

Glucose · linearity · Chemistry analyzer A

Glucose (mg/dL) · Linearity ✓ Criteria met

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

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

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Linearity	Each level mean within ± 3.0 mg/dL or $\pm 4.0\%$ of the fitted value, whichever is greater		5 of 5 levels within	✓ Met
Accuracy	No accuracy limit set		Largest bias: level 5	○ Not evaluated
Reportable range	Claimed 2–750 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		Covered, low: level 1; high: level 5	✓ Met

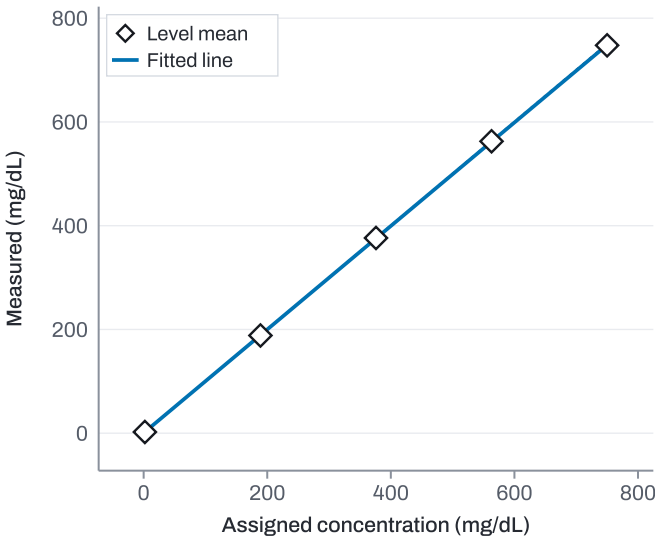


Figure 1. Level means against assigned concentration. Fitted line overlays $y = x$.

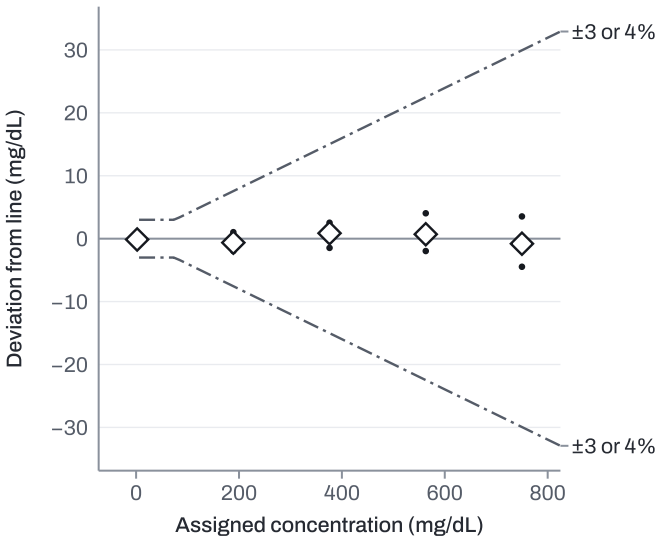


Figure 2. Deviation of each result from the fitted line.

Study details

Matrix	Serum	Method	Hexokinase	Reagent lot	GLU-R2609
Calibrator lot	GLU-C2609	Data	15 included	Design	5 levels × 3 replicates

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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.

Study row	Specimen	Level	Assigned (mg/dL)	Result (mg/dL)	Replicate	Source row
1	LIN-2609 L1	1	2	2	1	2
2	LIN-2609 L1	1	2	3	2	3
3	LIN-2609 L1	1	2	2	3	4
4	LIN-2609 L2	2	189	188	1	5
5	LIN-2609 L2	2	189	190	2	6
6	LIN-2609 L2	2	189	187	3	7
7	LIN-2609 L3	3	376	378	1	8
8	LIN-2609 L3	3	376	374	2	9
9	LIN-2609 L3	3	376	377	3	10
10	LIN-2609 L4	4	563	560	1	11
11	LIN-2609 L4	4	563	566	2	12
12	LIN-2609 L4	4	563	562	3	13
13	LIN-2609 L5	5	750	744	1	14
14	LIN-2609 L5	5	750	752	2	15
15	LIN-2609 L5	5	750	747	3	16

1 Results

1.1 Results by level (mg/dL)

Table 2. Results by level (mg/dL)

Level	Assigned	Mean	Deviation from line	Linearity	Bias
1	2	2.3	-0.1	✓	+0.3
2	189	188.3	-0.6	✓	-0.7
3	376	376.3	+0.9	✓	+0.3
4	563	562.7	+0.7	✓	-0.3
5	750	747.7	-0.8	✓	-2.3

1.2 Fitted line

Line through the 5 level means, 2–750 mg/dL: slope 0.997 (95% CI 0.993–1.002), intercept +0.472 mg/dL (–1.7 to 2.6), residual SD 0.876 mg/dL, R² > 0.9999.

1.3 Level detail

Table 3. Level detail (mg/dL)

Level	N	SD	Fitted	Fitted 95% CI	Deviation (%)	Recovery (%)
1	3	0.577	2.5	0.3–4.6	-5.4	116.7
2	3	1.53	189.0	187.4–190.5	-0.3	99.6
3	3	2.08	375.5	374.2–376.7	+0.2	100.1
4	3	3.06	562.0	560.4–563.5	+0.1	99.9
5	3	4.04	748.5	746.3–750.6	-0.1	99.7

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

1.4 Reportable range

Table 4. Claimed reportable range and the levels nearest its limits

End	Limit (mg/dL)	Window (mg/dL)	Closest level	Assigned (mg/dL)	Result
Lower	2	1.8–2.2	1	2	✓ Met
Upper	750	675.0–825.0	5	750	✓ Met

Window = limit ± 10% of the limit.