

Untitled study

Glucose (mg/dL) · Linearity × Criteria not met

3 of 3 questions judged · Accuracy and Reportable range not met · Linearity met

Study date **Not recorded**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Linearity	Each level mean within ± 3 mg/dL or $\pm 6\%$ of the fitted value, whichever is greater		5 of 5 levels within	✓ Met
Accuracy	Bias at each level Relative bias: within $\pm 5\%$; Recovery: within 95–105%; Bias (mean minus assigned value): within ± 4 mg/dL of the assigned value; Every replicate within the greater of 4 mg/dL and 6% of the assigned value		Outside the limit: level 3; 10 of 10 replicates within their allowance	✗ Not met
Reportable range	Claimed 0–200 mg/dL; a level within $\pm 10\%$ of each end or, at the lower end, from 0 up to the limit; all levels between acceptable		Not verified: level 3 between the ends does not meet its criteria.	✗ Not met

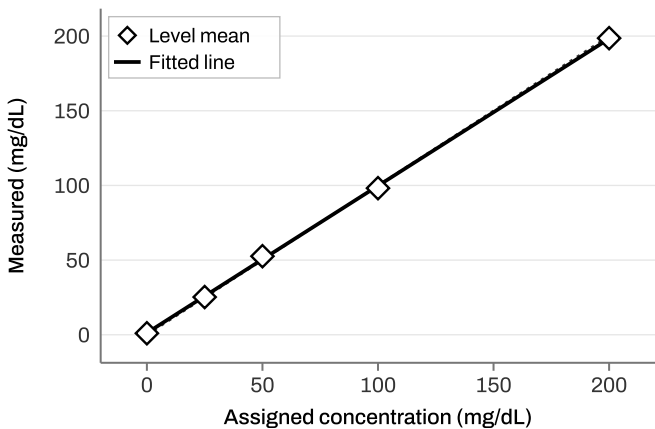


Figure 1. Level means against assigned concentration. Fitted line overlays $y = x$.

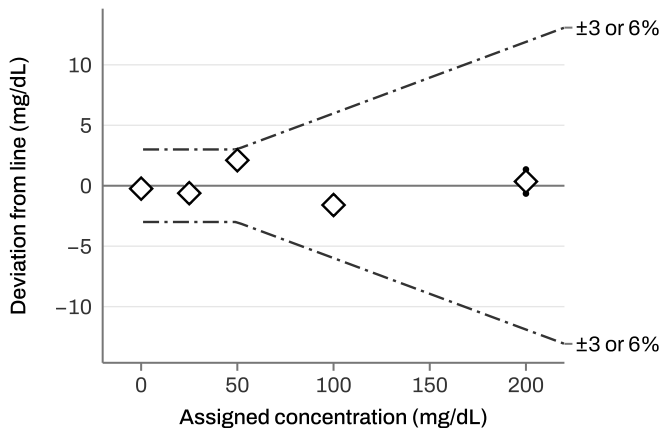


Figure 2. Deviation of each result from the fitted line.

Study details

Data 10 included

Design 5 levels × 2 replicates

Signed off by

Date

A Data listing

Source: manual entry. 10 rows, all included. Every row: within total-error allowance.

Study row	Specimen	Level	Assigned (mg/dL)	Result (mg/dL)	Replicate
1	L1	1	0	0.9	1
2	L1	1	0	1.1	2
3	L2	2	25	25.9	1
4	L2	2	25	24.6	2
5	L3	3	50	53.1	1
6	L3	3	50	52.1	2
7	L4	4	100	97.5	1
8	L4	4	100	98.8	2
9	L5	5	200	197.6	1
10	L5	5	200	199.6	2

1 Results

1.1 Results by level (mg/dL)

Table 2. Results by level (mg/dL)

Level	Assigned	Mean	Deviation from line	Linearity	Bias	Accuracy
1	0	1.00	−0.24	✓ Met	+1.00	⚠ Undecided
2	25	25.25	−0.62	✓ Met	+0.25	✓ Met
3	50	52.60	+2.11	✓ Met	+2.60	✗ Not met
4	100	98.15	−1.60	✓ Met	−1.85	✓ Met
5	200	198.60	+0.35	✓ Met	−1.40	✓ Met

1.2 Fitted line

Line through the 5 level means, 0–200 mg/dL: slope 0.985 (95% CI 0.953–1.017), intercept +1.24 mg/dL (−2.05 to 4.53), residual SD 1.59 mg/dL, R² 0.9997.

1.3 Replicate total-error check

· Every included replicate is compared with its independently assigned value. Equality with the allowance passes. Individual results and decisions are in the data listing.

Table 3. Total-error allowance by level

Level	Allowed absolute error (mg/dL)	Within / total	Result
1	4.00	2 / 2	✓
2	4.00	2 / 2	✓
3	4.00	2 / 2	✓
4	6.00	2 / 2	✓
5	12.00	2 / 2	✓

1.4 Level detail

Table 4. Level detail (mg/dL)

Level	N	SD	Fitted	Fitted 95% CI	Deviation (%)	Recovery (%)
1	2	0.141	1.24	−2.05 to 4.53	— ^a	— ^b
2	2	0.919	25.87	23.10–28.63	−2.39	101.00
3	2	0.707	50.49	48.10–52.89	+4.17	105.20
4	2	0.919	99.75	97.35–102.14	−1.60	98.15
5	2	1.41	198.25	193.67–202.84	+0.18	99.30

^a Relative deviation can't be calculated at a zero expected concentration.

^b Recovery can't be calculated at a zero expected concentration.

Fitted = the straight line at the assigned concentration. Deviation % = deviation from line / fitted × 100. Recovery = mean / assigned × 100.

1.5 Reportable range

Table 5. Claimed reportable range and the levels nearest its limits

End	Limit (mg/dL)	Window (mg/dL)	Closest level	Assigned (mg/dL)	Result
Lower	0	0.00–0.00	1	0	⊗ Undecided
Upper	200	180.00–220.00	5	200	✓ Met

Window = limit ± 10% of the limit.