Glucose · method comparison · Chemistry analyzer A

Glucose (mg/dL) · Method comparison ✓ Criteria met

4 of 4 questions judged · 4 questions met

Instrument **Chemistry analyzer A (CA-41027)** Comparator **Chemistry analyzer B** Test method **Chemistry analyzer A**

Study date **Sep 10, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Individual specimen agreement	At least 95% of specimens within ±6 mg/dL or ±8% of the comparative result, whichever is greater		39 of 40 within	✓
Bias at 70 mg/dL	|Bias| ≤ 3 mg/dL at 70 mg/dL		+1.6 mg/dL 1.6 mg/dL from target	✓
Bias at 126 mg/dL	|Bias| ≤ 4% at 126 mg/dL		+2.4 mg/dL 1.9% from target	✓
Bias at 200 mg/dL	|Bias| ≤ 4% at 200 mg/dL		+3.4 mg/dL 1.7% from target	✓

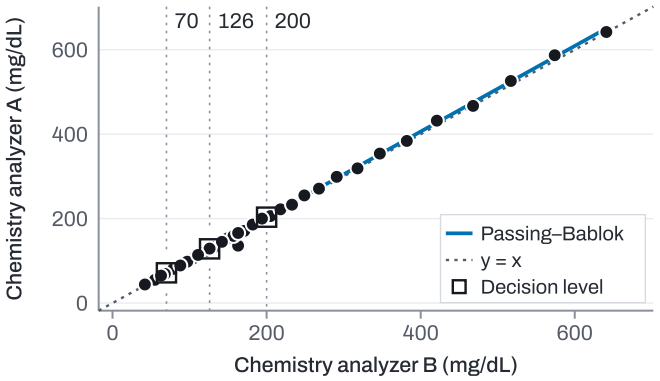

Figure 1. Test against comparative method.

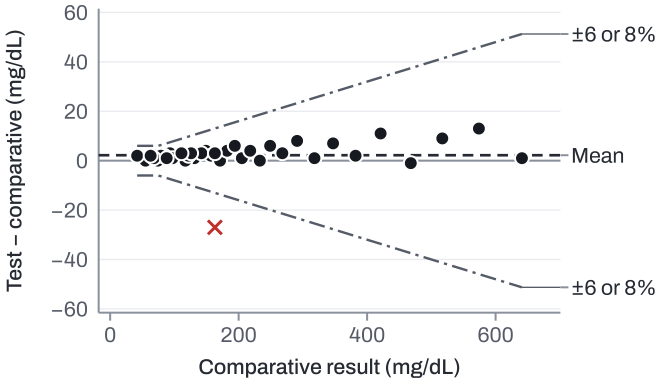

Figure 2. Differences; dash-dot: allowed difference; dashed: mean difference; ×: outside it.

Table 2. Regression and bias

Estimate	Value	95% CI
Slope	1.014	1.000–1.022
Intercept (mg/dL)	+0.666	−0.6 to 2.0
Mean bias (mg/dL)	+2.2	0.4–4.0

Study details

Matrix	Serum	Method	Hexokinase
Reagent lot	GLU-R2609	Calibrator lot	GLU-C2609
Data	40 included	Replicates	Single
Regression	Passing–Bablok		
Comparative range	42–641 mg/dL		
Decision levels	70, 126, 200 mg/dL		

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Signed off by

Oct 23, 2026, 13:25 UTC

Date

A Data listing

Source: CHEM-B_CHEM-A_glucose_20260910.csv. 40 rows, all included.

Study row	Specimen	Comparative (mg/dL)	Test (mg/dL)	Source row
1	MC-01	102	104	2
2	MC-02	131	132	3
3	MC-03	641	642	4
4	MC-04	93	96	5
5	MC-05	149	153	6
6	MC-06	468	467	7
7	MC-07	106	107	8
8	MC-08	163	136	9
9	MC-09	421	432	10
10	MC-10	157	159	11
11	MC-11	71	73	12
12	MC-12	142	145	13
13	MC-13	171	171	14
14	MC-14	117	117	15
15	MC-15	182	186	16
16	MC-16	205	206	17
17	MC-17	194	200	18
18	MC-18	74	74	19
19	MC-19	218	222	20
20	MC-20	517	526	21
21	MC-21	347	354	22
22	MC-22	122	124	23
23	MC-23	97	98	24
24	MC-24	55	55	25
25	MC-25	318	319	26
26	MC-26	84	86	27
27	MC-27	249	255	28
28	MC-28	79	81	29
29	MC-29	163	166	30
30	MC-30	126	129	31
31	MC-31	291	299	32
32	MC-32	111	114	33
33	MC-33	42	44	34
34	MC-34	68	69	35
35	MC-35	88	89	36
36	MC-36	574	587	37
37	MC-37	233	233	38
38	MC-38	382	384	39
39	MC-39	268	271	40
40	MC-40	63	65	41

1 Results

1.1 Specimen decisions

Table 3. Specimen decisions

Specimen	Comparative (mg/dL)	Difference (mg/dL)	Allowed difference (mg/dL)	Outcome
MC-01	102	+2.0	±8.2	✓ Met
MC-02	131	+1.0	±10.5	✓ Met
MC-03	641	+1.0	±51.3	✓ Met
MC-04	93	+3.0	±7.4	✓ Met
MC-05	149	+4.0	±11.9	✓ Met
MC-06	468	−1.0	±37.4	✓ Met
MC-07	106	+1.0	±8.5	✓ Met
MC-08	163	−27.0	±13.0	✕ Not met
MC-09	421	+11.0	±33.7	✓ Met
MC-10	157	+2.0	±12.6	✓ Met
MC-11	71	+2.0	±6.0	✓ Met
MC-12	142	+3.0	±11.4	✓ Met
MC-13	171	0.0	±13.7	✓ Met
MC-14	117	0.0	±9.4	✓ Met
MC-15	182	+4.0	±14.6	✓ Met
MC-16	205	+1.0	±16.4	✓ Met
MC-17	194	+6.0	±15.5	✓ Met
MC-18	74	0.0	±6.0	✓ Met
MC-19	218	+4.0	±17.4	✓ Met
MC-20	517	+9.0	±41.4	✓ Met
MC-21	347	+7.0	±27.8	✓ Met
MC-22	122	+2.0	±9.8	✓ Met
MC-23	97	+1.0	±7.8	✓ Met
MC-24	55	0.0	±6.0	✓ Met
MC-25	318	+1.0	±25.4	✓ Met
MC-26	84	+2.0	±6.7	✓ Met
MC-27	249	+6.0	±19.9	✓ Met
MC-28	79	+2.0	±6.3	✓ Met
MC-29	163	+3.0	±13.0	✓ Met
MC-30	126	+3.0	±10.1	✓ Met
MC-31	291	+8.0	±23.3	✓ Met
MC-32	111	+3.0	±8.9	✓ Met
MC-33	42	+2.0	±6.0	✓ Met
MC-34	68	+1.0	±6.0	✓ Met
MC-35	88	+1.0	±7.0	✓ Met
MC-36	574	+13.0	±45.9	✓ Met
MC-37	233	0.0	±18.6	✓ Met

Table 3. Specimen decisions

Specimen	Comparative (mg/dL)	Difference (mg/dL)	Allowed difference (mg/dL)	Outcome
MC-38	382	+2.0	±30.6	✓ Met
MC-39	268	+3.0	±21.4	✓ Met
MC-40	63	+2.0	±6.0	✓ Met

Difference = test – comparative.

1.2 Differences and limits of agreement

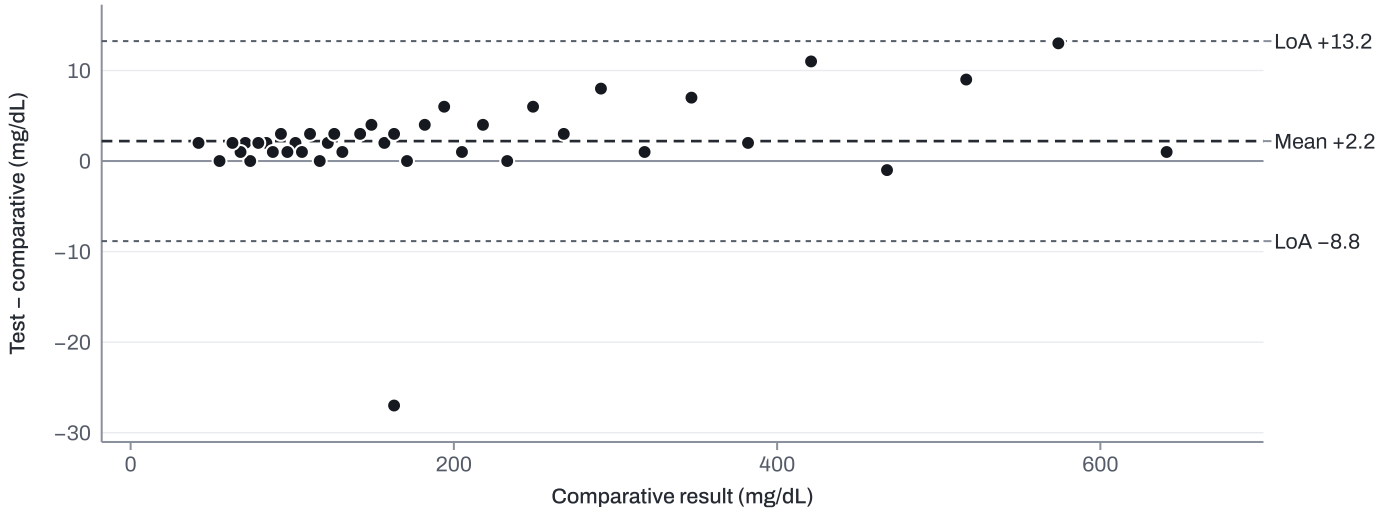

Figure 3. Test – comparative, with the mean and 95% limits of agreement.

Table 4. 95% limits of agreement for individual differences

Estimate	Difference (mg/dL)	95% CI (mg/dL)	Relative (%)	95% CI (%)
SD of differences	5.64			
Lower limit of agreement	−8.8	−12.0 to −5.7	−4.9	−6.6 to −3.2
Upper limit of agreement	+13.2	10.1–16.4	+7.3	5.6–9.0

Relative differences are percentages of the comparative result.

1.3 Ranges and fit details

Table 5. Ranges and fit details

Item	Value
Test range	44–642 mg/dL
Decision-level CIs	From the slope and intercept confidence region

1.4 Reportable-range coverage

· Coverage describes the span of observed concentrations inside the claimed interval. It does not make an acceptance decision.

Table 6. Observed and claimed ranges

Level	Axis	Claimed (mg/dL)	Observed (mg/dL)	Coverage (%)
*	Comparative method	2.0–750.0	42.0–641.0	80.1