

Glucose · response linearity

Glucose (mg/dL) · Linearity ✓ Criteria met

3 of 3 questions judged · Linearity, Accuracy and Reportable range met

Instrument **Chemistry analyzer A** Study date **Sep 22, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Linearity	Each level mean within ± 3 mg/dL or $\pm 4\%$ of the fitted value, whichever is greater		5 of 5 levels within	✓ Met
Accuracy	Bias at each level within ± 6 mg/dL or $\pm 8\%$ of the assigned value, whichever is greater		Largest bias: level 4	✓ Met
Reportable range	Claimed 2–600 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

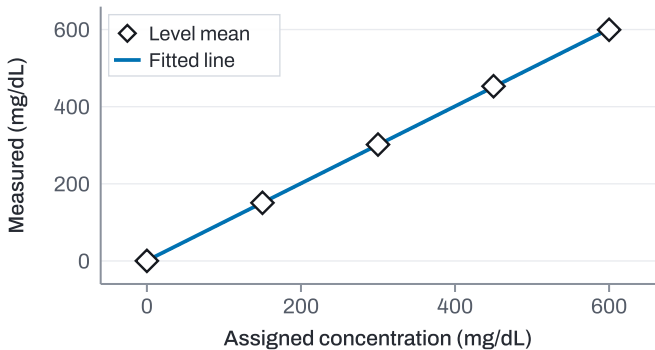


Figure 1. Level means against assigned concentration. Fitted line overlays $y = x$.

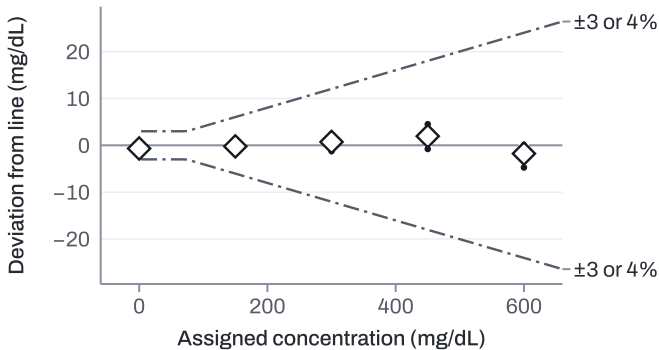


Figure 2. Deviation of each result from the fitted line.

Table 2. Results by level (mg/dL)

Level	Assigned	Mean	Deviation from line	Linearity	Bias	Accuracy
1	0	0.27	-0.68	✓	+0.27	✓
2	150	150.77	-0.23	✓	+0.77	✓
3	300	301.77	+0.73	✓	+1.77	✓
4	450	453.03	+1.95	✓	+3.03	✓
5	600	599.37	-1.77	✓	-0.63	✓

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, 13:23 UTC

Date

A Data listing

Source: linearity.csv. 15 rows, all included.

Study row	Specimen	Level	Assigned (mg/dL)	Result (mg/dL)	Replicate	Source row
1	00001	1	0	0.4	1	2
2	00002	1	0	0.1	2	3
3	00003	1	0	0.3	3	4
4	00004	2	150	151.8	1	5
5	00005	2	150	149.6	2	6
6	00006	2	150	150.9	3	7
7	00007	3	300	303.4	1	8
8	00008	3	300	299.8	2	9
9	00009	3	300	302.1	3	10
10	00010	4	450	455.6	1	11
11	00011	4	450	450.3	2	12
12	00012	4	450	453.2	3	13
13	00013	5	600	601.2	1	14
14	00014	5	600	596.4	2	15
15	00015	5	600	600.5	3	16

1 Results

1.1 Fitted line

Line through the 5 level means, 0–600 mg/dL: slope 1.000 (95% CI 0.989–1.011), intercept +0.947 mg/dL (–3.07 to 4.96), residual SD 1.63 mg/dL, $R^2 > 0.9999$.

1.2 Level detail

Table 3. Level detail (mg/dL)

Level	N	SD	Fitted	Fitted 95% CI	Deviation (%)	Recovery (%)
1	3	0.153	0.95	–3.07 to 4.96	— ^a	— ^b
2	3	1.11	150.99	148.16–153.83	–0.15	100.51
3	3	1.82	301.04	298.72–303.36	+0.24	100.59
4	3	2.65	451.09	448.25–453.92	+0.43	100.67
5	3	2.59	601.13	597.12–605.15	–0.29	99.89

^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.

1.3 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	1.80–2.20	1	0	✓ Met
Upper	600	540.00–660.00	5	600	✓ Met

Window = limit ± 10% of the limit.