	0.12

編號	檢體編號	X	Y	Diff
21	21	1.72	1.81	0.09
22	22	0.99	1.18	0.19
23	23	1.62	1.77	0.15
24	24	5.52	6.05	0.53
25	25	1.45	1.54	0.09
26	26	1.37	1.50	0.13
27	27	2.61	2.71	0.10
28	28	2.04	2.2	0.16
29	29	0.50	0.5	0.00
30	30	2.13	2.47	0.34
31	31	1.62	1.93	0.31
32	32	5.20	5.41	0.21
33	33	0.50	0.5	0.00
34	34	0.78	0.78	0.00
35	35	1.03	1.18	0.15
36	36	1.44	1.56	0.12
37	37	2.53	2.58	0.05
38	38	1.31	1.41	0.10
39	39	2.69	2.75	0.06
40	40	1.50	1.64	0.14

# Method Comparison

項目名稱：Insulin

測試機台(Y)：Alinity i (green)

項目單位：μU/mL

測試機台編號：Ai26835

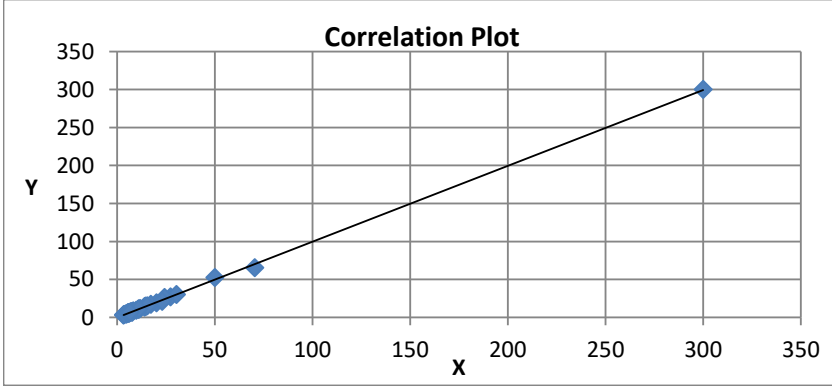
允收標準：R<sup>2</sup> ≥ 0.95 <TEa 25%

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai26835

測試結果：



N =	40
R <sup>2</sup> =	0.9995
R <sup>2</sup> ≥ 0.95	Pass

Y = a X + b	
Slope (a) =	0.9986
Intercept (b) =	-0.2284

X Mean =	20.31
X Maximum =	300
X Minimum =	3.3
Y Mean =	20.05
Y Maximum =	300
Y Minimum =	3.2
Average Diff% =	-2.25%

測試數據：

編號	檢體編號	X	Y	Diff
1	1	300	300	0
2	2	6.1	5.9	-0.2
3	3	3.4	3.3	-0.1
4	4	20.2	19.1	-1.1
5	5	11.1	10.7	-0.4
6	6	70.4	65.3	-5.1
7	7	14.6	14.5	-0.10
8	8	14.0	13.4	-0.60
9	9	7.6	6.7	-0.90
10	10	17.2	17.2	0.00
11	11	5.6	6.1	0.50
12	12	27.3	27	-0.30
13	13	7.3	7.2	-0.10
14	14	6.3	6	-0.30
15	15	3.3	3.2	-0.10
16	16	5.2	5	-0.20
17	17	7.4	7.2	-0.20
18	18	10.8	10.9	0.10
19	19	30.3	30	-0.30
20	20	5.6	5.2	-0.40

編號	檢體編號	X	Y	Diff
21	21	50.0	52.3	2.30
22	22	4.8	4.0	-0.80
23	23	14.5	14.7	0.20
24	24	8.3	8.3	0.00
25	25	4.5	4.4	-0.10
26	26	24.2	26.1	1.90
27	27	14.0	14.0	0.00
28	28	11.7	11.5	-0.20
29	29	6.4	6.2	-0.20
30	30	3.7	3.7	0.00
31	31	6.9	7.3	0.40
32	32	15.5	15.0	-0.50
33	33	6.3	5.9	-0.40
34	34	5.3	5.2	-0.10
35	35	5.8	5.7	-0.10
36	36	9.8	9.4	-0.40
37	37	11.0	10.8	-0.20
38	38	6.3	6.2	-0.10
39	39	6.6	6.5	-0.10
40	40	23.0	20.9	-2.10

# Method Comparison

項目名稱：LH

測試機台(Y)：Alinity i (green)

項目單位：mIU/mL

測試機台編號：Ai26836

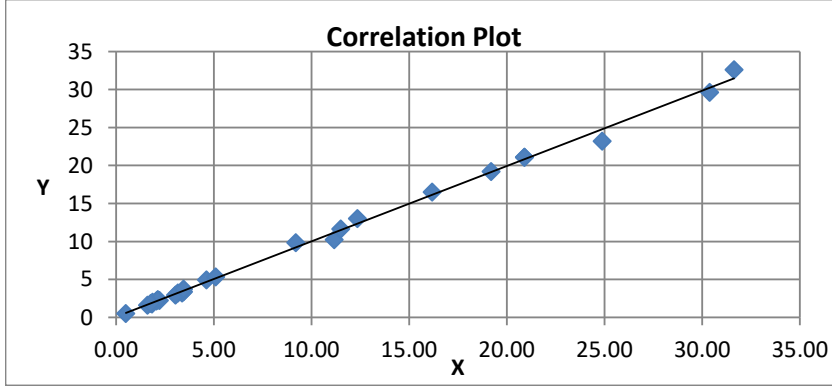
允收標準： $R^2 \geq 0.95$  <TEa 28%

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai26836

測試結果：



N =	40
R2 =	0.9961
$R2 \geq 0.95$	Pass

Y = a X + b	
Slope (a) =	0.9976
Intercept (b) =	0.0523

X Mean =	9.79
X Maximum =	31.630
X Minimum =	0.500
Y Mean =	9.82
Y Maximum =	32.59
Y Minimum =	0.48
Average Diff% =	0.83%

測試數據：

編號	檢體編號	X	Y	Diff
1	1	30.39	29.62	-0.77
2	2	1.86	1.97	0.11
3	3	31.63	32.59	0.96
4	4	12.35	12.98	0.63
5	5	4.62	4.91	0.29
6	6	20.91	21.08	0.17
7	7	3.38	3.2	-0.18
8	8	1.84	1.74	-0.10
9	9	3.45	3.35	-0.10
10	10	2.21	2.21	0.00
11	11	3.16	3.19	0.03
12	12	11.17	10.2	-0.97
13	13	11.50	11.64	0.14
14	14	3.04	2.91	-0.13
15	15	1.61	1.58	-0.03
16	16	24.88	23.19	-1.69
17	17	2.14	2.29	0.15
18	18	19.19	19.21	0.02
19	19	5.10	5.33	0.23
20	20	20.91	21.08	0.17

編號	檢體編號	X	Y	Diff
21	21	2.06	2.13	0.07
22	22	2.13	2.31	0.18
23	23	9.20	9.82	0.62
24	24	1.77	1.82	0.05
25	25	16.18	16.50	0.32
26	26	3.45	3.70	0.25
27	27	0.50	0.48	-0.02
28	28	4.50	4.81	0.31
29	29	2.69	2.74	0.05
30	30	18.46	17.68	-0.78
31	31	18.98	20.25	1.27
32	32	2.07	2.17	0.10
33	33	1.98	1.98	0.00
34	34	3.36	3.34	-0.02
35	35	20.59	20.93	0.34
36	36	26.25	24.47	-1.78
37	37	5.06	4.88	-0.18
38	38	3.68	3.72	0.04
39	39	30.90	32.43	1.53
40	40	2.62	2.51	-0.11

# Method Comparison

項目名稱：NSE

測試機台(Y)：Alinity i (green)

項目單位：ng/mL

測試機台編號：Ai26836

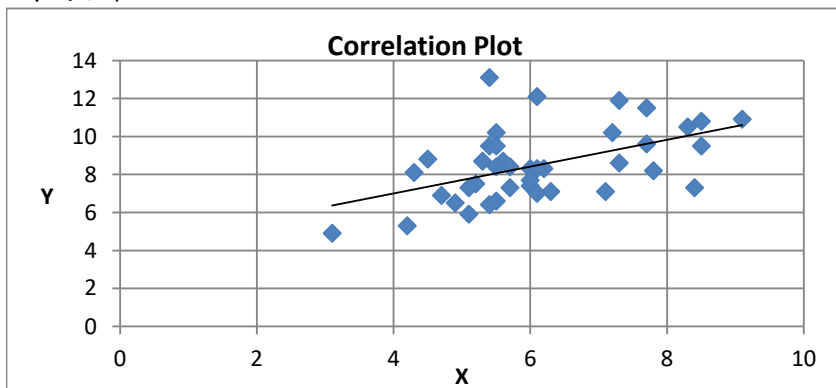
允收標準： $R^2 \geq 0.95$  <TEa 10%

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai26836

測試結果：



N =	40
R2 =	0.2619
R2 $\geq$ 0.95	Fail

Y = a X + b	
Slope (a) =	0.7064
Intercept (b) =	4.1758

X Mean =	6.13
X Maximum =	9.1
X Minimum =	3.1
Y Mean =	8.51
Y Maximum =	13.1
Y Minimum =	4.9
Average Diff% =	41.82%

測試數據：

編號	檢體編號	X	Y	Diff
1	1	8.5	10.8	2.3
2	2	4.9	6.5	1.6
3	3	5.2	7.5	2.3
4	4	4.5	8.8	4.3
5	5	4.3	8.1	3.8
6	6	5.1	7.3	2.2
7	7	3.10	4.9	1.80
8	8	5.60	8.7	3.10
9	9	5.40	13.1	7.70
10	10	5.40	9.5	4.10
11	11	6.00	8.3	2.30
12	12	8.40	7.3	-1.10
13	13	7.30	11.9	4.60
14	14	4.70	6.9	2.20
15	15	6.00	7.4	1.40
16	16	6.00	7.7	1.70
17	17	6.20	8.3	2.10
18	18	5.40	6.4	1.00
19	19	6.10	8.3	2.20
20	20	5.70	7.3	1.60

編號	檢體編號	X	Y	Diff
21	21	5.30	8.70	3.40
22	22	5.50	10.20	4.70
23	23	5.50	9.50	4.00
24	24	7.70	11.50	3.80
25	25	7.20	10.20	3.00
26	26	6.10	12.10	6.00
27	27	5.70	8.4	2.70
28	28	7.80	8.2	0.40
29	29	5.50	8.4	2.90
30	30	8.30	10.5	2.20
31	31	9.10	10.9	1.80
32	32	8.50	9.5	1.00
33	33	7.10	7.1	0.00
34	34	6.30	7.1	0.80
35	35	7.30	8.6	1.30
36	36	6.10	7	0.90
37	37	4.20	5.3	1.10
38	38	7.70	9.6	1.90
39	39	5.10	5.9	0.80
40	40	5.50	6.6	1.10

# Method Comparison

項目名稱：SCC

測試機台(Y)：Alinity i (green)

項目單位：ng/mL

測試機台編號：Ai26836

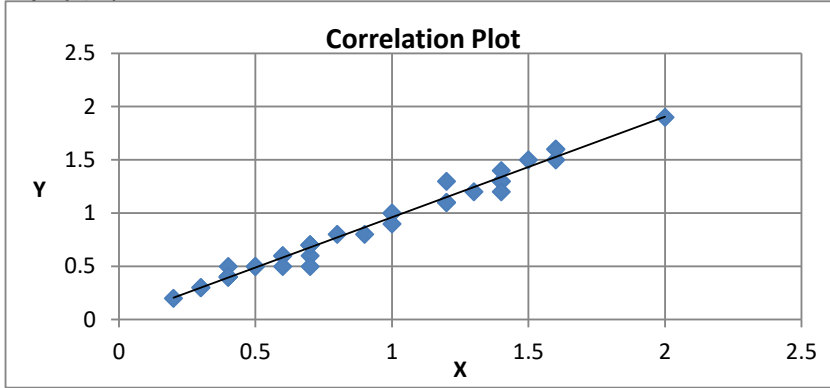
允收標準： $R^2 \geq 0.95$  <TEa 46%

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai26836

測試結果：



N =	40
R <sup>2</sup> =	0.9812
R <sup>2</sup> ≥ 0.95	Pass

Y = a X + b	
Slope (a) =	0.9447
Intercept (b) =	0.0156

X Mean =	0.87
X Maximum =	2
X Minimum =	0.2
Y Mean =	0.84
Y Maximum =	1.9
Y Minimum =	0.2
Average Diff% =	-2.79%

測試數據：

編號	檢體編號	X	Y	Diff
1	1	1.4	1.3	-0.1
2	2	0.7	0.7	0
3	3	0.5	0.5	0
4	4	1.6	1.6	0
5	5	0.3	0.3	0
6	6	0.7	0.6	-0.1
7	7	2.00	1.9	-0.10
8	8	1.30	1.2	-0.10
9	9	1.40	1.3	-0.10
10	10	1.60	1.5	-0.10
11	11	0.60	0.6	0.00
12	12	0.40	0.4	0.00
13	13	0.50	0.5	0.00
14	14	1.40	1.4	0.00
15	15	0.60	0.6	0.00
16	16	0.20	0.2	0.00
17	17	1.20	1.1	-0.10
18	18	0.80	0.8	0.00
19	19	0.40	0.4	0.00
20	20	0.40	0.4	0.00

編號	檢體編號	X	Y	Diff
21	21	0.30	0.30	0.00
22	22	0.40	0.50	0.10
23	23	1.20	1.30	0.10
24	24	0.70	0.70	0.00
25	25	0.70	0.50	-0.20
26	26	1.60	1.60	0.00
27	27	1.00	1	0.00
28	28	0.70	0.7	0.00
29	29	0.70	0.7	0.00
30	30	0.40	0.4	0.00
31	31	0.40	0.4	0.00
32	32	1.50	1.5	0.00
33	33	0.40	0.4	0.00
34	34	1.40	1.2	-0.20
35	35	1.20	1.1	-0.10
36	36	0.70	0.7	0.00
37	37	1.00	1	0.00
38	38	1.00	0.9	-0.10
39	39	0.60	0.5	-0.10
40	40	0.90	0.8	-0.10

# Method Comparison

項目名稱：TRAb

測試機台(Y)：Alinity i (green)

項目單位：IU/L

測試機台編號：Ai26835

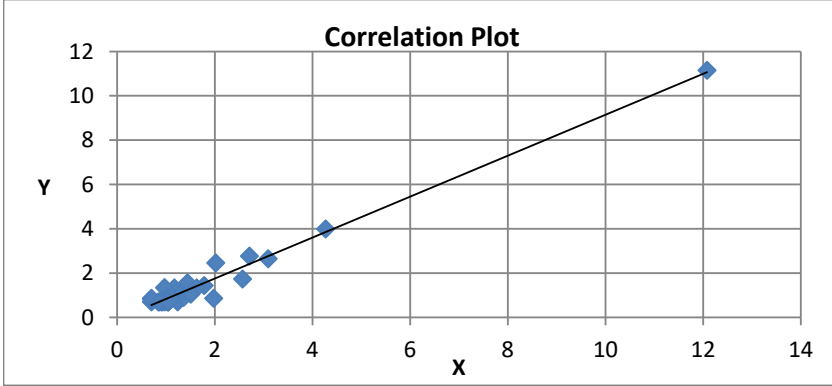
允收標準： $R^2 \geq 0.95$  <TEa 30%

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai26835

測試結果：



N =	40
R <sup>2</sup> =	0.9744
R <sup>2</sup> ≥ 0.95	Pass

Y = a X + b	
Slope (a) =	0.9240
Intercept (b) =	-0.0929

X Mean =	1.61
X Maximum =	12.08
X Minimum =	0.7
Y Mean =	1.40
Y Maximum =	11.15
Y Minimum =	0.7
Average Diff% =	-13.66%

測試數據：

編號	檢體編號	X	Y	Diff
1	1	1.08	0.84	-0.24
2	2	2.57	1.73	-0.84
3	3	2.71	2.76	0.05
4	4	0.91	0.7	-0.21
5	5	0.84	0.7	-0.14
6	6	2.02	2.46	0.44
7	7	0.96	0.85	-0.11
8	8	1.01	0.85	-0.16
9	9	0.70	0.7	0.00
10	10	1.05	1.03	-0.02
11	11	0.70	0.85	0.15
12	12	1.01	0.96	-0.05
13	13	1.24	0.7	-0.54
14	14	0.93	0.7	-0.23
15	15	1.16	1.06	-0.10
16	16	1.37	1.04	-0.33
17	17	1.17	1.32	0.15
18	18	1.36	0.89	-0.47
19	19	0.70	0.82	0.12
20	20	1.00	0.88	-0.12

編號	檢體編號	X	Y	Diff
21	21	0.97	1.34	0.37
22	22	3.09	2.64	-0.45
23	23	0.98	0.70	-0.28
24	24	1.44	1.55	0.11
25	25	1.28	1.04	-0.24
26	26	1.05	0.70	-0.35
27	27	1.78	1.43	-0.35
28	28	1.63	1.33	-0.30
29	29	4.27	3.99	-0.28
30	30	1.11	0.87	-0.24
31	31	1.98	0.85	-1.13
32	32	1.51	1.05	-0.46
33	33	12.08	11.15	-0.93
34	34	0.70	0.83	0.13
35	35	1.04	0.7	-0.34
36	36	1.05	0.71	-0.34
37	37	1.03	0.87	-0.16
38	38	1.10	0.88	-0.22
39	39	0.87	0.7	-0.17
40	40	1.04	0.7	-0.34

# Method Comparison

項目名稱：Anti-HBc

測試機台(Y)：Alinity i (green)

項目單位：S/CO

測試機台編號：Ai27152

允收標準：Agreement  $\geq 90\%$

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai27152

測試結果：

	X Reactive	X Nonreactive	Total
Y Reactive	26	0	26
Y Nonreactive	0	14	14
Total	26	14	40

Agreement	100.0%
Pos Agreement	100.0%
Neg Agreement	100.0%

Interpretation：

判讀	判讀標準
X Reactive	$\geq 1$ S/CO
X Nonreactive	$< 1$ S/CO
Y Reactive	$\geq 1$ S/CO
Y Nonreactive	$< 1$ S/CO

說明：

1. Agreement = 100%，驗證通過。

測試數據：

編號	檢體編號	X	Y	結果
1	1	2.01	1.68	一致
2	2	1.56	1.68	一致
3	3	1.86	1.72	一致
4	4	0.75	0.76	一致
5	5	1.19	1.08	一致
6	6	0.02	0.03	一致
7	7	1.89	1.60	一致
8	8	1.96	1.62	一致
9	9	1.95	1.68	一致
10	10	1.07	1.01	一致
11	11	1.63	1.38	一致
12	12	1.66	1.64	一致
13	13	0.12	0.12	一致
14	14	1.69	1.62	一致
15	15	1.77	1.74	一致
16	16	0.19	0.18	一致
17	17	0.02	0.02	一致
18	18	1.50	1.42	一致
19	19	1.09	1.00	一致
20	20	1.49	1.41	一致

編號	檢體編號	X	Y	結果
21	21	1.89	1.59	一致
22	22	1.85	1.71	一致
23	23	0.02	0.02	一致
24	24	1.91	1.74	一致
25	25	0.38	0.37	一致
26	26	1.32	1.21	一致
27	27	1.88	1.51	一致
28	28	0.02	0.02	一致
29	29	1.35	1.19	一致
30	30	1.79	1.68	一致
31	31	0.02	0.02	一致
32	32	0.02	0.02	一致
33	33	1.74	1.62	一致
34	34	0.02	0.02	一致
35	35	1.49	1.29	一致
36	36	0.12	0.11	一致
37	37	0.02	0.02	一致
38	38	1.43	1.32	一致
39	39	1.50	1.34	一致
40	40	0.02	0.02	一致

# Method Comparison

項目名稱：Anti-HBcM

測試機台(Y)：Alinity i (green)

項目單位：S/CO

測試機台編號：Ai27152

允收標準：Agreement  $\geq 90\%$

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai27152

測試結果：

	X Reactive	X Nonreactive	Total
Y Reactive	0	0	0
Y Nonreactive	0	40	40
Total	0	40	40

Agreement	100.0%
Pos Agreement	#DIV/0!
Neg Agreement	100.0%

Interpretation：

判讀	判讀標準
X Reactive	$\geq 1$ S/CO
X Nonreactive	$< 1$ S/CO
Y Reactive	$\geq 1$ S/CO
Y Nonreactive	$< 1$ S/CO

說明：

1. Agreement = 100%，驗證通過。

測試數據：

編號	檢體編號	X	Y	結果
1	1	0.08	0.08	一致
2	2	0.08	0.09	一致
3	3	0.11	0.11	一致
4	4	0.07	0.08	一致
5	5	0.06	0.06	一致
6	6	0.12	0.12	一致
7	7	0.07	0.07	一致
8	8	0.06	0.07	一致
9	9	0.07	0.07	一致
10	10	0.09	0.09	一致
11	11	0.13	0.13	一致
12	12	0.08	0.08	一致
13	13	0.06	0.07	一致
14	14	0.08	0.08	一致
15	15	0.18	0.18	一致
16	16	0.12	0.11	一致
17	17	0.16	0.15	一致
18	18	0.13	0.12	一致
19	19	0.06	0.06	一致
20	20	0.1	0.1	一致

編號	檢體編號	X	Y	結果
21	21	0.12	0.13	一致
22	22	0.07	0.07	一致
23	23	0.15	0.16	一致
24	24	0.08	0.08	一致
25	25	0.07	0.07	一致
26	26	0.08	0.08	一致
27	27	0.08	0.08	一致
28	28	0.14	0.16	一致
29	29	0.10	0.10	一致
30	30	0.12	0.12	一致
31	31	0.06	0.07	一致
32	32	0.07	0.07	一致
33	33	0.10	0.10	一致
34	34	0.07	0.07	一致
35	35	0.10	0.10	一致
36	36	0.07	0.06	一致
37	37	0.10	0.11	一致
38	38	0.09	0.09	一致
39	39	0.07	0.07	一致
40	40	0.07	0.08	一致

# Method Comparison

項目名稱：HAVAb IgM

測試機台(Y)：Alinity i (green)

項目單位：S/CO

測試機台編號：Ai27152

允收標準：Agreement  $\geq$ 90%

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai27152

測試結果：

	X Reactive	X Nonreactive	Total
Y Reactive	0	0	0
Y Nonreactive	0	40	40
Total	0	40	40

Agreement	100.0%
Pos Agreement	#DIV/0!
Neg Agreement	100.0%

Interpretation：

判讀	判讀標準
X Reactive	> 1.2 S/CO
X Grayzone	0.8-1.2 S/CO
X Nonreactive	< 0.8 S/CO
Y Reactive	> 1.2 S/CO
Y Grayzone	0.8-1.2 S/CO
Y Nonreactive	< 0.8 S/CO

說明：

1. Agreement = 100%，驗證通過。

測試數據：

編號	檢體編號	X	Y	結果
1	1	0.12	0.14	一致
2	2	0.09	0.11	一致
3	3	0.1	0.08	一致
4	4	0.18	0.17	一致
5	5	0.08	0.08	一致
6	6	0.11	0.14	一致
7	7	0.09	0.09	一致
8	8	0.11	0.14	一致
9	9	0.09	0.1	一致
10	10	0.18	0.21	一致
11	11	0.1	0.09	一致
12	12	0.1	0.11	一致
13	13	0.11	0.1	一致
14	14	0.11	0.1	一致
15	15	0.12	0.12	一致
16	16	0.15	0.16	一致
17	17	0.57	0.6	一致
18	18	0.12	0.09	一致
19	19	0.25	0.25	一致
20	20	0.12	0.12	一致

編號	檢體編號	X	Y	結果
21	21	0.1	0.13	一致
22	22	0.09	0.07	一致
23	23	0.1	0.08	一致
24	24	0.1	0.11	一致
25	25	0.1	0.11	一致
26	26	0.11	0.1	一致
27	27	0.11	0.14	一致
28	28	0.09	0.1	一致
29	29	0.09	0.12	一致
30	30	0.12	0.13	一致
31	31	0.11	0.11	一致
32	32	0.08	0.08	一致
33	33	0.11	0.1	一致
34	34	0.09	0.11	一致
35	35	0.11	0.13	一致
36	36	0.12	0.14	一致
37	37	0.17	0.17	一致
38	38	0.09	0.08	一致
39	39	0.13	0.15	一致
40	40	0.15	0.18	一致

萬芳醫院測試報告

# Method Comparison

項目名稱：HBeAg

測試機台(Y)：Alinity i (green)

項目單位：S/CO

測試機台編號：Ai27152

允收標準：Agreement  $\geq 90\%$

原始機台(X)：Alinity i (red)

測試日期：2024/06/03-07/25

原始機台編號：Ai27152

測試結果：

	X Reactive	X Nonreactive	Total
Y Reactive	1	0	1
Y Nonreactive	0	39	39
Total	1	39	40

Agreement	100.0%
Pos Agreement	100.0%
Neg Agreement	100.0%

Interpretation：

判讀	判讀標準
X Reactive	$\geq 1$ S/CO
X Nonreactive	$< 1$ S/CO
Y Reactive	$\geq 1$ S/CO
Y Nonreactive	$< 1$ S/CO

說明：

1. Agreement = 100%，驗證通過。

測試數據：

編號	檢體編號	X	Y	結果
1	1	0.374	0.345	一致
2	2	0.322	0.339	一致
3	3	0.326	0.24	一致
4	4	0.307	0.412	一致
5	5	0.293	0.309	一致
6	6	0.368	0.326	一致
7	7	0.343	0.326	一致
8	8	0.347	0.289	一致
9	9	0.234	0.332	一致
10	10	0.351	0.41	一致
11	11	1.073	3.287	一致
12	12	0.418	0.364	一致
13	13	0.335	0.309	一致
14	14	0.347	0.358	一致
15	15	0.347	0.335	一致
16	16	0.366	0.351	一致
17	17	0.335	0.376	一致
18	18	0.186	0.316	一致
19	19	0.343	0.381	一致
20	20	0.349	0.341	一致

編號	檢體編號	X	Y	結果
21	21	0.297	0.305	一致
22	22	0.399	0.165	一致
23	23	0.335	0.318	一致
24	24	0.349	0.339	一致
25	25	0.297	0.259	一致
26	26	0.345	0.322	一致
27	27	0.295	0.347	一致
28	28	0.33	0.201	一致
29	29	0.351	0.201	一致
30	30	0.309	0.353	一致
31	31	0.351	0.309	一致
32	32	0.349	0.391	一致
33	33	0.351	0.312	一致
34	34	0.332	0.286	一致
35	35	0.322	0.358	一致
36	36	0.343	0.192	一致
37	37	0.303	0.209	一致
38	38	0.307	0.36	一致
39	39	0.297	0.157	一致
40	40	0.366	0.335	一致

## Alternate Method Comparison Summary

<i>Y Method</i>	<i>X Method</i>	<i>Analyte</i>	<i>N</i>	<i>Slope</i>	<i>Intercept</i>	<i>Corr Coef (R)</i>	<i>Accept</i>
plasma	✓ serum	ASO	37/37	0.977	-0.12	0.9991	_____
	✓ serum	b2M	31/31	0.998	-0.054	0.9989	_____
	✓ serum	C3	37/37	0.959	2.68	0.9949	_____
	✓ serum	C4	37/37	0.907	-1.35	0.9914	_____
	✓ serum	GGT	37/37	0.995	-0.54	0.9998	_____
	✓ serum	Transferrin	37/37	0.960	7.36	0.9976	_____

❖ Required parameters are missing.

✓ Experiment 'passes' (or adequate number of results).

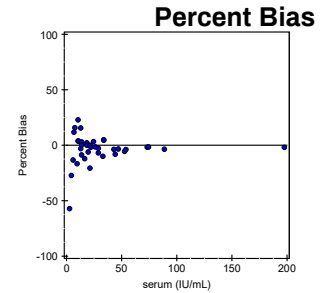
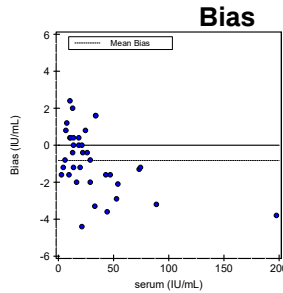
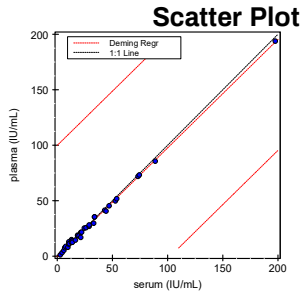
✗ Experiment 'fails' (or not enough results).

● Experiment has outliers or subrange analysis.

# Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma



## Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.977 (0.963 to 0.992)	0.973 (0.945 to 0.994)	0.977 (0.962 to 0.991)
<b>Intercept</b>	-0.12 (-0.79 to 0.55)	0.20 (-0.74 to 0.98)	-0.09 (-0.76 to 0.57)
<b>Std Err Est</b>	1.48	--	1.48

95% Confidence Intervals are shown in parentheses

## Supporting Statistics

Corr Coef (R)	0.9991 (RSQ 0.9982)	SubRange Bounds	None
Bias	-0.83 (-2.64 %)	Points (Plotted/Total)	37/37
X Mean +/- SD	31.29 +/- 34.90	Outliers	Not Tested
Y Mean +/- SD	30.46 +/- 34.12	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	1.68		100.00 IU/mL (conc) or 25.0%

## Experiment Description

	X Method	Y Method
Expt Date	18 七月 2024	18 七月 2024
Rep SD	1	1
Result Ranges	2.8 to 197.6	1.2 to 193.8
Units	IU/mL	IU/mL
Reagent	--	--
Calibrators	--	--
Analyst	staff	staff
Comment		

Accepted by:

Signature

Date

## Alternate (Quantitative) Method Comparison

**X Method serum**
**Y Method plasma**

### Experimental Results

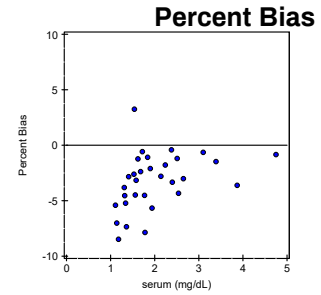
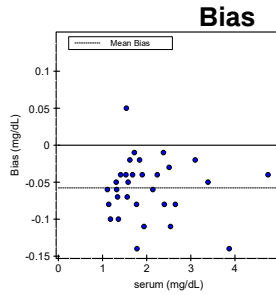
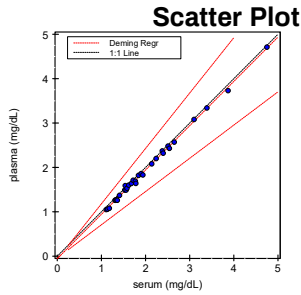
Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
R01	88.8	85.6	-3.2	R14	28.9	26.9	-2.0	R27	13.7	13.7	0.0
R02	47	45.4	-1.6	R15	13.7	14.1	0.4	R28	33	29.7	-3.3
R03	197.6	193.8	-3.8	R16	74.4	73.2	-1.2	R29	22.1	21.7	-0.4
R04	52.7	49.8	-2.9	R17	12.9	12.5	-0.4	R30	26.1	25.7	-0.4
R05	10.5	12.9	2.4	R18	6	5.2	-0.8	R31	10.9	11.3	0.4
R06	44.2	40.6	-3.6	R19	24.5	25.3	0.8	R32	21.3	16.9	-4.4
R07	73.2	71.9	-1.3	R20	33.8	35.4	1.6	R33	13.7	12.5	-1.2
R08	33.8	35.4	1.6	R21	19.7	18.5	-1.2	R34	4.4	3.2	-1.2
R09	16.5	14.5	-2.0	R22	6.8	7.6	0.8	R35	9.6	8	-1.6
R10	2.8	1.2	-1.6	R23	43	41.4	-1.6	R36	18.5	18.9	0.4
R11	12.9	14.9	2.0	R24	7.6	8.8	1.2	R37	18.5	18.5	0.0
R12	10.5	10.9	0.4	R25	28.9	28.1	-0.8				
R13	53.9	51.8	-2.1	R26	21.3	21.3	0.0				

Values with an "X" were excluded from the calculations.

# Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma



## Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.998 (0.980 to 1.016)	1.000 (0.985 to 1.025)	0.997 (0.979 to 1.015)
<b>Intercept</b>	-0.054 (-0.094 to -0.015)	-0.050 (-0.097 to -0.028)	-0.052 (-0.091 to -0.012)
<b>Std Err Est</b>	0.041	--	0.041

95% Confidence Intervals are shown in parentheses

## Supporting Statistics

Corr Coef (R)	0.9989 (RSQ 0.9977)	SubRange Bounds	None
Bias	-0.058 (-2.859 %)	Points (Plotted/Total)	31/31
X Mean +/- SD	2.019 +/- 0.840	Outliers	Not Tested
Y Mean +/- SD	1.962 +/- 0.838	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	0.040		0.050 mg/dL (conc) or 25.0%

## Experiment Description

	X Method	Y Method
Expt Date	18 七月 2024	18 七月 2024
Rep SD	1	1
Result Ranges	1.11 to 4.75	1.05 to 4.71
Units	mg/dL	mg/dL
Reagent	--	--
Calibrators	--	--
Analyst	staff	staff
Comment		

Accepted by: \_\_\_\_\_

Signature

Date

## Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma

### Experimental Results

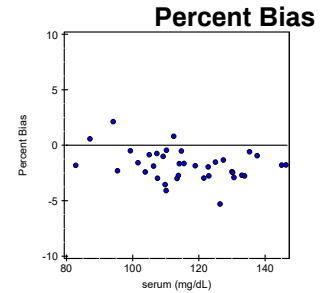
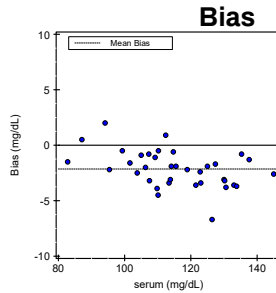
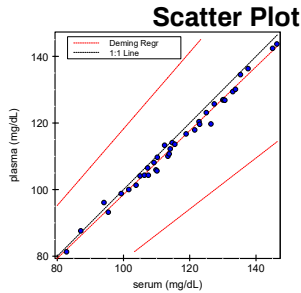
Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
R01	3.39	3.34	-0.05	R13	1.94	1.83	-0.11	R24	1.54	1.59	0.05
R02	3.1	3.08	-0.02	R14	1.18	1.08	-0.10	R25	2.54	2.43	-0.11
R03	1.68	1.64	-0.04	R15	1.36	1.26	-0.10	R26	2.4	2.32	-0.08
R04	1.84	1.82	-0.02	R16	1.11	1.05	-0.06	R27	1.77	1.69	-0.08
R05	1.14	1.06	-0.08	R17	1.53	1.49	-0.04	R28	1.58	1.53	-0.05
R06	1.31	1.26	-0.05	R18	2.51	2.48	-0.03	R29	2.38	2.37	-0.01
R07	1.72	1.71	-0.01	R19	2.65	2.57	-0.08	R30	3.87	3.73	-0.14
R08	1.41	1.37	-0.04	R20	1.32	1.26	-0.06	R31	4.75	4.71	-0.04
R09	1.9	1.86	-0.04	R21	1.56	1.49	-0.07	R32	1.78	1.64	-0.14
R10	1.62	1.6	-0.02	R22	2.24	2.2	-0.04				
R12	1.34	1.27	-0.07	R23	2.14	2.08	-0.06				

Values with an "X" were excluded from the calculations.

# Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma



## Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.959 (0.925 to 0.992)	0.960 (0.919 to 0.994)	0.954 (0.920 to 0.987)
<b>Intercept</b>	2.68 (-1.23 to 6.59)	2.50 (-1.43 to 7.41)	3.23 (-0.68 to 7.13)
<b>Std Err Est</b>	1.50	--	1.49

95% Confidence Intervals are shown in parentheses

## Supporting Statistics

Corr Coef (R)	0.9949 (RSQ 0.9897)	SubRange Bounds	None
Bias	-2.14 (-1.84 %)	Points (Plotted/Total)	37/37
X Mean +/- SD	116.22 +/- 15.17	Outliers	Not Tested
Y Mean +/- SD	114.08 +/- 14.55	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	1.63		10.00 mg/dL (conc) or 20.0%

## Experiment Description

	X Method	Y Method
Expt Date	18 七月 2024	18 七月 2024
Rep SD	1	1
Result Ranges	82.8 to 146.3	81.3 to 143.7
Units	mg/dL	mg/dL
Reagent	--	--
Calibrators	--	--
Analyst	staff	staff
Comment		

Accepted by:

Signature

Date

## Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma

### Experimental Results

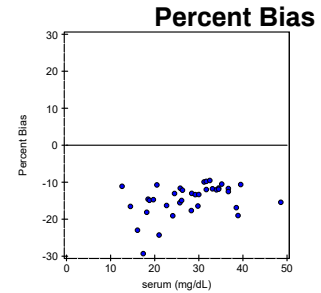
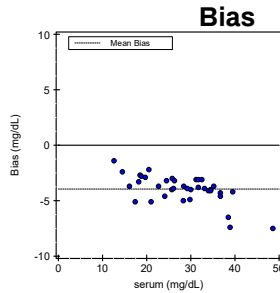
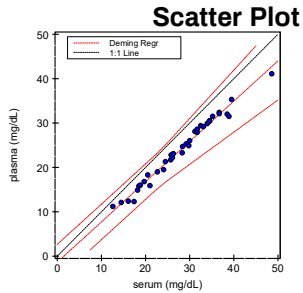
Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
R01	105	104.1	-0.9	R14	114.1	112.2	-1.9	R27	101.6	100	-1.6
R02	110.2	109.7	-0.5	R15	126.4	119.7	-6.7	R28	109.8	105.9	-3.9
R03	115.5	113.6	-1.9	R16	94.1	96.1	2.0	R29	130	126.9	-3.1
R04	107.3	106.5	-0.8	R17	110.1	105.6	-4.5	R30	82.8	81.3	-1.5
R05	87.1	87.6	0.5	R18	145	142.4	-2.6	R31	107.5	104.3	-3.2
R06	99.3	98.8	-0.5	R19	123	119.6	-3.4	R32	103.8	101.3	-2.5
R07	125	123.1	-1.9	R20	106.3	104.3	-2.0	R33	113.4	110	-3.4
R08	112.4	113.3	0.9	R21	133	129.4	-3.6	R34	118.9	116.7	-2.2
R09	137.6	136.3	-1.3	R22	130.2	127	-3.2	R35	130.6	126.8	-3.8
R10	135.3	134.5	-0.8	R23	133.8	130.1	-3.7	R36	121.5	117.9	-3.6
R11	127.4	125.7	-1.7	R24	114.7	114.1	-0.6	R37	113.8	110.7	-3.1
R12	122.8	120.4	-2.4	R25	95.4	93.2	-2.2				
R13	109.2	108.1	-1.1	R26	146.3	143.7	-2.6				

Values with an "X" were excluded from the calculations.

# Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma



## Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.907 (0.866 to 0.948)	0.920 (0.887 to 0.965)	0.900 (0.859 to 0.941)
<b>Intercept</b>	-1.35 (-2.53 to -0.16)	-1.36 (-2.80 to -0.60)	-1.15 (-2.33 to 0.04)
<b>Std Err Est</b>	0.98	--	0.98

95% Confidence Intervals are shown in parentheses

## Supporting Statistics

Corr Coef (R)	0.9914 (RSQ 0.9829)	SubRange Bounds	None
Bias	-3.95 (-14.11 %)	Points (Plotted/Total)	37/37
X Mean +/- SD	27.99 +/- 8.15	Outliers	Not Tested
Y Mean +/- SD	24.04 +/- 7.40	Scatter Plot Bounds	Allowable Total Error
Std Dev Diff	1.26		4.00 mg/dL (conc) or 20.0%

## Experiment Description

	X Method	Y Method
Expt Date	18 七月 2024	18 七月 2024
Rep SD	1	1
Result Ranges	12.6 to 48.6	11.2 to 41.1
Units	mg/dL	mg/dL
Reagent	--	--
Calibrators	--	--
Analyst	staff	staff
Comment		

Accepted by: \_\_\_\_\_

Signature

Date

## Alternate (Quantitative) Method Comparison

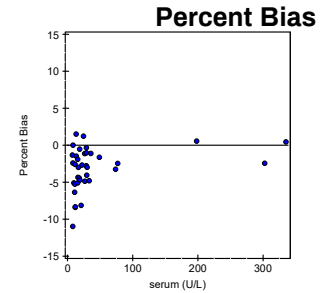
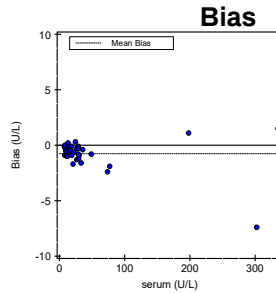
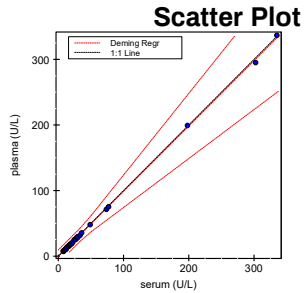
**X Method serum**
**Y Method plasma**

### Experimental Results

Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
R01	24.1	19.5	-4.6	R14	28.3	23.3	-5.0	R27	26.1	22.2	-3.9
R02	32.5	29.4	-3.1	R15	36.7	32.1	-4.6	R28	34.5	30.4	-4.1
R03	14.5	12.1	-2.4	R16	17.4	12.3	-5.1	R29	18.2	14.9	-3.3
R04	34.5	30.5	-4.0	R17	16.1	12.4	-3.7	R30	19.7	16.8	-2.9
R05	12.6	11.2	-1.4	R18	38.9	31.5	-7.4	R31	28.4	24.7	-3.7
R06	18.8	16	-2.8	R19	39.5	35.3	-4.2	R32	24.5	21.3	-3.2
R07	25.8	22.8	-3.0	R20	29.2	25.3	-3.9	R33	26.3	23.1	-3.2
R08	31.7	27.9	-3.8	R21	30	26	-4	R34	35.2	31.5	-3.7
R09	36.7	32.4	-4.3	R22	34	29.9	-4.1	R35	31.7	28.6	-3.1
R10	31.2	28.1	-3.1	R23	33.1	29.2	-3.9	R36	18.5	15.8	-2.7
R11	38.5	32	-6.5	R24	22.7	19	-3.7	R37	29.8	24.9	-4.9
R12	25.7	21.7	-4.0	R25	20.5	18.3	-2.2				
R13	21	15.9	-5.1	R26	48.6	41.1	-7.5				

Values with an "X" were excluded from the calculations.

## Alternate (Quantitative) Method Comparison

**X Method serum**
**Y Method plasma**


### Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.995 (0.989 to 1.001)	0.985 (0.974 to 1.004)	0.995 (0.989 to 1.001)
<b>Intercept</b>	-0.54 (-1.05 to -0.04)	-0.35 (-0.69 to -0.01)	-0.54 (-1.04 to -0.03)
<b>Std Err Est</b>	1.30	--	1.30

95% Confidence Intervals are shown in parentheses

### Supporting Statistics

Corr Coef (R)	0.9998 (RSQ 0.9997)	SubRange Bounds	None
Bias	-0.76 (-1.74 %)	Points (Plotted/Total)	37/37
X Mean +/- SD	43.76 +/- 74.36	Outliers	Not Tested
Y Mean +/- SD	43.00 +/- 73.99	Scatter Plot Bounds	Allowable Total Error
Std Dev Diff	1.34		10.00 U/L (conc) or 25.0%

### Experiment Description

	X Method	Y Method
Expt Date	18 七月 2024	18 七月 2024
Rep SD	1	1
Result Ranges	7.5 to 335.1	7.3 to 336.6
Units	U/L	U/L
Reagent	--	--
Calibrators	--	--
Analyst	staff	staff
Comment		

Accepted by: \_\_\_\_\_

Signature

Date

## Alternate (Quantitative) Method Comparison

X Method serum

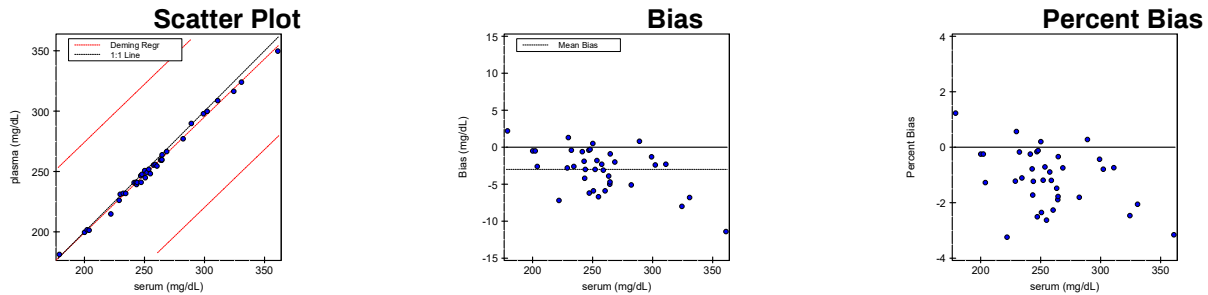
Y Method plasma

### Experimental Results

Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
R01	29.1	28.8	-0.3	R14	29.6	28.4	-1.2	R27	26.7	25.4	-1.3
R02	16.1	15.4	-0.7	R15	302.5	295.1	-7.4	R28	198.1	199.2	1.1
R03	335.1	336.6	1.5	R16	7.5	7.4	-0.1	R29	26.4	26.1	-0.3
R04	11.9	10.9	-1.0	R17	77.1	75.2	-1.9	R30	22.3	21.7	-0.6
R05	8.2	7.3	-0.9	R18	24.6	24.9	0.3	R31	30.1	29.2	-0.9
R06	8.3	8.1	-0.2	R19	9.8	9.3	-0.5	R32	11.6	11.3	-0.3
R07	20.9	19.2	-1.7	R20	13.5	13.3	-0.2	R33	15.7	14.9	-0.8
R08	13.3	13.5	0.2	R21	73.8	71.4	-2.4	R34	16.7	16.2	-0.5
R09	18.7	18.6	-0.1	R22	8.5	8.5	0.0	R35	12	11	-1
R10	18	17.2	-0.8	R23	29	28.9	-0.1	R36	28.8	28	-0.8
R11	48.9	48.1	-0.8	R24	15.7	15.4	-0.3	R37	19.1	18.2	-0.9
R12	11	10.3	-0.7	R25	11.4	10.8	-0.6				
R13	35.8	35.4	-0.4	R26	33.3	31.7	-1.6				

Values with an "X" were excluded from the calculations.

## Alternate (Quantitative) Method Comparison

**X Method serum**
**Y Method plasma**


### Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.960 (0.937 to 0.982)	0.964 (0.935 to 0.993)	0.958 (0.935 to 0.980)
<b>Intercept</b>	7.36 (1.49 to 13.23)	6.28 (-0.92 to 13.40)	7.92 (2.05 to 13.79)
<b>Std Err Est</b>	2.49	--	2.48

95% Confidence Intervals are shown in parentheses

### Supporting Statistics

Corr Coef (R)	0.9976 (RSQ 0.9953)	SubRange Bounds	None
Bias	-3.00 (-1.17 %)	Points (Plotted/Total)	37/37
X Mean +/- SD	257.02 +/- 37.19	Outliers	Not Tested
Y Mean +/- SD	254.03 +/- 35.69	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	2.91		75.00 mg/dL (conc) or 20.0%

### Experiment Description

	X Method	Y Method
Expt Date	18 七月 2024	18 七月 2024
Rep SD	1	1
Result Ranges	179.1 to 361.1	181.3 to 349.7
Units	mg/dL	mg/dL
Reagent	--	--
Calibrators	--	--
Analyst	staff	staff
Comment		

Accepted by: \_\_\_\_\_

Signature

Date

## Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma

### Experimental Results

Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
R01	361.1	349.7	-11.4	R14	264.5	259.8	-4.7	R27	258.9	255.8	-3.1
R02	243.9	240.9	-3.0	R15	222	214.8	-7.2	R28	263.4	259.5	-3.9
R03	242.9	241	-1.9	R16	324.4	316.4	-8.0	R29	202.2	201.7	-0.5
R04	289	289.8	0.8	R17	247.2	241	-6.2	R30	228.9	226.1	-2.8
R05	264.7	263.8	-0.9	R18	330.8	324	-6.8	R31	203.9	201.3	-2.6
R06	247.9	247.6	-0.3	R19	241.4	240.8	-0.6	R32	302.2	299.8	-2.4
R07	234.4	231.8	-2.6	R20	299.1	297.8	-1.3	R33	232.3	231.9	-0.4
R08	257.6	255.3	-2.3	R21	268.5	266.5	-2.0	R34	246.9	246.5	-0.4
R09	254.9	248.2	-6.7	R22	282.2	277.1	-5.1	R35	250.2	250.7	0.5
R10	264.3	259.3	-5.0	R23	253.6	251.8	-1.8	R36	229.8	231.1	1.3
R11	243.4	239.2	-4.2	R24	200.1	199.6	-0.5	R37	179.1	181.3	2.2
R12	311	308.7	-2.3	R25	260.4	254.5	-5.9				
R13	252.1	249.1	-3.0	R26	250.7	244.8	-5.9				

Values with an "X" were excluded from the calculations.

# Alternate (Quantitative) Method Comparison

## Report Interpretation Guide

There are many reasons for doing method comparison studies. Perhaps the most common:

- To determine the relationship of the Medical Decision Points (MDPs) of an old method with those of a new method. In other words, "Can I continue to use the same MDPs with the new method?"
- To validate a new method being brought into the lab, by demonstrating the statistical relationship to the method currently in use.

The statistical tool used is linear regression. The methods can be considered statistically identical if:

- The slope is 1.00 (within 95% confidence)
- The intercept is 0.00 (within 95% confidence)
- The predicted Y MDPs are equal to the X MDPs (within 95% confidence)

Not all regressions are method comparisons. This Report Interpretation assumes that X and Y are alternative methods for measuring the same quantity, and that the purpose of the experiment is to determine whether X is statistically identical to Y. If the purpose is to predict weight as a function of height, or to predict APTT levels from Heparin levels, some of the interpretive comments may not apply.

### Regression Approaches

The report shows at least two, and (optionally) three sets of regression coefficients.

**Regular Regression:** This is the ordinary least squares regression line commonly provided in spreadsheets and general statistical software. It is shown only to provide a familiar frame of reference; it is not used to estimate Medical Decision Points. The problem with using regular regression to compare methods is that it assumes the X method is measured with no random error -- not very likely for clinical laboratory results. Regular regression often underestimates the true slope, sometimes by a significant amount.

**Deming Regression:** This approach assumes that both the X and Y methods are subject to measurement error. In theory, a **Representative SD** (precision estimate) is input for each method. In practice, only the ratio of the two precisions affects the calculation. If exact precisions are unknown, entering 1.0 for both Representative SDs says "these methods have about the same precision", and gives reasonable results in most cases.

Several studies have shown that Deming Regression is the best approach to use when the two methods are expected to be identical, and the data is well-distributed and free of outliers. It can, however, be seriously affected by outliers. EP Evaluator provides the option to automatically exclude extreme outliers, or the user can exclude them manually.

The default Regression Lines on the AMC graphs are Deming Regression Lines. A Passing Bablok regression line can be enabled in Preferences\calculations. When MDPs are estimated by linear regression, Deming linear regression is used.

**Passing-Bablok Regression:** Passing-Bablok regression is a non-parametric regression technique developed specifically to be resistant to outliers. Non-parametric statistical calculations make no assumptions about the shape of the population distribution, while parametric approaches assume that the population has a Gaussian distribution.

**Main strengths:** There is no need to exclude perceived outliers, either manually or automatically. Like Deming, it does not assume that X is free from error. Comparative studies show that it performs about as well as Deming Regression in most cases, and better than Deming when outliers are present.

**Main weaknesses:** Passing-Bablok is computationally intensive, particularly for large N, and it may be unreliable for very small N. EP Evaluator does not show Passing-Bablok statistics when  $N < 10$  or  $N > 500$ .

### Removing Outliers

An outlier is a point so far from the others as to arouse suspicion that it was generated by a different mechanism. Some common causes: typing a number with the decimal point in the wrong place, analyzing the wrong sample, or entering incorrect specimen identification. The best way to deal with an outlier is to (manually) determine its cause and correct it. Another option is to use a statistical procedure to remove outliers automatically.

EP Evaluator uses a somewhat complex iterative algorithm to identify outliers. The goal is to eliminate points whose distance from the regression line exceeds 10 times the Standard Error of Estimate (SEE), where SEE is computed not from the full data set, but from the data set with outliers excluded. When outliers are included, the SEE is over-stated, and the regression coefficients are suspect.

An outlier is, by definition, a rare occurrence. If more than 5% of the points are excluded, either by the mathematical algorithm or the user, the report is stamped PRELIMINARY. It is then incumbent on the user to re-evaluate both methods to determine their suitability.

### Interpreting your Results

When interpreting a method comparison report, there are two areas which must be addressed:

# Alternate (Quantitative) Method Comparison Report Interpretation Guide

- First, is the QUALITY OF THE DATA adequate to accurately draw conclusions?
- Second, what conclusions can be drawn from those data?

These issues MUST be addressed in this order. If the data quality is not adequate, then any additional conclusions drawn from those data may well be wrong.

## Data Quality Statistics

The most important elements of a good method comparison study are a reasonable N (number of x-y pairs) and a good distribution of results. Generally a good experiment will include 30 to 50 specimens with their results distributed more or less evenly across the method's reportable range.

**Results Range:** The minimum and maximum values of X and Y. It is inappropriate to draw conclusions outside the range of data studied. When evaluating MDPs, it is important to include data points that cover the full range of MDPs.

**Result Range Analysis:** This (optional) table shows how the X values are distributed within the range. A relatively even distribution is desirable. If 99% of the values are at the low end and 1% are at the high end, with none in the middle, the regression slope is almost totally determined by the handful of high points.

**Points (Plotted/Total):** More commonly called N, the number of x-y pairs in the regression. "Plotted" is the number on which calculations are based. The difference between Plotted and Total is points that were excluded, either manually or by the automatic outlier removal procedure. CLSI considers N=40 to be the minimum for a good method comparison study. Increasing N improves the quality up to a point, but a good distribution of data is much more important than a large N.

**Correlation Coefficient (R):** R generally corresponds to the width of an ellipse drawn around the data. The narrower the ellipse relative to its length, the higher R will be. If there is large amount of error, the width of the ellipse will increase which will in turn cause a lower R.

R ranges from -1 to 1. Zero means there is absolutely no relationship. +1 or -1 means there is a perfect relationship, and a very high-quality regression. An R of 1.000 could be achieved just as easily with a slope and intercept of 1.000 and 0.0 as with a slope and intercept of 0.5 and 400 respectively. In other words, it specifies the degree of correlation, not the degree to which the two methods match.

In a method comparison setting, R has special significance:

- A small R may be a sign that the Results Range is

inadequate. Adding samples to increase the range of X will improve both the R value, and the quality of the study.

- If R is less than a user-selectable cutoff value (0.90, 0.95, or 0.975), regression is not used to evaluate Medical Decision Points. Instead, they are evaluated by the method of Partitioned Biases, as explained in more detail, below. The coefficient of determination r-squared (RSQ) is also provided in parenthesis when enabled in the Preferences\Reports menu.

## Interpreting the Regression Statistics

Assuming that the quality of the data is adequate, you may proceed to interpreting the results.

**Slope, Intercept, and their Confidence Intervals:** When two methods are statistically identical, the 95% confidence interval for the slope includes 1.00, and the 95% confidence interval for the intercept includes 0.0.

Example: If the 95% CI for the slope is 0.92 to 1.02, 1.00 is included in the interval. However, if the 95% CI is 0.82 to 0.92, 1.00 is not included in the interval.

If the experiment were repeated with different data, the slope and intercept would be a bit different. But 95% of such experiments are expected to fall within the confidence interval.

**Medical Decision Point Analysis:** A Medical Decision Point is an analyte concentration at which medical decisions change. If the concentration is to one side of the MDP, one decision is made; if on the other side of the MDP, a different decision is made. For example, Fasting Plasma Glucose above 126 mg/dL (7 mmol/L) indicates hyperglycemia which, if confirmed, establishes a diagnosis of diabetes. For obvious reasons, it is particularly important that the two methods agree at the MDPs.

When the two methods are statistically identical, the 95% Confidence Interval for each Y MDP includes the corresponding X MDP.

**Standard Error of Estimate (SEE):** measures the spread of the x-y data around the linear regression line. If both methods have the same constant precision SD across the full analytical range, SEE should be about 1.4 times the precision SD.

## Bias, and its Relationship with Regression

**Bias** is the difference Y-X. The **Bias Plot** is a scatter plot with X on the x-axis, and Y-X on the y-axis. The ideal bias plot would have all points falling exactly on the zero line.

# Alternate (Quantitative) Method Comparison

## Report Interpretation Guide

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That is unlikely to occur in practice, because both X and Y are measured with some random error. A good bias plot is centered on the zero-line, and forms an envelope of approximately constant width about it.

**Constant Bias** is present when Y is consistently greater than (or less than) X by a constant amount. The bias plot forms a constant-width envelope around the average bias line instead of the zero line. The regression intercept measures constant bias. In fact, if the slope is exactly 1.000, the regression intercept is equal to the average bias.

**Proportional Bias** is present when Y differs from X in a way that is proportional to X. For example, Y may be consistently 5% higher than X instead of 5 units higher. On the Bias plot, the points center around an upward or downward-sloping line instead of a horizontal line. The regression slope is a measure of proportional bias.

The **Method of Partitioned Biases** comes into play when R is below the cutoff value (0.90, 0.95, or 0.975). In this situation, the Bias Plot is divided into three segments, with the same number of points in each segment. It is assumed that bias is approximately constant within each segment. This segmented structure provides an estimate of bias and its 95% confidence interval at the Medical Decision Points. The method of Partitioned Bias is an alternative approach used to define medical decision points. If it is used then slope, etc. are not used.

### Preliminary Report

The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing. Causes:

- Less than 3 unexcluded x-y pairs.
- More than 5% of points are outliers.
- Excluding outliers reduced the range of X by more than 50%. The range of X is a significant aspect of data quality, and it should be confirmed by the analyst in this case, rather than by a mathematical algorithm.

## Alternate Method Comparison Summary

<i>Y Method</i>	<i>X Method</i>	<i>Analyte</i>	<i>N</i>	<i>Slope</i>	<i>Intercept</i>	<i>Corr Coef (R)</i>	<i>Accept</i>
plasma	✓ serum	AFP	40/40	1.092	-0.178	0.9877	_____
	✓ serum	CEA	40/40	1.018	-0.022	0.9994	_____

❖ Required parameters are missing.

✓ Experiment 'passes' (or adequate number of results).

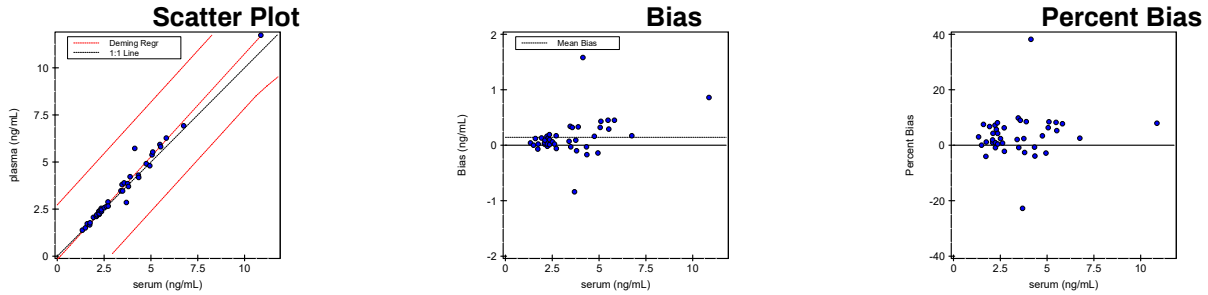
✗ Experiment 'fails' (or not enough results).

● Experiment has outliers or subrange analysis.

# Alternate (Quantitative) Method Comparison

X Method serum

Y Method plasma



## Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	1.092 (1.036 to 1.149)	1.072 (1.026 to 1.103)	1.078 (1.022 to 1.134)
<b>Intercept</b>	-0.178 (-0.398 to 0.042)	-0.108 (-0.198 to 0.000)	-0.127 (-0.346 to 0.091)
<b>Std Err Est</b>	0.315	--	0.314

95% Confidence Intervals are shown in parentheses

## Supporting Statistics

Corr Coef (R)	0.9877	SubRange Bounds	None
Bias	0.143 (4.117 %)	Points (Plotted/Total)	40/40
X Mean +/- SD	3.473 +/- 1.819	Outliers	Not Tested
Y Mean +/- SD	3.616 +/- 1.985	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	0.341		2.900 ng/mL (conc) or 25.0%

## Experiment Description

	X Method	Y Method
Expt Date	12 十二月 2025	12 十二月 2025
Rep SD	1	1
Result Ranges	1.34 to 10.87	1.38 to 11.73
Units	ng/mL	ng/mL
Reagent	--	--
Calibrators	--	--
Analyst	Avon Chen	Avon Chen
Comment		

Accepted by:

Signature

Date

## Alternate (Quantitative) Method Comparison

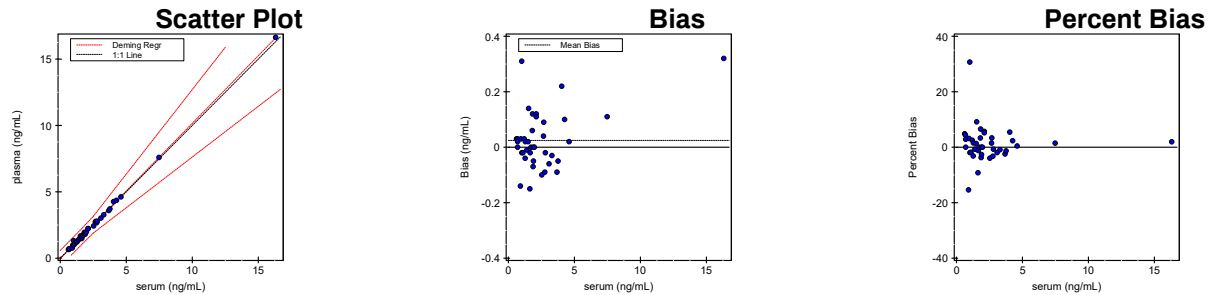
**X Method serum**
**Y Method plasma**

### Experimental Results

Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
01	3.69	2.85	-0.84	15	2.35	2.54	0.19	29	6.75	6.92	0.17
02	2.62	2.64	0.02	16	10.87	11.73	0.86	30	4.35	4.18	-0.17
03	2.71	2.88	0.17	17	2.36	2.37	0.01	31	5.1	5.53	0.43
04	5.06	5.38	0.32	18	3.89	4.22	0.33	32	1.6	1.72	0.12
05	4.94	4.8	-0.14	19	2.09	2.11	0.02	33	3.4	3.47	0.07
06	2.24	2.22	-0.02	20	3.46	3.8	0.34	34	5.52	5.81	0.29
07	1.73	1.66	-0.07	21	2.09	2.13	0.04	35	3.76	3.85	0.09
08	2.51	2.57	0.06	22	5.82	6.27	0.45	36	2.72	2.66	-0.06
09	4.75	4.91	0.16	23	1.5	1.5	0.0	37	4.14	5.72	1.58
10	3.57	3.89	0.32	24	1.34	1.38	0.04	38	2.36	2.46	0.10
11	4.33	4.3	-0.03	25	2.24	2.26	0.02	39	1.75	1.77	0.02
12	5.48	5.93	0.45	26	3.49	3.46	-0.03	40	2.29	2.42	0.13
13	3.8	3.7	-0.1	27	2.22	2.38	0.16				
14	2.11	2.2	0.09	28	1.93	2.06	0.13				

Values with an "X" were excluded from the calculations.

# Alternate (Quantitative) Method Comparison

**X Method serum**
**Y Method plasma**


## Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	1.018 (1.007 to 1.030)	1.005 (0.978 to 1.025)	1.018 (1.006 to 1.029)
<b>Intercept</b>	-0.022 (-0.063 to 0.020)	-0.003 (-0.046 to 0.044)	-0.020 (-0.061 to 0.021)
<b>Std Err Est</b>	0.093	--	0.093

95% Confidence Intervals are shown in parentheses

## Supporting Statistics

Corr Coef (R)	0.9994	SubRange Bounds	None
Bias	0.025 (0.977 %)	Points (Plotted/Total)	40/40
X Mean +/- SD	2.508 +/- 2.617	Outliers	Not Tested
Y Mean +/- SD	2.532 +/- 2.665	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	0.103		0.600 ng/mL (conc) or 25.0%

## Experiment Description

	X Method	Y Method
Expt Date	12 十二月 2025	12 十二月 2025
Rep SD	1	1
Result Ranges	0.62 to 16.32	0.65 to 16.64
Units	ng/mL	ng/mL
Reagent	--	--
Calibrators	--	--
Analyst	Avon Chen	Avon Chen
Comment		

Accepted by: \_\_\_\_\_

Signature

Date

## Alternate (Quantitative) Method Comparison

**X Method serum**
**Y Method plasma**

### Experimental Results

Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
01	0.91	0.77	-0.14	15	0.7	0.72	0.02	29	0.7	0.7	0.0
02	1.27	1.23	-0.04	16	4.04	4.26	0.22	30	2.68	2.77	0.09
03	1.2	1.23	0.03	17	0.95	0.98	0.03	31	2.11	2.23	0.12
04	3.3	3.27	-0.03	18	1.9	1.9	0.0	32	1.63	1.48	-0.15
05	0.62	0.65	0.03	19	1.97	1.97	0.00	33	1.83	1.95	0.12
06	1.65	1.63	-0.02	20	16.32	16.64	0.32	34	2.11	2.22	0.11
07	1.87	1.8	-0.07	21	1.28	1.3	0.02	35	1.53	1.67	0.14
08	4.6	4.62	0.02	22	3.08	3.02	-0.06	36	1.49	1.51	0.02
09	2.76	2.67	-0.09	23	2.8	2.78	-0.02	37	1.01	1.32	0.31
10	3.76	3.71	-0.05	24	3.68	3.59	-0.09	38	1.1	1.08	-0.02
11	1.02	1	-0.02	25	2.66	2.7	0.04	39	1.81	1.87	0.06
12	1.72	1.72	0.00	26	1.9	1.85	-0.05	40	2.53	2.43	-0.10
13	1.4	1.39	-0.01	27	0.68	0.71	0.03				
14	7.48	7.59	0.11	28	4.26	4.36	0.10				

Values with an "X" were excluded from the calculations.

# Alternate (Quantitative) Method Comparison Report Interpretation Guide

There are many reasons for doing method comparison studies. Perhaps the most common:

- To determine the relationship of the Medical Decision Points (MDPs) of an old method with those of a new method. In other words, "Can I continue to use the same MDPs with the new method?"
- To validate a new method being brought into the lab, by demonstrating the statistical relationship to the method currently in use.

The statistical tool used is linear regression. The methods can be considered statistically identical if:

- The slope is 1.00 (within 95% confidence)
- The intercept is 0.00 (within 95% confidence)
- The predicted Y MDPs are equal to the X MDPs (within 95% confidence)

Not all regressions are method comparisons. This Report Interpretation assumes that X and Y are alternative methods for measuring the same quantity, and that the purpose of the experiment is to determine whether X is statistically identical to Y. If the purpose is to predict weight as a function of height, or to predict APTT levels from Heparin levels, some of the interpretive comments may not apply.

## Regression Approaches

The report shows at least two, and (optionally) three sets of regression coefficients.

**Regular Regression:** This is the ordinary least squares regression line commonly provided in spreadsheets and general statistical software. It is shown only to provide a familiar frame of reference; it is not used to estimate Medical Decision Points. The problem with using regular regression to compare methods is that it assumes the X method is measured with no random error -- not very likely for clinical laboratory results. Regular regression often underestimates the true slope, sometimes by a significant amount.

**Deming Regression:** This approach assumes that both the X and Y methods are subject to measurement error. In theory, a **Representative SD** (precision estimate) is input for each method. In practice, only the ratio of the two precisions affects the calculation. If exact precisions are unknown, entering 1.0 for both Representative SDs says "these methods have about the same precision", and gives reasonable results in most cases.

Several studies have shown that Deming Regression is the best approach to use when the two methods are expected to be identical, and the data is well-distributed and free of outliers. It can, however, be seriously affected by outliers. EP Evaluator provides the option to automatically exclude extreme outliers, or the user can exclude them manually.

The default Regression Lines on the AMC graphs are Deming Regression Lines. A Passing Bablok regression line can be enabled in Preferences\calculations. When MDPs are estimated by linear regression, Deming linear regression is used.

**Passing-Bablok Regression:** Passing-Bablok regression is a non-parametric regression technique developed specifically to be resistant to outliers. Non-parametric statistical calculations make no assumptions about the shape of the population distribution, while parametric approaches assume that the population has a Gaussian distribution.

**Main strengths:** There is no need to exclude perceived outliers, either manually or automatically. Like Deming, it does not assume that X is free from error. Comparative studies show that it performs about as well as Deming Regression in most cases, and better than Deming when outliers are present.

**Main weaknesses:** Passing-Bablok is computationally intensive, particularly for large N, and it may be unreliable for very small N. EP Evaluator does not show Passing-Bablok statistics when  $N < 10$  or  $N > 500$ .

## Removing Outliers

An outlier is a point so far from the others as to arouse suspicion that it was generated by a different mechanism. Some common causes: typing a number with the decimal point in the wrong place, analyzing the wrong sample, or entering incorrect specimen identification. The best way to deal with an outlier is to (manually) determine its cause and correct it. Another option is to use a statistical procedure to remove outliers automatically.

EP Evaluator uses a somewhat complex iterative algorithm to identify outliers. The goal is to eliminate points whose distance from the regression line exceeds 10 times the Standard Error of Estimate (SEE), where SEE is computed not from the full data set, but from the data set with outliers excluded. When outliers are included, the SEE is over-stated, and the regression coefficients are suspect.

An outlier is, by definition, a rare occurrence. If more than 5% of the points are excluded, either by the mathematical algorithm or the user, the report is stamped PRELIMINARY. It is then incumbent on the user to re-evaluate both methods to determine their suitability.

## Interpreting your Results

When interpreting a method comparison report, there are two areas which must be addressed:

# Alternate (Quantitative) Method Comparison Report Interpretation Guide

- First, is the QUALITY OF THE DATA adequate to accurately draw conclusions?
- Second, what conclusions can be drawn from those data?

These issues MUST be addressed in this order. If the data quality is not adequate, then any additional conclusions drawn from those data may well be wrong.

## Data Quality Statistics

The most important elements of a good method comparison study are a reasonable N (number of x-y pairs) and a good distribution of results. Generally a good experiment will include 30 to 50 specimens with their results distributed more or less evenly across the method's reportable range.

**Results Range:** The minimum and maximum values of X and Y. It is inappropriate to draw conclusions outside the range of data studied. When evaluating MDPs, it is important to include data points that cover the full range of MDPs.

**Result Range Analysis:** This (optional) table shows how the X values are distributed within the range. A relatively even distribution is desirable. If 99% of the values are at the low end and 1% are at the high end, with none in the middle, the regression slope is almost totally determined by the handful of high points.

**Points (Plotted/Total):** More commonly called N, the number of x-y pairs in the regression. "Plotted" is the number on which calculations are based. The difference between Plotted and Total is points that were excluded, either manually or by the automatic outlier removal procedure. CLSI considers N=40 to be the minimum for a good method comparison study. Increasing N improves the quality up to a point, but a good distribution of data is much more important than a large N.

**Correlation Coefficient (R):** R generally corresponds to the width of an ellipse drawn around the data. The narrower the ellipse relative to its length, the higher R will be. If there is large amount of error, the width of the ellipse will increase which will in turn cause a lower R.

R ranges from -1 to 1. Zero means there is absolutely no relationship. +1 or -1 means there is a perfect relationship, and a very high-quality regression. An R of 1.000 could be achieved just as easily with a slope and intercept of 1.000 and 0.0 as with a slope and intercept of 0.5 and 400 respectively. In other words, it specifies the degree of correlation, not the degree to which the two methods match.

In a method comparison setting, R has special significance:

- A small R may be a sign that the Results Range is

inadequate. Adding samples to increase the range of X will improve both the R value, and the quality of the study.

- If R is less than a user-selectable cutoff value (0.90, 0.95, or 0.975), regression is not used to evaluate Medical Decision Points. Instead, they are evaluated by the method of Partitioned Biases, as explained in more detail, below. The coefficient of determination r-squared (RSQ) is also provided in parenthesis when enabled in the Preferences\Reports menu.

## Interpreting the Regression Statistics

Assuming that the quality of the data is adequate, you may proceed to interpreting the results.

**Slope, Intercept, and their Confidence Intervals:** When two methods are statistically identical, the 95% confidence interval for the slope includes 1.00, and the 95% confidence interval for the intercept includes 0.0.

Example: If the 95% CI for the slope is 0.92 to 1.02, 1.00 is included in the interval. However, if the 95% CI is 0.82 to 0.92, 1.00 is not included in the interval.

If the experiment were repeated with different data, the slope and intercept would be a bit different. But 95% of such experiments are expected to fall within the confidence interval.

**Medical Decision Point Analysis:** A Medical Decision Point is an analyte concentration at which medical decisions change. If the concentration is to one side of the MDP, one decision is made; if on the other side of the MDP, a different decision is made. For example, Fasting Plasma Glucose above 126 mg/dL (7 mmol/L) indicates hyperglycemia which, if confirmed, establishes a diagnosis of diabetes. For obvious reasons, it is particularly important that the two methods agree at the MDPs.

When the two methods are statistically identical, the 95% Confidence Interval for each Y MDP includes the corresponding X MDP.

**Standard Error of Estimate (SEE):** measures the spread of the x-y data around the linear regression line. If both methods have the same constant precision SD across the full analytical range, SEE should be about 1.4 times the precision SD.

## Bias, and its Relationship with Regression

**Bias** is the difference Y-X. The **Bias Plot** is a scatter plot with X on the x-axis, and Y-X on the y-axis. The ideal bias plot would have all points falling exactly on the zero line.

# Alternate (Quantitative) Method Comparison

## Report Interpretation Guide

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That is unlikely to occur in practice, because both X and Y are measured with some random error. A good bias plot is centered on the zero-line, and forms an envelope of approximately constant width about it.

**Constant Bias** is present when Y is consistently greater than (or less than) X by a constant amount. The bias plot forms a constant-width envelope around the average bias line instead of the zero line. The regression intercept measures constant bias. In fact, if the slope is exactly 1.000, the regression intercept is equal to the average bias.

**Proportional Bias** is present when Y differs from X in a way that is proportional to X. For example, Y may be consistently 5% higher than X instead of 5 units higher. On the Bias plot, the points center around an upward or downward-sloping line instead of a horizontal line. The regression slope is a measure of proportional bias.

The **Method of Partitioned Biases** comes into play when R is below the cutoff value (0.90, 0.95, or 0.975). In this situation, the Bias Plot is divided into three segments, with the same number of points in each segment. It is assumed that bias is approximately constant within each segment. This segmented structure provides an estimate of bias and its 95% confidence interval at the Medical Decision Points. The method of Partitioned Bias is an alternative approach used to define medical decision points. If it is used then slope, etc. are not used.

### Preliminary Report

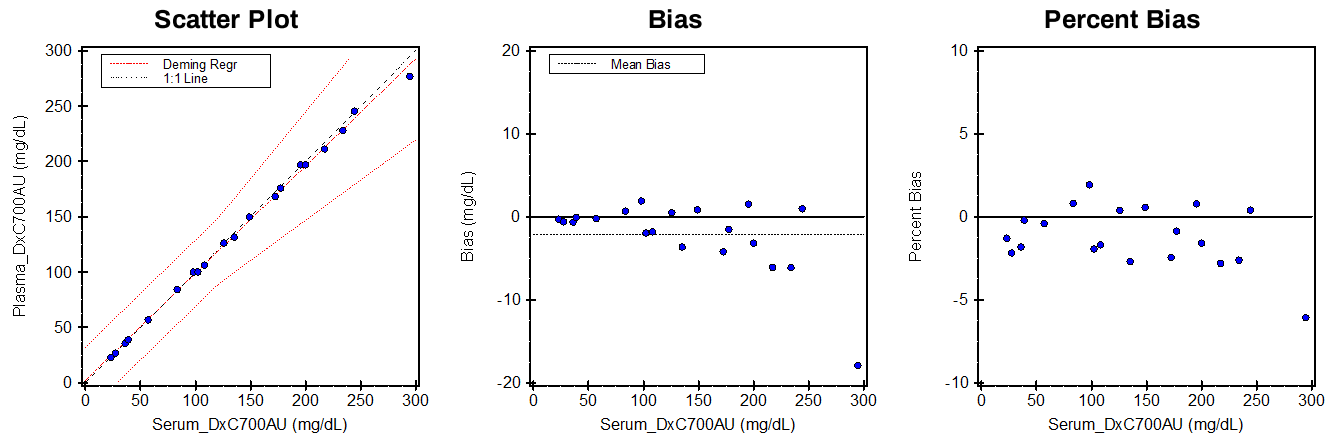
The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing. Causes:

- Less than 3 unexcluded x-y pairs.
- More than 5% of points are outliers.
- Excluding outliers reduced the range of X by more than 50%. The range of X is a significant aspect of data quality, and it should be confirmed by the analyst in this case, rather than by a mathematical algorithm.

## Alternate (Quantitative) Method Comparison

X Method Serum\_DxC700AU

Y Method Plasma\_DxC700AU



### Regression Analysis

	Deming	Passing-Bablok	Regular
<b>Slope</b>	0.968 (0.946 to 0.990)	0.979 (0.965 to 1.004)	0.967 (0.945 to 0.989)
<b>Intercept</b>	2.233 (-1.212 to 5.678)	0.571 (-0.763 to 1.826)	2.367 (-1.077 to 5.811)
<b>Std Err Est</b>	3.632	--	3.632

95% Confidence Intervals are shown in parentheses

### Supporting Statistics

Corr Coef (R)	0.9989 (RSQ 0.9979)	SubRange Bounds	None
Bias	-2.106 (-1.548 %)	Points (Plotted/Total)	20/20
X Mean ± SD	135.977 ± 79.555	Outliers	Not Tested
Y Mean ± SD	133.871 ± 77.019	Scatter Plot Bounds	Allowable Total Error
Std Dev Diffs	4.398		30.000 mg/dL (conc) or 25.0%

### Experiment Description

	X Method	Y Method
Expt Date	17 Jul 2024	17 Jul 2024
Rep SD	1	1
Result Ranges	23.14 to 294.63	22.84 to 276.71
Units	mg/dL	mg/dL
Reagent	--	--
Calibrators	--	--
Analyst	Eudora Chang	Eudora Chang
Comment		

Accepted by: \_\_\_\_\_

Signature

Date

## Alternate (Quantitative) Method Comparison

X Method Serum\_DxC700AU

Y Method Plasma\_DxC700AU

### Experimental Results

Specimen	X	Y	Bias	Specimen	X	Y	Bias	Specimen	X	Y	Bias
P01	36.07	35.41	-0.66	P16	98.08	99.97	1.89	P30	27.48	26.88	-0.60
P02	102.16	100.18	-1.98	P17	217.21	211.1	-6.11	P302	38.93	38.85	-0.08
P04	177.35	175.81	-1.54	P18	195.34	196.85	1.51	P303	148.92	149.75	0.83
P07	172.33	168.1	-4.23	P203	135.19	131.54	-3.65	P305	83.53	84.2	0.67
P08	200.05	196.86	-3.19	P204	57.08	56.84	-0.24	P306	125.66	126.14	0.48
P10	108.22	106.39	-1.83	P205	23.14	22.84	-0.30	P37	244.26	245.23	0.97
P15	294.63	276.71	-17.92	P29	233.91	227.78	-6.13				

Values with an "X" were excluded from the calculations.