

Untitled study

Glucose (mg/dL) · Analyzer comparability × Criteria not met

2 of 2 questions judged · Instrument bias vs reference analyzer not met · Individual specimen agreement met

Reference **A** Study date **Not recorded**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Instrument bias vs reference analyzer	Within ± 3 mg/dL at each analyzer		1 of 2 analyzers within 1 not met	× Not met
Individual specimen agreement	At least 95% of specimens within ± 6 mg/dL or $\pm 10\%$ of the reference result, whichever is greater at each analyzer		2 of 2 analyzers within	✓ Met

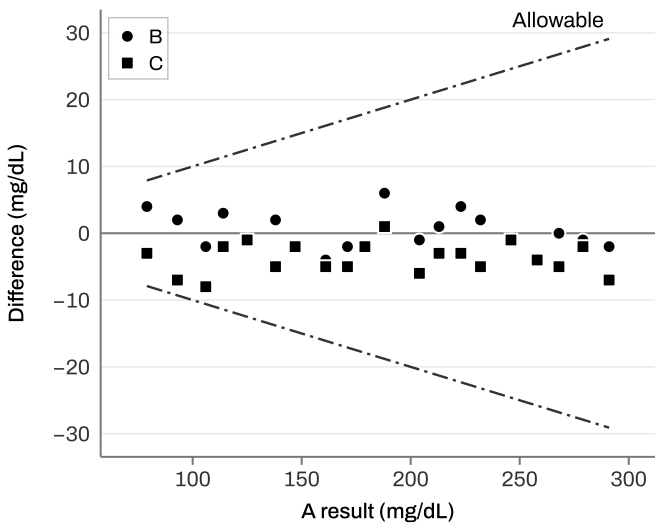


Figure 1. Difference from A by concentration.

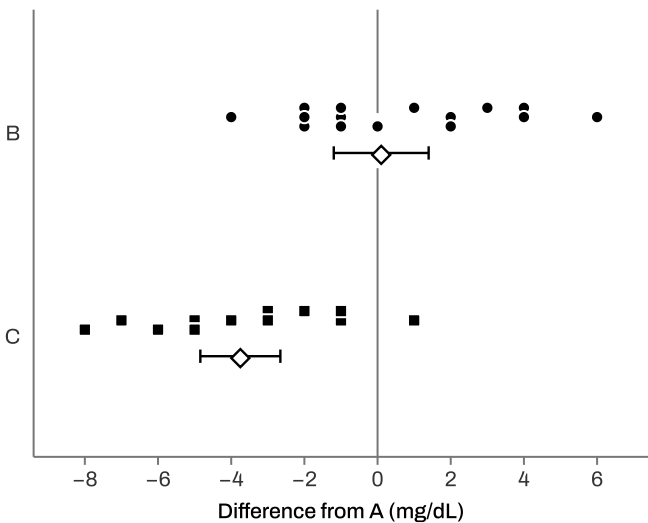


Figure 2. Differences by analyzer; open diamond: mean, 95% CI.

Table 2. Agreement with A (mg/dL)

Analyzer	Mean difference	95% CI	Largest difference	Specimen	Within limit	Required	Result
B	+0.1	-1.2 to 1.4	+6.0	S11	20 of 20	19 of 20	✓ Met
C	-3.8	-4.8 to -2.7	-8.0	S03	20 of 20	19 of 20	× Not met

Specimens span 79–291 mg/dL on A. Each difference is the analyzer’s result minus A’s.

Study details

Data 60 included

Design 20 specimens × 3 analyzers

Signed off by

Date

A Data listing

Source: manual entry. 60 rows, all included.

Study row	Specimen	Analyzer	Level	Result (mg/dL)
1	S01	A	Low	79
2	S01	B	Low	83
3	S01	C	Low	76
4	S02	A	Low	93
5	S02	B	Low	95
6	S02	C	Low	86
7	S03	A	Low	106
8	S03	B	Low	104
9	S03	C	Low	98
10	S04	A	Low	114
11	S04	B	Low	117
12	S04	C	Low	112
13	S05	A	Low	125
14	S05	B	Low	124
15	S05	C	Low	124
16	S06	A	Low	138
17	S06	B	Low	140
18	S06	C	Low	133
19	S07	A	Low	147
20	S07	B	Low	145
21	S07	C	Low	145
22	S08	A	Low	161
23	S08	B	Low	157
24	S08	C	Low	156
25	S09	A	Low	171
26	S09	B	Low	169
27	S09	C	Low	166
28	S10	A	High	179
29	S10	B	High	177
30	S10	C	High	177
31	S11	A	High	188
32	S11	B	High	194
33	S11	C	High	189
34	S12	A	High	204
35	S12	B	High	203
36	S12	C	High	198
37	S13	A	High	213
38	S13	B	High	214
39	S13	C	High	210
40	S14	A	High	223
41	S14	B	High	227
42	S14	C	High	220
43	S15	A	High	232

Study row	Specimen	Analyzer	Level	Result (mg/dL)
44	S15	B	High	234
45	S15	C	High	227
46	S16	A	High	246
47	S16	B	High	245
48	S16	C	High	245
49	S17	A	High	258
50	S17	B	High	254
51	S17	C	High	254
52	S18	A	High	268
53	S18	B	High	268
54	S18	C	High	263
55	S19	A	High	279
56	S19	B	High	278
57	S19	C	High	277
58	S20	A	High	291
59	S20	B	High	289
60	S20	C	High	284

1 Results

1.1 Differences by specimen

Table 3. Differences by specimen (mg/dL)

Specimen	A	Allowed	B difference	Result	C difference	Result
S01	79	±7.9	+4.0	✓	-3.0	✓
S02	93	±9.3	+2.0	✓	-7.0	✓
S03	106	±10.6	-2.0	✓	-8.0	✓
S04	114	±11.4	+3.0	✓	-2.0	✓
S05	125	±12.5	-1.0	✓	-1.0	✓
S06	138	±13.8	+2.0	✓	-5.0	✓
S07	147	±14.7	-2.0	✓	-2.0	✓
S08	161	±16.1	-4.0	✓	-5.0	✓
S09	171	±17.1	-2.0	✓	-5.0	✓
S10	179	±17.9	-2.0	✓	-2.0	✓
S11	188	±18.8	+6.0	✓	+1.0	✓
S12	204	±20.4	-1.0	✓	-6.0	✓
S13	213	±21.3	+1.0	✓	-3.0	✓
S14	223	±22.3	+4.0	✓	-3.0	✓
S15	232	±23.2	+2.0	✓	-5.0	✓
S16	246	±24.6	-1.0	✓	-1.0	✓
S17	258	±25.8	-4.0	✓	-4.0	✓
S18	268	±26.8	0.0	✓	-5.0	✓
S19	279	±27.9	-1.0	✓	-2.0	✓
S20	291	±29.1	-2.0	✓	-7.0	✓

1.2 Differences by analyzer and level

Table 4. Spread of the differences from A (mg/dL)

Analyzer	Specimens	SD	95% limits of agreement
B	20	2.77	-5.3 to 5.5
C	20	2.34	-8.3 to 0.8

About 95% of an analyzer's specimen differences are expected within its limits of agreement.

Table 5. Mean difference by concentration level (mg/dL)

Analyzer	Level	Specimens	Mean difference	SD
B	High	11	+0.2	2.89
B	Low	9	0.0	2.78
C	High	11	-3.4	2.34
C	Low	9	-4.2	2.39