

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

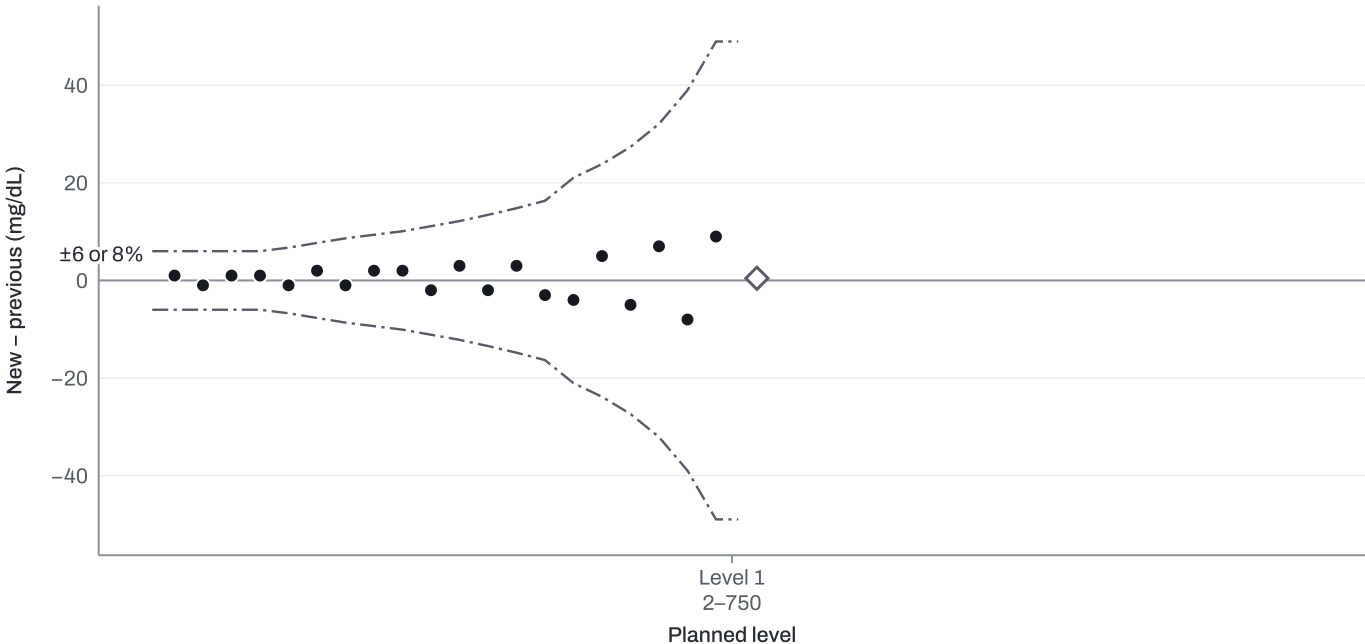


Figure 1. Each specimen’s difference by planned level, in order of concentration; dash-dot: its allowed difference; open diamonds: level mean difference.

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				

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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

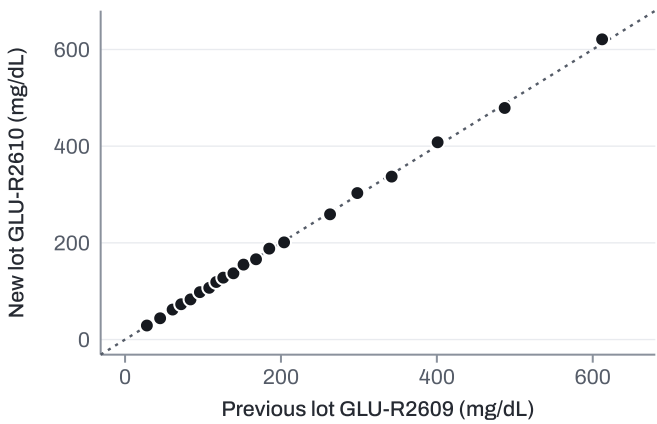


Figure 2. New lot against previous lot; dotted line: equal results.

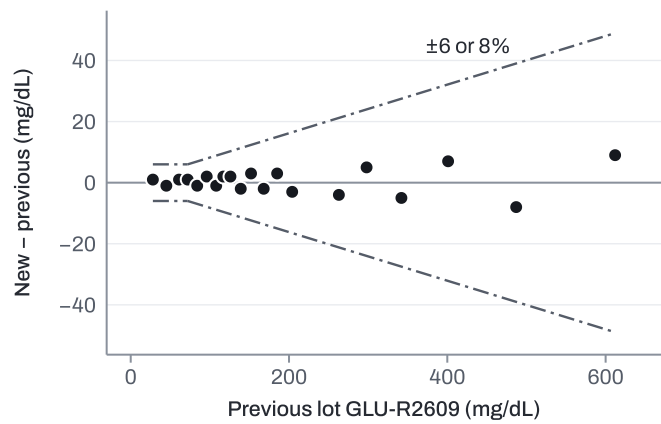


Figure 3. Each specimen's difference with its allowed range.

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