

Untitled study

Glucose (mg/dL) · Multi-day precision ✓ Criteria met

5 of 5 questions judged · 5 questions met

Study date **Not recorded**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Repeatability SD · Level Low	≤ 2 mg/dL		1.11 mg/dL	✓
Within-laboratory SD · Level Low	≤ 2.5 mg/dL		1.42 mg/dL	✓
Within-laboratory SD	Level Low SD ≤ 2.5 mg/dL; Level High SD ≤ 4.8 mg/dL		2 of 2 levels within	✓
Within-laboratory CV · Level High	≤ 2%		1.11%	✓
Repeatability CV · Level High	≤ 1.5%		1.07%	✓

Table 2. Results by level (mg/dL)

Level	Mean	Repeatability SD	Repeatability CV (%)	Within-lab SD	Within-lab CV (%)	Result
Low	79.83	1.11	1.39	1.42	1.78	✓ Met
High	239.77	2.55	1.07	2.65	1.11	✓ Met

Table 3. Manufacturer claim verification

Level	Component	Claimed SD (mg/dL)	Verification limit (mg/dL)	Claim result
Low	Repeatability	1.20	1.50	Consistent with the claim
Low	Within-laboratory	1.60	2.10	Consistent with the claim
High	Within-laboratory	4.00	4.95	Consistent with the claim

Study details

Data 50 included Design 5 days × 1 run × 5 replicates

Signed off by

Date

A Data listing

Source: manual entry. 50 rows, all included.

Study row	Specimen	Level	Result (mg/dL)	Day	Replicate
1	QC-Low	Low	82.0	D1	1
2	QC-Low	Low	78.3	D1	2
3	QC-Low	Low	80.6	D1	3
4	QC-Low	Low	78.6	D1	4
5	QC-Low	Low	80.6	D1	5
6	QC-Low	Low	79.1	D2	1
7	QC-Low	Low	79.0	D2	2
8	QC-Low	Low	80.0	D2	3
9	QC-Low	Low	77.1	D2	4
10	QC-Low	Low	77.3	D2	5
11	QC-Low	Low	79.9	D3	1
12	QC-Low	Low	79.8	D3	2
13	QC-Low	Low	81.7	D3	3
14	QC-Low	Low	78.5	D3	4
15	QC-Low	Low	80.3	D3	5
16	QC-Low	Low	79.8	D4	1
17	QC-Low	Low	79.7	D4	2
18	QC-Low	Low	79.5	D4	3
19	QC-Low	Low	78.0	D4	4
20	QC-Low	Low	79.6	D4	5
21	QC-Low	Low	80.3	D5	1
22	QC-Low	Low	81.8	D5	2
23	QC-Low	Low	81.4	D5	3
24	QC-Low	Low	81.5	D5	4
25	QC-Low	Low	81.3	D5	5
26	QC-High	High	239.5	D1	1
27	QC-High	High	240.0	D1	2
28	QC-High	High	237.9	D1	3
29	QC-High	High	243.4	D1	4
30	QC-High	High	242.5	D1	5
31	QC-High	High	239.9	D2	1
32	QC-High	High	237.8	D2	2
33	QC-High	High	241.9	D2	3
34	QC-High	High	242.3	D2	4
35	QC-High	High	240.9	D2	5
36	QC-High	High	239.3	D3	1
37	QC-High	High	236.4	D3	2
38	QC-High	High	243.2	D3	3
39	QC-High	High	236.2	D3	4
40	QC-High	High	237.8	D3	5
41	QC-High	High	234.1	D4	1
42	QC-High	High	237.7	D4	2
43	QC-High	High	239.9	D4	3

Study row	Specimen	Level	Result (mg/dL)	Day	Replicate
44	QC-High	High	237.0	D4	4
45	QC-High	High	241.6	D4	5
46	QC-High	High	238.5	D5	1
47	QC-High	High	244.1	D5	2
48	QC-High	High	242.8	D5	3
49	QC-High	High	237.6	D5	4
50	QC-High	High	241.9	D5	5

1 Results

1.1 Level plots

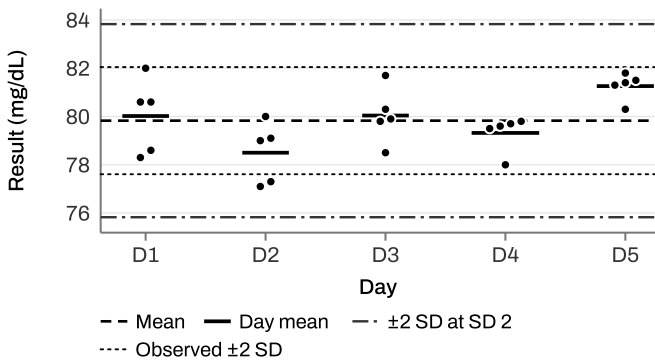


Figure 1. Level Low: results by day.

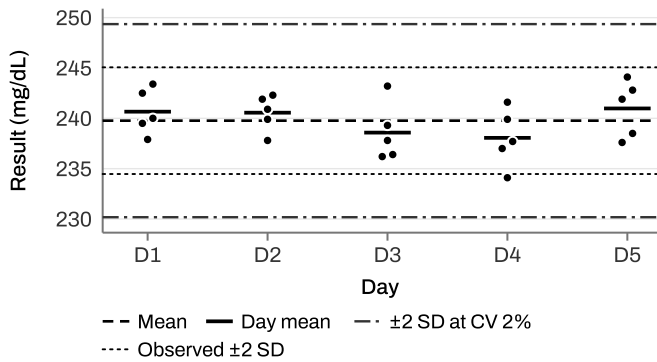


Figure 2. Level High: results by day.

1.2 Precision claim evidence

Observed SD is listed in the precision summary. A manufacturer claim uses its own one-sided verification limit.

Table 4. Verification degrees of freedom

Level	Component	Degrees of freedom	Confidence (%)	Method / result detail
Low	Repeatability	20	95.00	Chi-square
Low	Within-laboratory	12.87	95.00	Satterthwaite approximation
High	Within-laboratory	22.67	95.00	Satterthwaite approximation

1.3 Results by day

Table 5. Results by day (mg/dL)

Day	Level Low mean	Level Low SD	Level High mean	Level High SD
D1	80.02	1.55	240.66	2.25
D2	78.50	1.25	240.56	1.80
D3	80.04	1.15	238.58	2.87
D4	79.32	0.746	238.06	2.87
D5	81.26	0.568	240.98	2.80

5 results on each day.

1.4 Additional estimates

Table 6. Median, range, variance components and mean interval (mg/dL)

Level	Median	Lowest–highest	Between-day/run SD	Mean 95% CI
Low	79.80	77.1–82.0	0.890	78.56–81.09
High	239.90	234.1–244.1	0.707	238.10–241.44

2 Study notes

- 1. With one run per day, the between-day/run SD combines day and run effects.