

Chemistry analyzer A · glucose

Tests	Glucose	Instruments	Chemistry analyzer A (CA-41027)
Calculated	Oct 23, 2026	Reports	7
Prepared	Oct 23, 2026, 13:25 UTC		

7 ✓ Criteria met	0 × Criteria not met	0 ⚠ Undecided
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Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.

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Checklist edition: 9 December 2025.

Chemistry analyzer A (CA-41027) · Glucose · calibration verification · Chemistry analyzer A Data 3 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
COM.40300	Unmodified FDA-cleared or approved nonwaived tests. Written assessment for each test and instrument, including investigation of discordant results.	Decision page · p. 6 Results · p. 7 Data listing · p. 7
CHM.13550	Chemistry AMR verification materials covering low, middle and high concentrations. Material suitability and preparation instructions.	Range coverage · p. 7 Data listing · p. 7
CHM.13600	Chemistry AMR verification with applicable timing, triggers and exceptions. AMR schedule and applicable event records.	Range coverage · p. 7 Decision page · p. 6
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 6 Sign-off · p. 6
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 7

Chemistry analyzer A (CA-41027) · Glucose · dilution verification · Chemistry analyzer A Data 4 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
CHM.13710	Chemistry results above or below the AMR. Reporting and dilution procedures.	Decision page · p. 8 Results · p. 9
CHM.13720	Applicable chemistry dilution protocols. Validated dilution protocol and diluent suitability.	Decision page · p. 8 Results · p. 9
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 8 Sign-off · p. 8
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 9

Chemistry analyzer A (CA-41027) · Glucose · linearity · Chemistry analyzer A Data 3 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
COM.40300	Unmodified FDA-cleared or approved nonwaived tests. Written assessment for each test and instrument, including investigation of discordant results.	Decision page · p. 10 Results · p. 11 Data listing · p. 11
CHM.13550	Chemistry AMR verification materials covering low, middle and high concentrations. Material suitability and preparation instructions.	Range coverage · p. 12 Data listing · p. 11
CHM.13600	Chemistry AMR verification with applicable timing, triggers and exceptions. AMR schedule and applicable event records.	Range coverage · p. 12 Decision page · p. 10
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 10 Sign-off · p. 10
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 11

Chemistry analyzer A (CA-41027) · Glucose · lot comparison · Chemistry analyzer A Data 3 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
COM.30450	New reagent lots and shipments, including shipments of the same lot. Material suitability and lot or shipment acceptance records.	Study details · p. 13 Decision page · p. 13 Data listing · p. 14
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 13 Sign-off · p. 13
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 14

Chemistry analyzer A (CA-41027) · Glucose · method comparison · Chemistry analyzer A Data 3 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
COM.40300	Unmodified FDA-cleared or approved nonwaived tests. Written assessment for each test and instrument, including investigation of discordant results.	Decision page · p. 18 Results · p. 20 Data listing · p. 19
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 18 Sign-off · p. 18

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 19

Chemistry analyzer A (CA-41027) · Glucose · multi-day precision · Chemistry analyzer A Data 2 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
COM.40300	Unmodified FDA-cleared or approved nonwaived tests. Written assessment for each test and instrument, including investigation of discordant results.	Decision page · p. 22 Results · p. 24 Data listing · p. 23
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 22 Sign-off · p. 22
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 23

Chemistry analyzer A (CA-41027) · Glucose · repeatability · Chemistry analyzer A Data 2 · report 1

Requirement	Applicability and associated laboratory evidence	Supporting sections and binder pages
COM.40300	Unmodified FDA-cleared or approved nonwaived tests. Written assessment for each test and instrument, including investigation of discordant results.	Decision page · p. 25 Results · p. 27 Data listing · p. 26
COM.40475	Approval of nonwaived test validation or verification before clinical use. Director or qualified designee signed written assessment and approval tied to each test and instrument.	Decision page · p. 25 Sign-off · p. 25
GEN.20377	Laboratory record retention. Keep method validation and verification records for the life of the test plus two years, or longer when applicable retention rules require it.	Downloaded evidence archive
GEN.20450	Corrections to laboratory records. Retained original values and traceable corrections.	Data listing · p. 26

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

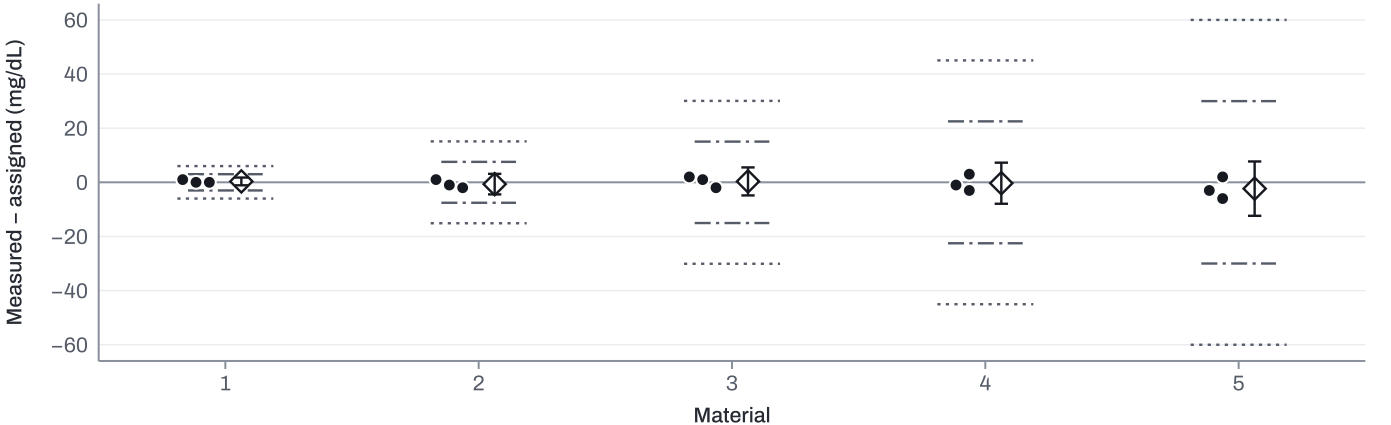


Figure 1. Difference from the assigned value at each level: dots, each replicate; open diamonds, the mean with its 95% CI; dash-dot ticks, allowed bias of the mean; dotted ticks, allowed error of each replicate.

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

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

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

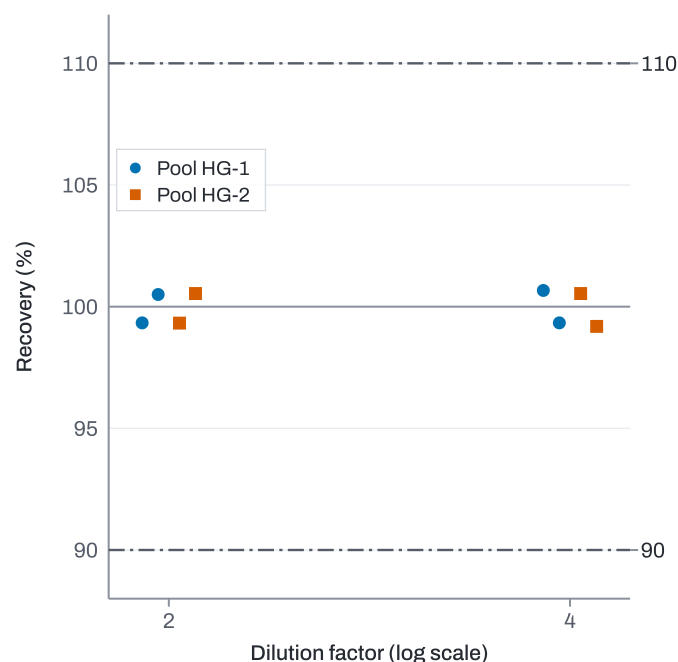
Endpoint	Window (mg/dL)	Material	Result
Lower	1.8–2.2	1	✓ Met
Upper	675.0–825.0	5	✓ Met

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

Instrument **Chemistry analyzer A (CA-41027)** Study date **Sep 16, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Recovery	Between 90% and 110% at each dilution		8 of 8 dilutions within	✓ Met



Diluted result (mg/dL)

Dilution factor (log scale)

Pool HG-1

Pool HG-2

Dilution factor (log scale)	Pool HG-1 (mg/dL)	Pool HG-2 (mg/dL)
2	~600	~750
3	~600	~750
4	~300	~370
5	~300	~370

Figure 2. Diluted results; dash-dot lines: reportable range.

Table 2. Results by pool (mg/dL)

Pool	Expected	Factors	Recovery (%)	Within limit	Verified range	Result
HG-1	1200	×2 to ×4	99.3–100.7	4 of 4	1192.0–1208.0	✓ Met
HG-2	1480	×2 to ×4	99.2–100.5	4 of 4	1468.0–1488.0	✓ Met

Study details

Matrix	Serum	Method	Hexokinase	Reagent lot	GLU-R2609
Calibrator lot	GLU-C2609	Data	8 included	Reportable range	2-750 mg/dL

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

Signed off by

Oct 23, 2026, 13:25 UTC

Date _____

A Data listing

Source: CHEM-A_glucose_dilutions_20260916.csv. 8 rows, all included.

Study row	Specimen	Pool	Factor	Result (mg/dL)	Replicate	Source row
1	HG-1	HG-1	2	596	1	2
2	HG-1	HG-1	2	603	2	3
3	HG-1	HG-1	4	302	3	4
4	HG-1	HG-1	4	298	4	5
5	HG-2	HG-2	2	735	1	6
6	HG-2	HG-2	2	744	2	7
7	HG-2	HG-2	4	372	3	8
8	HG-2	HG-2	4	367	4	9

1 Results

1.1 Dilutions

Table 3. Dilutions

Pool	Specimen	Row	Preparation	Factor	Measured (mg/dL)	In range	Corrected (mg/dL)	Recovery (%)	Result
HG-1	HG-1	1	Stated	×2	596	Yes	1192.0	99.3	✓
HG-1	HG-1	2	Stated	×2	603	Yes	1206.0	100.5	✓
HG-1	HG-1	3	Stated	×4	302	Yes	1208.0	100.7	✓
HG-1	HG-1	4	Stated	×4	298	Yes	1192.0	99.3	✓
HG-2	HG-2	5	Stated	×2	735	Yes	1470.0	99.3	✓
HG-2	HG-2	6	Stated	×2	744	Yes	1488.0	100.5	✓
HG-2	HG-2	7	Stated	×4	372	Yes	1488.0	100.5	✓
HG-2	HG-2	8	Stated	×4	367	Yes	1468.0	99.2	✓

Diluent: Saline. Preparation: specimen + diluent volumes, serial steps or a stated factor. Factor = (specimen + diluent) / specimen. Corrected = measured × factor. Recovery = corrected / expected × 100. In range: measured inside the reportable range, 2–750 mg/dL.

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

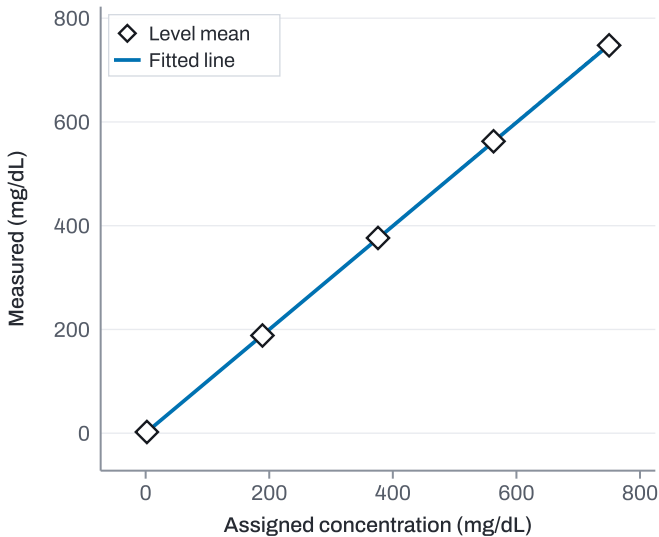


Figure 1. Level means against assigned concentration. Fitted line overlays $y = x$.

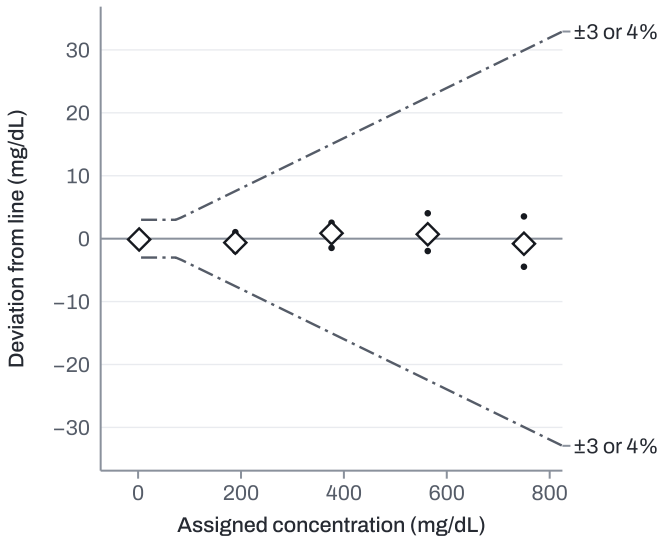


Figure 2. Deviation of each result from the fitted line.

Study details

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

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

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.

Glucose · lot comparison · Chemistry analyzer A

Glucose (mg/dL) · Reagent lot comparison ✓ Criteria met

2 of 2 questions judged · Specimens and Lot plan met

Instrument **Chemistry analyzer A (CA-41027)** Previous lot **GLU-R2609** New lot **GLU-R2610**
Study date **Oct 8, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Specimens	95% within ± 6 mg/dL or $\pm 8\%$ of the previous lot, whichever is greater		20 of 20 within	✓ Met
Lot plan	20 matched pairs, each level in its planned range		20 pairs	✓ Met

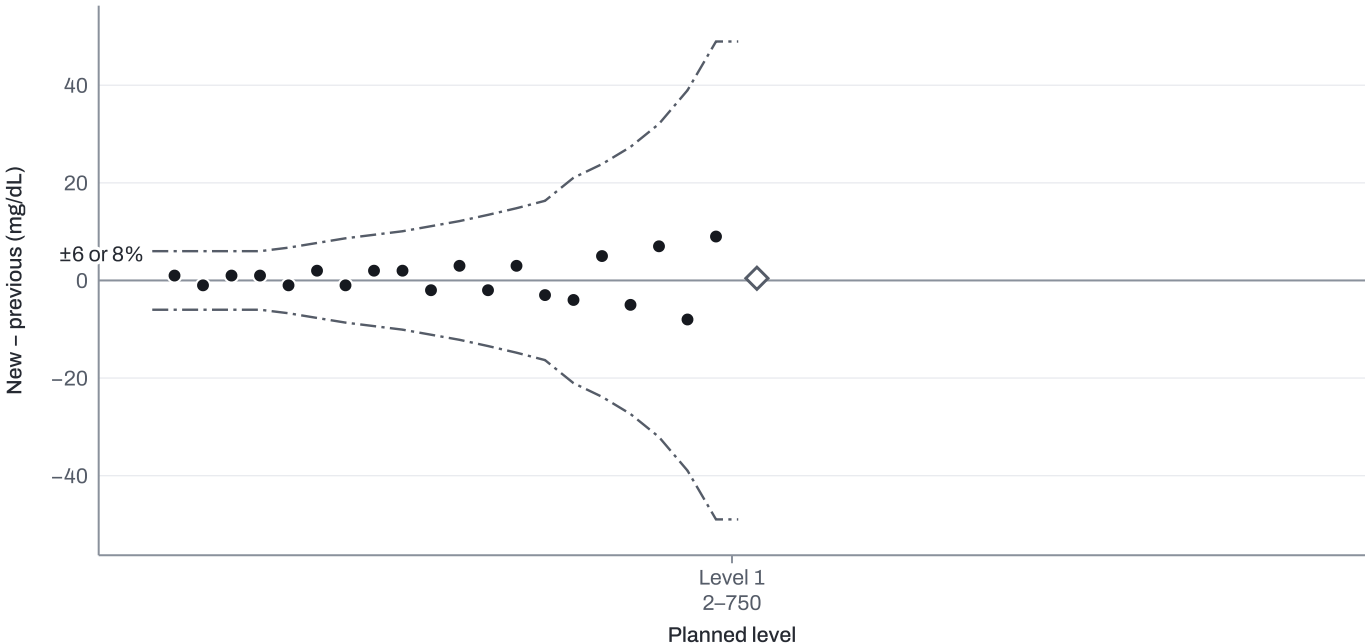


Figure 1. Each specimen’s difference by planned level, in order of concentration; dash-dot: its allowed difference; open diamonds: level mean difference.

Mean difference (new – previous) over 20 pairs +0.5 mg/dL (95% CI –1.4 to 2.3); SD of the differences 4.03 mg/dL.

Study details

Matrix	Serum	Method	Hexokinase	Calibrator lot	GLU-C2609
Data	40 included · 2 excluded				

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

Signed off by

Oct 23, 2026, 13:25 UTC

Date

A Data listing

Source: CHEM-A_results_20261008.csv. Patient specimens. 42 rows.

Study row	Specimen	Lot	Original (mg/dL)	Current (mg/dL)	Included	Source row	Note
1	LC-01	GLU-R2609	28	28	Yes	2	
2	LC-02	GLU-R2609	45	45	Yes	4	
3	LC-03	GLU-R2609	61	61	Yes	6	
4	LC-04	GLU-R2609	72	72	Yes	8	
5	LC-05	GLU-R2609	84	84	Yes	10	
6	LC-06	GLU-R2609	96	96	Yes	12	
7	LC-07	GLU-R2609	108	108	Yes	14	
8	LC-08	GLU-R2609	117	117	Yes	16	
9	LC-09	GLU-R2609	126	126	Yes	18	
10	LC-10	GLU-R2609	139	139	Yes	20	
11	LC-11	GLU-R2609	152	152	Yes	22	
12	LC-12	GLU-R2609	168	168	Yes	24	
13	LC-13	GLU-R2609	185	185	Yes	26	
14	LC-14	GLU-R2609	204	204	Yes	28	
15	LC-15	GLU-R2609	231	231	No	30	Excluded: Clot flagged by analyzer
16	LC-16	GLU-R2609	263	263	Yes	32	
17	LC-17	GLU-R2609	298	298	Yes	34	
18	LC-18	GLU-R2609	342	342	Yes	36	
19	LC-19	GLU-R2609	401	401	Yes	38	
20	LC-20	GLU-R2609	487	487	Yes	40	
21	LC-21	GLU-R2609	612	612	Yes	42	
22	LC-01	GLU-R2610	29	29	Yes	44	
23	LC-02	GLU-R2610	44	44	Yes	45	

Study row	Specimen	Lot	Original (mg/dL)	Current (mg/dL)	Included	Source row	Note
24	LC-03	GLU-R2610	62	62	Yes	46	
25	LC-04	GLU-R2610	73	73	Yes	47	
26	LC-05	GLU-R2610	83	83	Yes	48	
27	LC-06	GLU-R2610	98	98	Yes	49	
28	LC-07	GLU-R2610	107	107	Yes	50	
29	LC-08	GLU-R2610	119	119	Yes	51	
30	LC-09	GLU-R2610	128	128	Yes	52	
31	LC-10	GLU-R2610	137	137	Yes	53	
32	LC-11	GLU-R2610	155	155	Yes	54	
33	LC-12	GLU-R2610	166	166	Yes	55	
34	LC-13	GLU-R2610	188	188	Yes	56	
35	LC-14	GLU-R2610	201	201	Yes	57	
36	LC-15	GLU-R2610	198	198	No	58	Excluded: Clot flagged by analyzer
37	LC-16	GLU-R2610	259	259	Yes	59	
38	LC-17	GLU-R2610	303	303	Yes	60	
39	LC-18	GLU-R2610	337	337	Yes	61	
40	LC-19	GLU-R2610	408	408	Yes	62	
41	LC-20	GLU-R2610	479	479	Yes	63	
42	LC-21	GLU-R2610	621	621	Yes	64	

1 Results

1.1 Specimen results

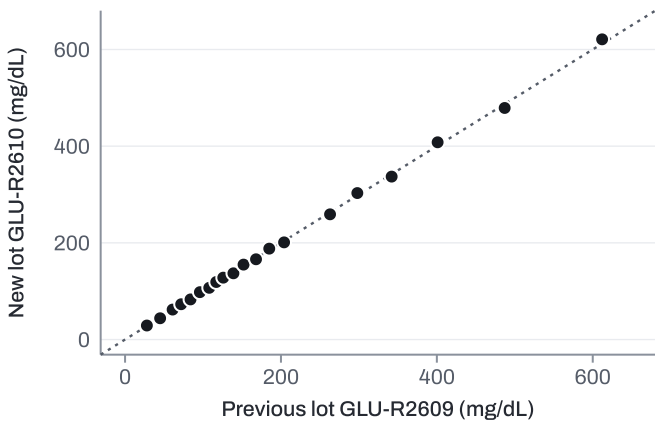


Figure 2. New lot against previous lot; dotted line: equal results.

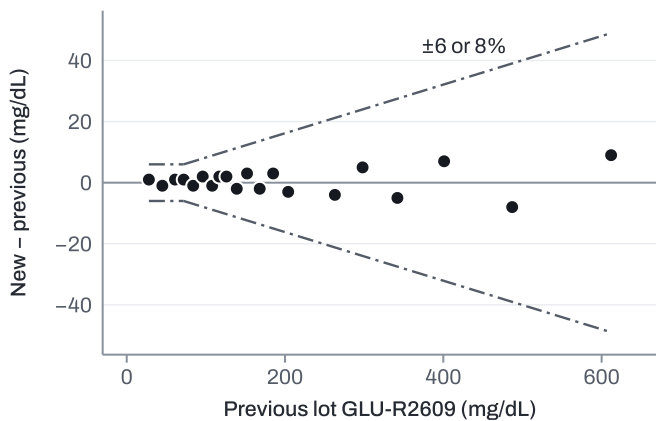


Figure 3. Each specimen's difference with its allowed range.

Table 2. Specimen results (mg/dL)

Specimen	Previous lot GLU-R2609	New lot GLU-R2610	Difference	Allowed	Result
LC-01	28	29	+1.0	±6.0	✓
LC-02	45	44	-1.0	±6.0	✓
LC-03	61	62	+1.0	±6.0	✓
LC-04	72	73	+1.0	±6.0	✓
LC-05	84	83	-1.0	±6.7	✓
LC-06	96	98	+2.0	±7.7	✓
LC-07	108	107	-1.0	±8.6	✓
LC-08	117	119	+2.0	±9.4	✓
LC-09	126	128	+2.0	±10.1	✓
LC-10	139	137	-2.0	±11.1	✓
LC-11	152	155	+3.0	±12.2	✓
LC-12	168	166	-2.0	±13.4	✓
LC-13	185	188	+3.0	±14.8	✓
LC-14	204	201	-3.0	±16.3	✓
LC-16	263	259	-4.0	±21.0	✓
LC-17	298	303	+5.0	±23.8	✓
LC-18	342	337	-5.0	±27.4	✓
LC-19	401	408	+7.0	±32.1	✓
LC-20	487	479	-8.0	±39.0	✓
LC-21	612	621	+9.0	±49.0	✓

Difference = new – previous.

1.2 Plan coverage

Table 3. Plan coverage

Level	Previous-lot results (mg/dL)	Inside the planned range
1	28–612	20 of 20

1.3 Reportable-range coverage

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

Table 4. Observed and claimed ranges

Level	Axis	Claimed (mg/dL)	Observed (mg/dL)	Coverage (%)
*	Previous lot GLU-R2609	2.0–750.0	28.0–612.0	78.1

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	✓

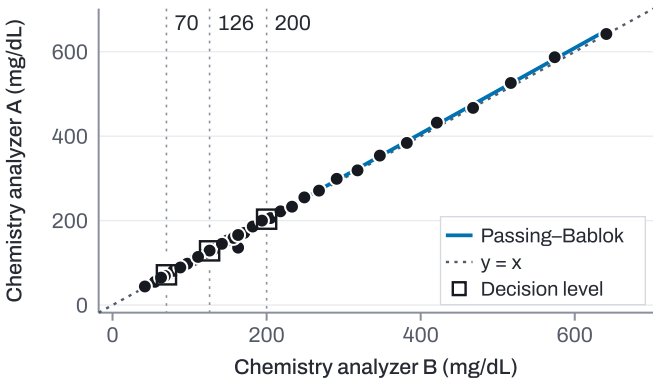


Figure 1. Test against comparative method.

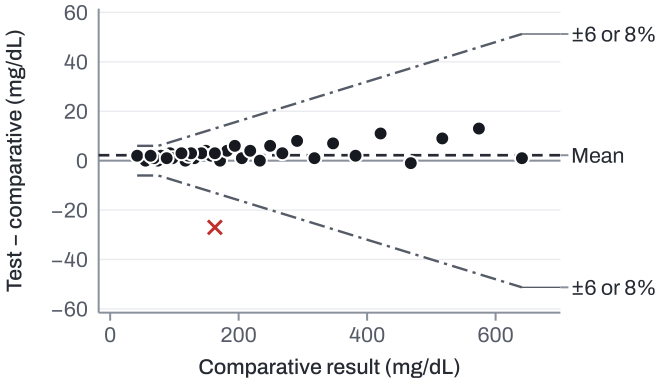


Figure 2. Differences; dash-dot: allowed difference; dashed: mean difference; x: outside it.

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		

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

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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

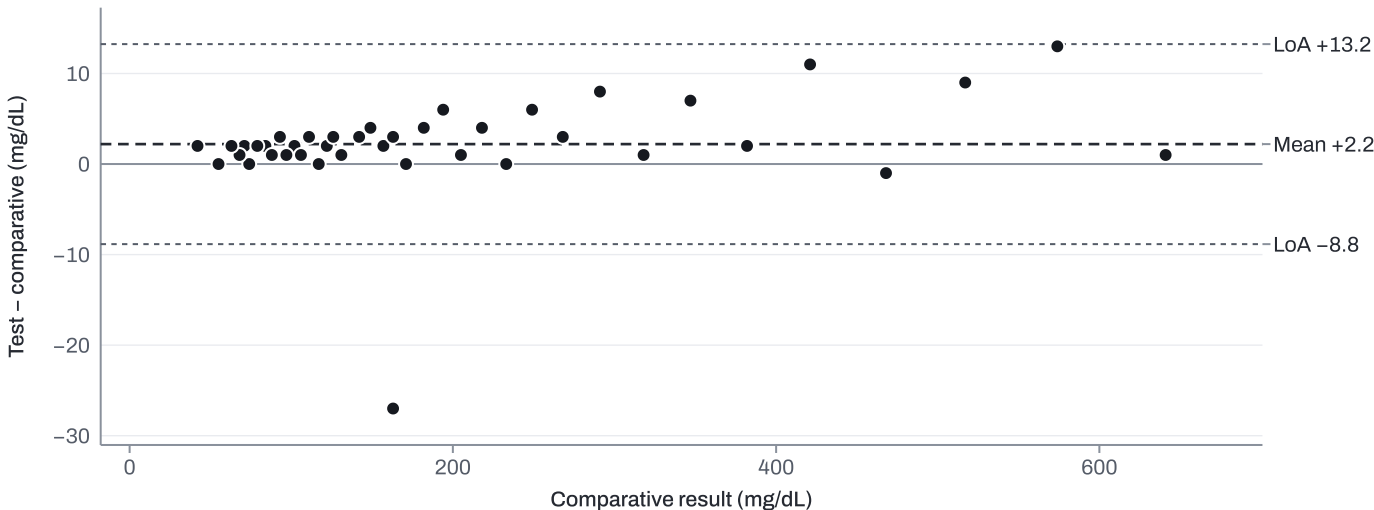


Figure 3. Test – comparative, with the mean and 95% limits of agreement.

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

Glucose · multi-day precision · Chemistry analyzer A

Glucose (mg/dL) · Multi-day precision ✓ Criteria met

Instrument **Chemistry analyzer A (CA-41027)** Study date **Sep 8, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Within-laboratory SD	Level 1 SD ≤ 1.8 mg/dL; Level 2 SD ≤ 5.7 mg/dL		2 of 2 levels within	✓ Met

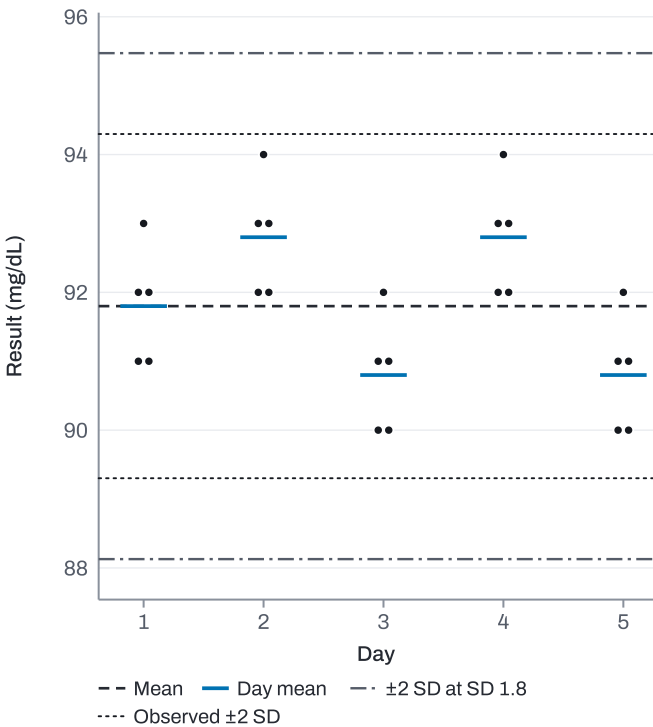


Figure 1. Level 1: results by day.

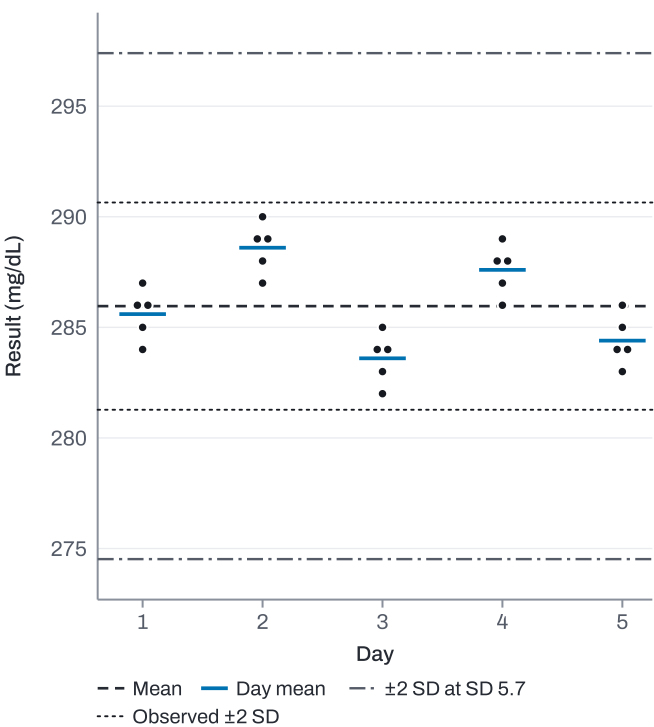


Figure 2. Level 2: results by day.

Table 2. Results by level (mg/dL)

Level	Mean	Repeatability SD	Repeatability CV (%)	Within-lab SD	Within-lab CV (%)	Result
1	91.8	0.837	0.9	1.25	1.4	✓ Met
2	286.0	1.14	0.4	2.34	0.8	✓ Met

Study details

Matrix	Serum	Method	Hexokinase	Reagent lot	GLU-R2609
Calibrator lot	GLU-C2609	Data	50 included	Design	5 days × 1 run × 5 replicates

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

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Oct 23, 2026, 13:25 UTC

Date

A Data listing

Source: CHEM-A_QC-2611_days-1-5_20260912.csv. 50 rows, all included.

Study row	Specimen	Level	Result (mg/dL)	Day	Replicate	Source row
1	QC-2611 L1	1	92	1	1	2
2	QC-2611 L1	1	91	1	2	3
3	QC-2611 L1	1	93	1	3	4
4	QC-2611 L1	1	92	1	4	5
5	QC-2611 L1	1	91	1	5	6
6	QC-2611 L1	1	93	2	1	7
7	QC-2611 L1	1	94	2	2	8
8	QC-2611 L1	1	92	2	3	9
9	QC-2611 L1	1	93	2	4	10
10	QC-2611 L1	1	92	2	5	11
11	QC-2611 L1	1	91	3	1	12
12	QC-2611 L1	1	90	3	2	13
13	QC-2611 L1	1	92	3	3	14
14	QC-2611 L1	1	91	3	4	15
15	QC-2611 L1	1	90	3	5	16
16	QC-2611 L1	1	92	4	1	17
17	QC-2611 L1	1	93	4	2	18
18	QC-2611 L1	1	92	4	3	19
19	QC-2611 L1	1	94	4	4	20
20	QC-2611 L1	1	93	4	5	21
21	QC-2611 L1	1	90	5	1	22
22	QC-2611 L1	1	91	5	2	23
23	QC-2611 L1	1	92	5	3	24
24	QC-2611 L1	1	91	5	4	25
25	QC-2611 L1	1	90	5	5	26
26	QC-2611 L2	2	286	1	1	27
27	QC-2611 L2	2	284	1	2	28
28	QC-2611 L2	2	287	1	3	29
29	QC-2611 L2	2	285	1	4	30
30	QC-2611 L2	2	286	1	5	31
31	QC-2611 L2	2	289	2	1	32
32	QC-2611 L2	2	290	2	2	33
33	QC-2611 L2	2	288	2	3	34
34	QC-2611 L2	2	287	2	4	35
35	QC-2611 L2	2	289	2	5	36
36	QC-2611 L2	2	283	3	1	37
37	QC-2611 L2	2	285	3	2	38
38	QC-2611 L2	2	284	3	3	39
39	QC-2611 L2	2	282	3	4	40
40	QC-2611 L2	2	284	3	5	41
41	QC-2611 L2	2	287	4	1	42
42	QC-2611 L2	2	288	4	2	43
43	QC-2611 L2	2	286	4	3	44

Study row	Specimen	Level	Result (mg/dL)	Day	Replicate	Source row
44	QC-2611 L2	2	289	4	4	45
45	QC-2611 L2	2	288	4	5	46
46	QC-2611 L2	2	284	5	1	47
47	QC-2611 L2	2	283	5	2	48
48	QC-2611 L2	2	285	5	3	49
49	QC-2611 L2	2	286	5	4	50
50	QC-2611 L2	2	284	5	5	51

1 Results

1.1 Results by day

Table 3. Results by day (mg/dL)

Day	Level 1 mean	Level 1 SD	Level 2 mean	Level 2 SD
1	91.8	0.837	285.6	1.14
2	92.8	0.837	288.6	1.14
3	90.8	0.837	283.6	1.14
4	92.8	0.837	287.6	1.14
5	90.8	0.837	284.4	1.14

5 results on each day.

1.2 Additional estimates

Table 4. Median, range, variance components and mean interval (mg/dL)

Level	Median	Lowest–highest	Between-day/run SD	Mean 95% CI
1	92.0	90–94	0.927	90.6–93.0
2	286.0	282–290	2.05	283.3–288.6

2 Study notes

1. With one run per day, the between-day/run SD combines day and run effects.

Glucose · repeatability · Chemistry analyzer A

Glucose (mg/dL) · Repeatability (single run) ✓ Criteria met

Instrument **Chemistry analyzer A (CA-41027)** Study date **Sep 8, 2026**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Sample SD	Level 1 SD ≤ 1.8 mg/dL; Level 2 SD ≤ 5.7 mg/dL		2 of 2 levels within	✓ Met

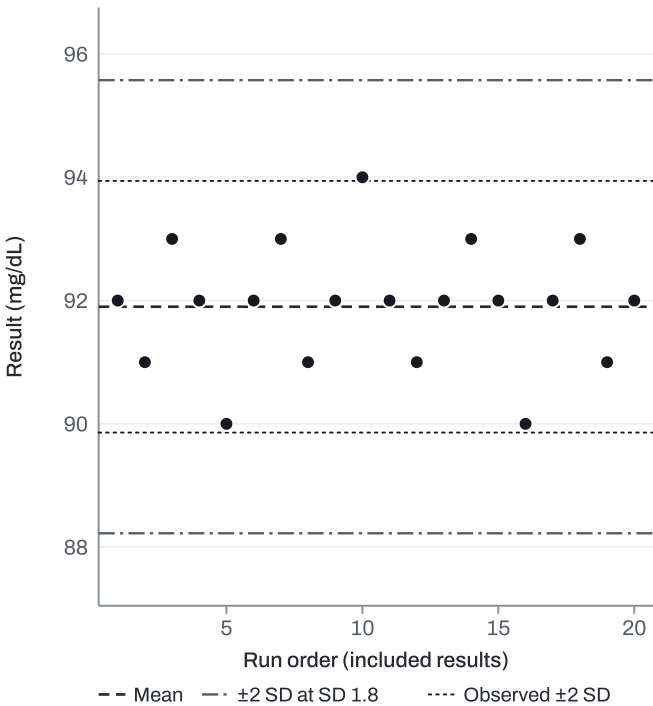


Figure 1. Level 1: results in run order.

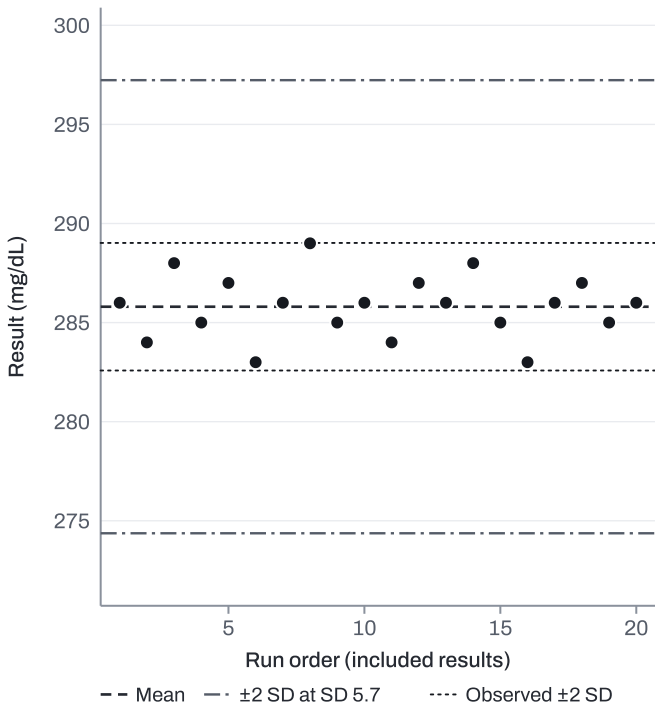


Figure 2. Level 2: results in run order.

Table 2. Results by level (mg/dL)

Level	Mean	Mean 95% CI	SD	CV (%)	Result
1	91.9	91.4–92.4	1.02	1.1	✓ Met
2	285.8	285.0–286.6	1.61	0.6	✓ Met

Study details

Matrix Serum	Method Hexokinase	Reagent lot GLU-R2609
Calibrator lot GLU-C2609	Data 40 included	

Alex Rivera, MLS(ASCP)
alex.rivera@example.test

Signed off by

Oct 23, 2026, 13:24 UTC

Date

A Data listing

Source: CHEM-A_QC-2611_within-run_20260908.csv. 40 rows, all included.

Study row	Specimen	Level	Result (mg/dL)	Replicate	Source row
1	QC-2611 L1	1	92	1	2
2	QC-2611 L1	1	91	2	3
3	QC-2611 L1	1	93	3	4
4	QC-2611 L1	1	92	4	5
5	QC-2611 L1	1	90	5	6
6	QC-2611 L1	1	92	6	7
7	QC-2611 L1	1	93	7	8
8	QC-2611 L1	1	91	8	9
9	QC-2611 L1	1	92	9	10
10	QC-2611 L1	1	94	10	11
11	QC-2611 L1	1	92	11	12
12	QC-2611 L1	1	91	12	13
13	QC-2611 L1	1	92	13	14
14	QC-2611 L1	1	93	14	15
15	QC-2611 L1	1	92	15	16
16	QC-2611 L1	1	90	16	17
17	QC-2611 L1	1	92	17	18
18	QC-2611 L1	1	93	18	19
19	QC-2611 L1	1	91	19	20
20	QC-2611 L1	1	92	20	21
21	QC-2611 L2	2	286	1	22
22	QC-2611 L2	2	284	2	23
23	QC-2611 L2	2	288	3	24
24	QC-2611 L2	2	285	4	25
25	QC-2611 L2	2	287	5	26
26	QC-2611 L2	2	283	6	27
27	QC-2611 L2	2	286	7	28
28	QC-2611 L2	2	289	8	29
29	QC-2611 L2	2	285	9	30
30	QC-2611 L2	2	286	10	31
31	QC-2611 L2	2	284	11	32
32	QC-2611 L2	2	287	12	33
33	QC-2611 L2	2	286	13	34
34	QC-2611 L2	2	288	14	35
35	QC-2611 L2	2	285	15	36
36	QC-2611 L2	2	283	16	37

Study row	Specimen	Level	Result (mg/dL)	Replicate	Source row
37	QC-2611 L2	2	286	17	38
38	QC-2611 L2	2	287	18	39
39	QC-2611 L2	2	285	19	40
40	QC-2611 L2	2	286	20	41

1 Results

1.1 Additional estimates

Table 3. Median and range (mg/dL)

Level	Median	Lowest–highest
1	92.0	90–94
2	286.0	283–289