

Untitled study

Glucose (mg/dL) · Method comparison ✓ Criteria met

7 of 7 questions judged · 7 questions met

Instrument **Analyzer B** Comparator **Analyzer A** Study date **Not recorded**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Slope (primary regression)	Between 0.95 and 1.05		1.018 1.000–1.031	✓
Intercept (primary regression)	Within ±5 mg/dL		+0.263 mg/dL –2.4 to 3.0	✓
Mean bias (test minus comparative)	Within ±3 mg/dL		+2.9 mg/dL 1.9–3.8	✓
Mean relative bias (%)	Within ±5%		+1.6%	✓
Bias at a medical decision level	Bias ≤ 6 mg/dL at 126 mg/dL		+2.5 mg/dL 2.5 mg/dL from target	✓
Bias at a medical decision level	Bias ≤ 3% at 100 mg/dL		+2.0 mg/dL 2.0% from target	✓
Individual specimen agreement	At least 95% of specimens within ±6 mg/dL or ±10% of the comparative result, whichever is greater		40 of 40 within	✓

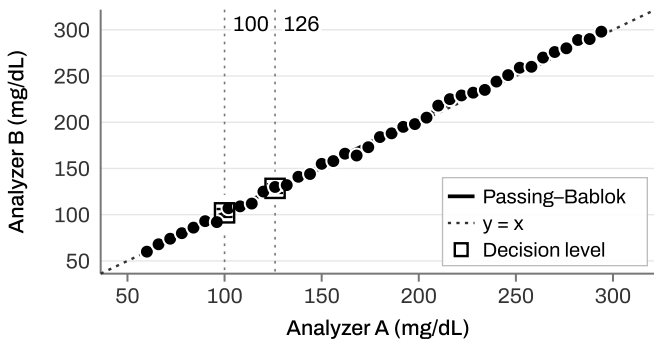


Figure 1. Test against comparative method.

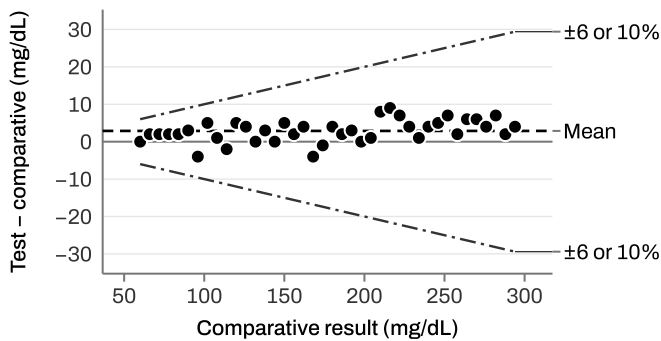


Figure 2. Each specimen's difference; dash-dot: its allowed difference; dashed: mean difference.

Study details

Data	40 included	Replicates	Single	Regression	Passing–Bablok
Comparative range	60–294 mg/dL	Decision levels	100, 126 mg/dL		

Signed off by

Date

A Data listing

Source: manual entry. 40 rows, all included.

Study row	Specimen	Comparative (mg/dL)	Test (mg/dL)
1	S01	60	60
2	S02	66	68
3	S03	72	74
4	S04	78	80
5	S05	84	86
6	S06	90	93
7	S07	96	92
8	S08	102	107
9	S09	108	109
10	S10	114	112
11	S11	120	125
12	S12	126	130
13	S13	132	132
14	S14	138	141
15	S15	144	144
16	S16	150	155
17	S17	156	158
18	S18	162	166
19	S19	168	164
20	S20	174	173
21	S21	180	184
22	S22	186	188
23	S23	192	195
24	S24	198	198
25	S25	204	205
26	S26	210	218
27	S27	216	225
28	S28	222	229
29	S29	228	232
30	S30	234	235
31	S31	240	244
32	S32	246	251
33	S33	252	259
34	S34	258	260
35	S35	264	270
36	S36	270	276
37	S37	276	280
38	S38	282	289
39	S39	288	290
40	S40	294	298

1 Results

1.1 Specimen decisions

Table 2. Specimen decisions

Specimen	Comparative (mg/dL)	Difference (mg/dL)	Allowed difference (mg/dL)	Outcome
S01	60	0.0	±6.0	✓
S02	66	+2.0	±6.6	✓
S03	72	+2.0	±7.2	✓
S04	78	+2.0	±7.8	✓
S05	84	+2.0	±8.4	✓
S06	90	+3.0	±9.0	✓
S07	96	−4.0	±9.6	✓
S08	102	+5.0	±10.2	✓
S09	108	+1.0	±10.8	✓
S10	114	−2.0	±11.4	✓
S11	120	+5.0	±12.0	✓
S12	126	+4.0	±12.6	✓
S13	132	0.0	±13.2	✓
S14	138	+3.0	±13.8	✓
S15	144	0.0	±14.4	✓
S16	150	+5.0	±15.0	✓
S17	156	+2.0	±15.6	✓
S18	162	+4.0	±16.2	✓
S19	168	−4.0	±16.8	✓
S20	174	−1.0	±17.4	✓
S21	180	+4.0	±18.0	✓
S22	186	+2.0	±18.6	✓
S23	192	+3.0	±19.2	✓
S24	198	0.0	±19.8	✓
S25	204	+1.0	±20.4	✓
S26	210	+8.0	±21.0	✓
S27	216	+9.0	±21.6	✓
S28	222	+7.0	±22.2	✓
S29	228	+4.0	±22.8	✓
S30	234	+1.0	±23.4	✓
S31	240	+4.0	±24.0	✓
S32	246	+5.0	±24.6	✓
S33	252	+7.0	±25.2	✓
S34	258	+2.0	±25.8	✓
S35	264	+6.0	±26.4	✓
S36	270	+6.0	±27.0	✓
S37	276	+4.0	±27.6	✓

Table 2. Specimen decisions

Specimen	Comparative (mg/dL)	Difference (mg/dL)	Allowed difference (mg/dL)	Outcome
S38	282	+7.0	±28.2	✓
S39	288	+2.0	±28.8	✓
S40	294	+4.0	±29.4	✓

Difference = test – comparative.

1.2 Differences and limits of agreement

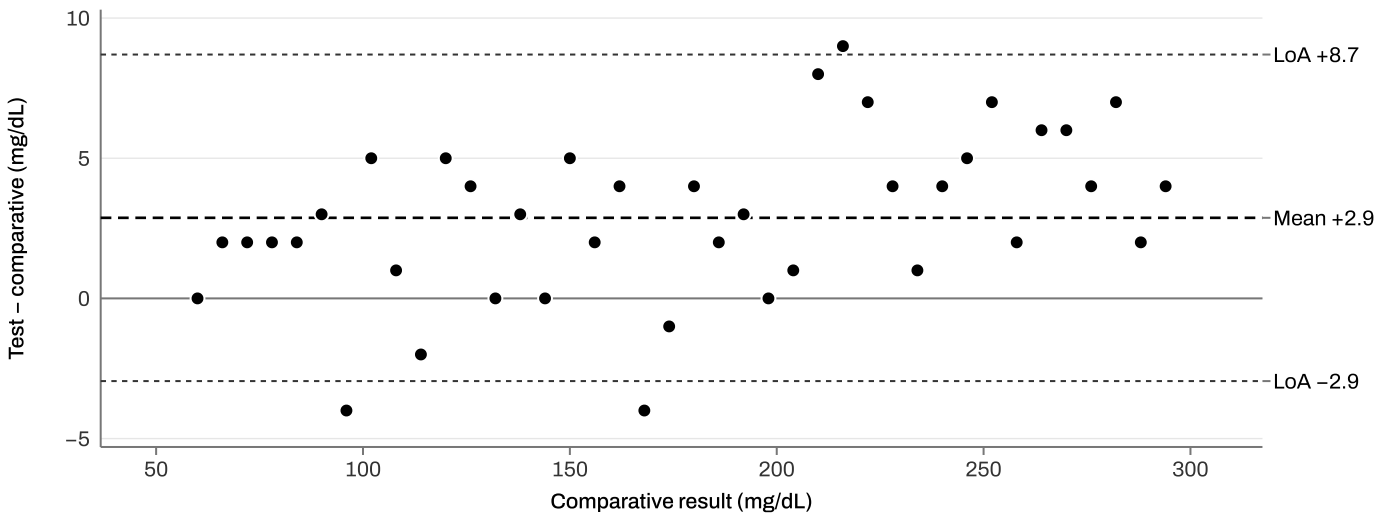


Figure 3. Test – comparative, with the mean and 95% limits of agreement.

Table 3. 95% limits of agreement for individual differences

Estimate	Difference (mg/dL)	95% CI (mg/dL)	Relative (%)	95% CI (%)
SD of differences	2.97			
Lower limit of agreement	-2.9	-4.6 to -1.3	-2.0	-3.0 to -1.0
Upper limit of agreement	+8.7	7.1–10.3	+5.2	4.2–6.2

Relative differences are percentages of the comparative result.

1.3 Ranges and fit details

Table 4. Ranges and fit details

Item	Value
Test range	60–298 mg/dL
Decision-level CIs	From the slope and intercept confidence region