

# 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  |

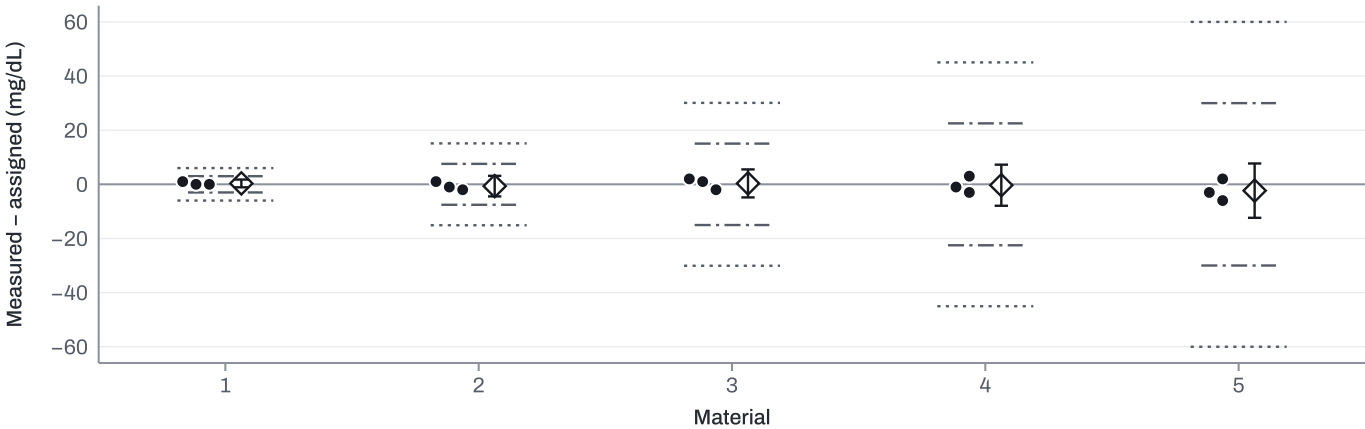


**Figure 1.** Difference from the assigned value at each level: dots, each replicate; open diamonds, the mean with its 95% CI; dash-dot ticks, allowed bias of the mean; dotted ticks, allowed error of each replicate.

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 <b>Serum</b>             | Method <b>Hexokinase</b> | Reagent lot <b>GLU-R2609</b>    |
| Calibrator lot <b>GLU-C2609</b> | Data <b>15 included</b>  | Design <b>5 material levels</b> |

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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. 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  |