

Untitled study

Glucose (mg/dL) · Reagent lot comparison ✓ Criteria met

2 of 2 questions judged · Specimens and Lot plan met

Previous lot **LOT-A** New lot **LOT-B** Study date **Not recorded**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Specimens	95% within ± 6 mg/dL or $\pm 10\%$ of the previous lot, whichever is greater		19 of 20 within	✓ Met
Lot plan	20 matched pairs, each level in its planned range		20 pairs	✓ Met

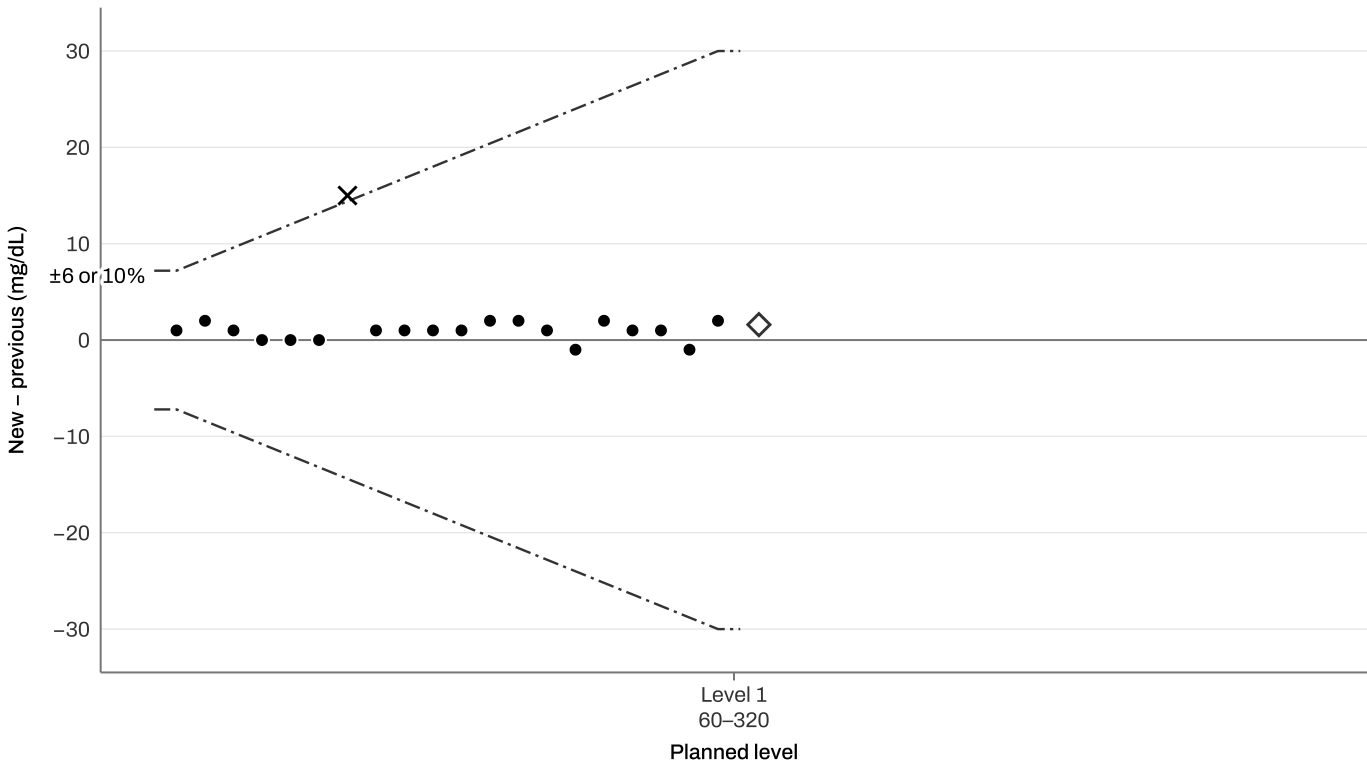


Figure 1. Each specimen's difference by planned level, in order of concentration; dash-dot: its allowed difference; x: outside it; open diamonds: level mean difference.

Mean difference (new – previous) over 20 pairs +1.6 mg/dL (95% CI 0.1–3.1); SD of the differences 3.28 mg/dL.

Study details

Data 40 included

Signed off by

Date

A Data listing

Source: manual entry. Patient specimens. 40 rows, all included.

Study row	Specimen	Lot	Result (mg/dL)
1	L01	LOT-A	72
2	L01	LOT-B	73
3	L02	LOT-A	84
4	L02	LOT-B	86
5	L03	LOT-A	96
6	L03	LOT-B	97
7	L04	LOT-A	108
8	L04	LOT-B	108
9	L05	LOT-A	120
10	L05	LOT-B	120
11	L06	LOT-A	132
12	L06	LOT-B	132
13	L07	LOT-A	144
14	L07	LOT-B	159
15	L08	LOT-A	156
16	L08	LOT-B	157
17	L09	LOT-A	168
18	L09	LOT-B	169
19	L10	LOT-A	180
20	L10	LOT-B	181
21	L11	LOT-A	192
22	L11	LOT-B	193
23	L12	LOT-A	204
24	L12	LOT-B	206
25	L13	LOT-A	216
26	L13	LOT-B	218
27	L14	LOT-A	228
28	L14	LOT-B	229
29	L15	LOT-A	240
30	L15	LOT-B	239
31	L16	LOT-A	252
32	L16	LOT-B	254
33	L17	LOT-A	264
34	L17	LOT-B	265
35	L18	LOT-A	276
36	L18	LOT-B	277
37	L19	LOT-A	288
38	L19	LOT-B	287
39	L20	LOT-A	300
40	L20	LOT-B	302

1 Results

1.1 Specimen results

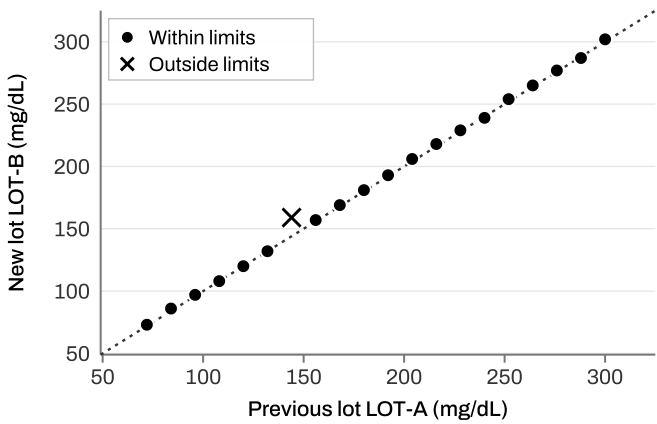


Figure 2. New lot against previous lot; dotted line: equal results.

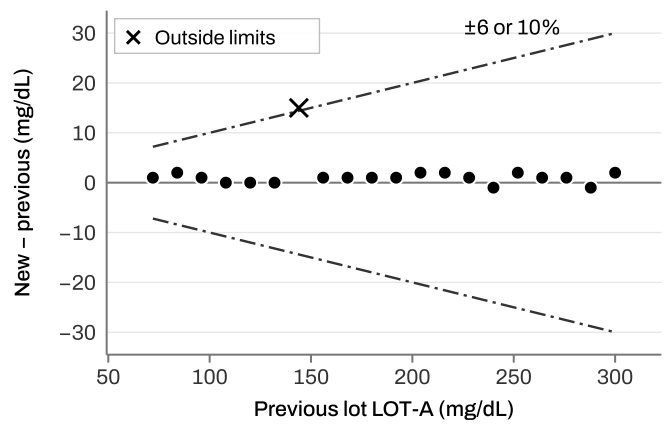


Figure 3. Each specimen's difference with its allowed range.

Table 2. Specimen results (mg/dL)

Specimen	Previous lot LOT-A	New lot LOT-B	Difference	Allowed	Result
L01	72	73	+1.0	±7.2	✓ Met
L02	84	86	+2.0	±8.4	✓ Met
L03	96	97	+1.0	±9.6	✓ Met
L04	108	108	0.0	±10.8	✓ Met
L05	120	120	0.0	±12.0	✓ Met
L06	132	132	0.0	±13.2	✓ Met
L07	144	159	+15.0	±14.4	✗ Not met
L08	156	157	+1.0	±15.6	✓ Met
L09	168	169	+1.0	±16.8	✓ Met
L10	180	181	+1.0	±18.0	✓ Met
L11	192	193	+1.0	±19.2	✓ Met
L12	204	206	+2.0	±20.4	✓ Met
L13	216	218	+2.0	±21.6	✓ Met
L14	228	229	+1.0	±22.8	✓ Met
L15	240	239	-1.0	±24.0	✓ Met
L16	252	254	+2.0	±25.2	✓ Met
L17	264	265	+1.0	±26.4	✓ Met
L18	276	277	+1.0	±27.6	✓ Met
L19	288	287	-1.0	±28.8	✓ Met
L20	300	302	+2.0	±30.0	✓ Met

Difference = new – previous.

1.2 Plan coverage

Table 3. Plan coverage

Level	Previous-lot results (mg/dL)	Inside the planned range
1	72–300	20 of 20