

Untitled study

Glucose (mg/dL) · Calibration verification ✓ Criteria met

3 of 3 questions judged · Accuracy, Range coverage and Linearity met

Study date **Not recorded**

Table 1. Acceptance criteria

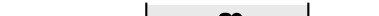
Question	Limit	Allowed	Finding	Result
Accuracy	Each mean within its bias limit; each replicate within its replicate limit		3 of 3 materials within	✓ Met
Range coverage	Low and high within 10% of 50 and 300 mg/dL (or zero at the low end), with a middle material		Covered	✓ Met
Linearity	Each deviation within its allowance		3 of 3 within	✓ Met

Table 2. Accuracy by material

Level	Assigned (mg/dL)	Mean (mg/dL)	Bias (mg/dL)	Bias limit (mg/dL)	Replicate limit (mg/dL)	Within / total	Accuracy
Low	50	49.97	-0.03	3.00	6.00	3/3 within	✓ Met
Mid	150	150.87	0.87	7.50	15.00	3/3 within	✓ Met
High	300	299.43	-0.57	15.00	30.00	3/3 within	✓ Met

Table 3. Linearity by material

Level	Deviation (mg/dL)	Limit (mg/dL)	Result
Low	-0.44	3.00	✓ Met
Mid	0.73	7.51	✓ Met
High	-0.29	14.99	✓ Met

Table 4. Precision index by material

Level	Index (≤ 1)	Result
Low	0.473	✓ Met
Mid	0.338	✓ Met
High	0.375	✓ Met

Study details

Data 9 included

Design 3 material levels

Signed off by _____

Date _____

A Data listing

Source: manual entry. 9 rows, all included. Every row: within total-error allowance.

Study row	Level	Result (mg/dL)	Replicate
1	Low	49.2	1
2	Low	50.6	2
3	Low	50.1	3
4	Mid	152.0	1
5	Mid	149.5	2
6	Mid	151.1	3
7	High	296.8	1
8	High	302.4	2
9	High	299.1	3

1 Results

1.1 Supporting estimates

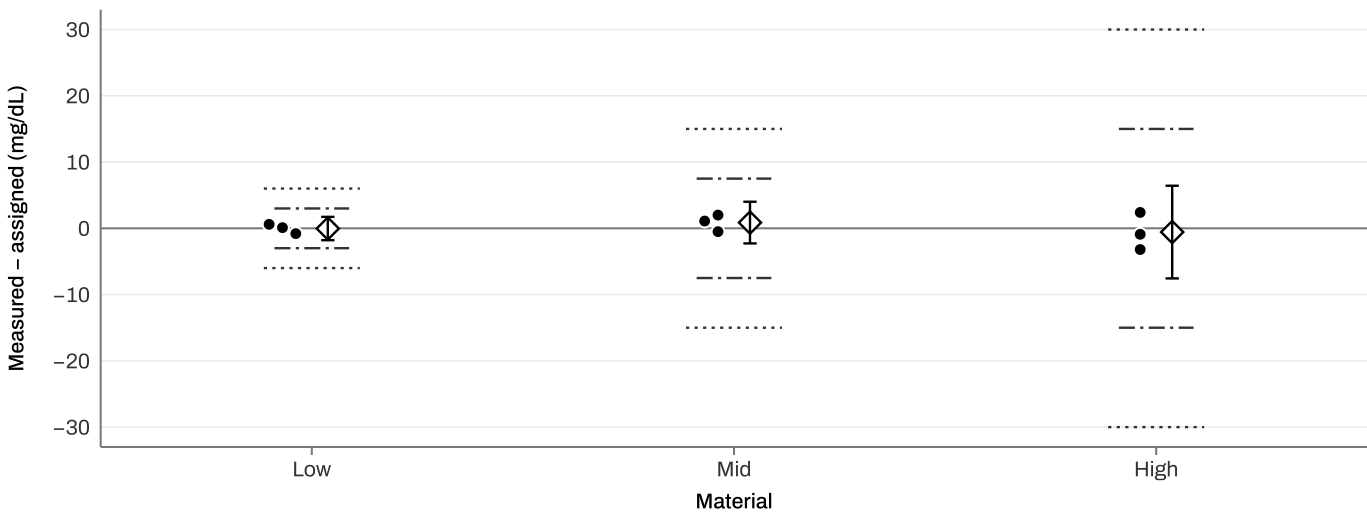


Figure 1. Difference from the assigned value at each level: dots, each replicate; open diamonds, the mean with its 95% CI; dash-dot ticks, allowed bias of the mean; dotted ticks, allowed error of each replicate.

Table 5. Intervals and error allowances

Level	Mean 95% CI (mg/dL)	Bias (%)	Recovery (%)	SD (mg/dL)
Low	48.20–51.73	–0.07	99.93	0.709
Mid	147.72–154.01	0.58	100.58	1.27
High	292.44–306.43	–0.19	99.81	2.81

1.2 Range coverage · Middle material: Mid.

Table 6. Endpoint coverage

Endpoint	Window (mg/dL)	Material	Result
Lower	45.00–55.00	Low	✓ Met
Upper	270.00–330.00	High	✓ Met

1.3 Linearity · Each level mean is compared with the unweighted fitted line; R² is descriptive only.

Table 7. Deviation from the fitted line

Level	Fitted (mg/dL)
Low	50.41
Mid	150.13
High	299.73

1.4 Precision index · Sample SD divided by its random-error allowance; the index must be at most 1.

Table 8. Precision against random error

Level	90% CI	SD allowance (mg/dL)
Low	0.273–2.088	1.50
Mid	0.195–1.491	3.75
High	0.217–1.657	7.50