Glucose · calibration verification · Chemistry analyzer A

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

2 of 2 questions judged · Accuracy and Range coverage met

Instrument **Chemistry analyzer A (CA-41027)** Study date **Sep 15, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Accuracy	Each mean within its bias limit; each replicate within its replicate limit		5 of 5 materials within	✓ Met
Range coverage	Low and high within 10% of 2 and 750 mg/dL (or zero at the low end), with a middle material		Covered	✓ Met

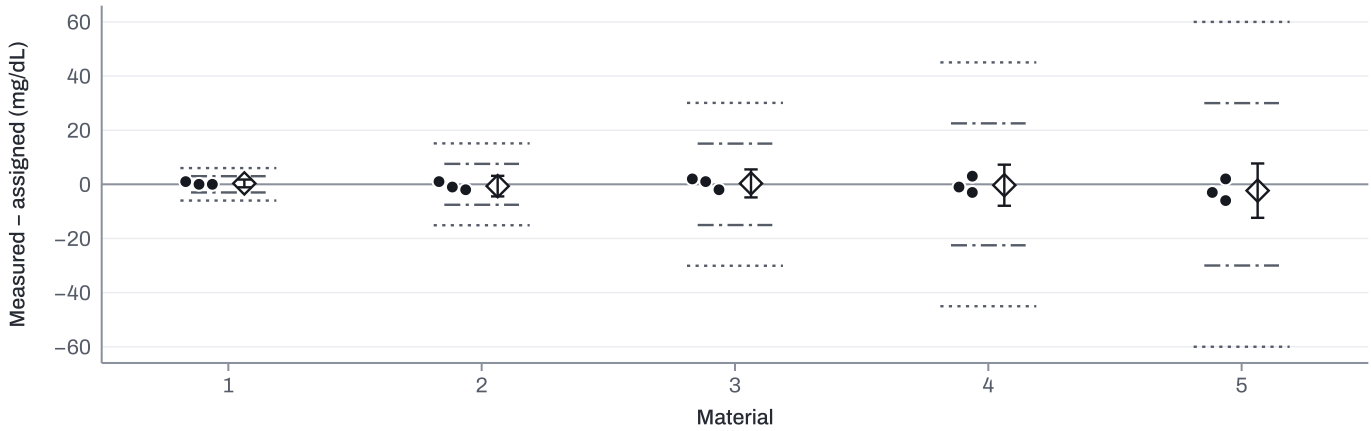

Figure 1. Difference from the assigned value at each level: dots, each replicate; open diamonds, the mean with its 95% CI; dash-dot ticks, allowed bias of the mean; dotted ticks, allowed error of each replicate.

Table 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
1	2	2.3	0.3	3.0	6.0	3/3 within	✓
2	189	188.3	−0.7	7.6	15.1	3/3 within	✓
3	376	376.3	0.3	15.0	30.1	3/3 within	✓
4	563	562.7	−0.3	22.5	45.0	3/3 within	✓
5	750	747.7	−2.3	30.0	60.0	3/3 within	✓

Study details

Matrix	Serum	Method	Hexokinase	Reagent lot	GLU-R2609
Calibrator lot	GLU-C2609	Data	15 included	Design	5 material levels

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Signed off by

Oct 23, 2026, 13:25 UTC
Date

A Data listing

Source: CHEM-A_LIN-2609_20260915.csv. 15 rows, all included. Every row: within total-error allowance.

Study row	Material	Level	Result (mg/dL)	Replicate	Source row
1	LIN-2609 L1	1	2	1	2
2	LIN-2609 L1	1	3	2	3
3	LIN-2609 L1	1	2	3	4
4	LIN-2609 L2	2	188	1	5
5	LIN-2609 L2	2	190	2	6
6	LIN-2609 L2	2	187	3	7
7	LIN-2609 L3	3	378	1	8
8	LIN-2609 L3	3	374	2	9
9	LIN-2609 L3	3	377	3	10
10	LIN-2609 L4	4	560	1	11
11	LIN-2609 L4	4	566	2	12
12	LIN-2609 L4	4	562	3	13
13	LIN-2609 L5	5	744	1	14
14	LIN-2609 L5	5	752	2	15
15	LIN-2609 L5	5	747	3	16

1 Results

1.1 Supporting estimates

Table 3. Intervals and error allowances

Level	Mean 95% CI (mg/dL)	Bias (%)	Recovery (%)	SD (mg/dL)
1	0.9–3.8	16.7	116.7	0.577
2	184.5–192.1	−0.4	99.6	1.53
3	371.2–381.5	0.1	100.1	2.08
4	555.1–570.3	−0.1	99.9	3.06
5	737.6–757.7	−0.3	99.7	4.04

1.2 Range coverage · Middle material: 3.

Table 4. Endpoint coverage

Endpoint	Window (mg/dL)	Material	Result
Lower	1.8–2.2	1	✓ Met
Upper	675.0–825.0	5	✓ Met