

Untitled study

Cholesterol (mg/dL) · Bias against an assigned value ✓ Criteria met

6 of 6 questions judged · 6 questions met

Study date **Not recorded**

Table 1. Acceptance criteria

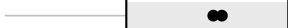
Question	Limit	Allowed	Finding	Result
Bias (mean minus assigned value)	Within ± 2 mg/dL at each level		2 of 2 levels within	✓
Relative bias	Within $\pm 3\%$ at each level		2 of 2 levels within	✓
Recovery	Between 97% and 103% at each level		2 of 2 levels within	✓
Bias (mean minus assigned value)	Level Low $ \text{Bias} \leq 2$ mg/dL; Level High $ \text{Bias} \leq 2\%$ of the assigned value 150 mg/dL (3 mg/dL)		2 of 2 levels within	✓
Sample CV	$\leq 2\%$ at each level		2 of 2 levels within	✓
Mean · Level High	Within $\pm 2\%$ of 150 mg/dL		150.22 mg/dL 0.15% from target	✓

Table 2. Results by level (mg/dL)

Level	Assigned	Mean	Bias	Bias 95% CI	Relative bias (%)	Recovery (%)	CV (%)	Result
Low	50	50.36	+0.36	-0.32 to 1.04	+0.72	100.72	1.09	✓ Met
High	150	150.22	+0.22	-2.34 to 2.78	+0.15	100.15	1.37	✓ Met

Study details

Data 10 included

Signed off by

Date _____

A Data listing

Source: manual entry. 10 rows, all included.

Study row	Specimen	Level	Result (mg/dL)	Replicate
1	CRM-Low	Low	50.8	1
2	CRM-Low	Low	50.6	2
3	CRM-Low	Low	50.5	3
4	CRM-Low	Low	50.5	4
5	CRM-Low	Low	49.4	5
6	CRM-High	High	152.6	1
7	CRM-High	High	152.0	2
8	CRM-High	High	148.9	3
9	CRM-High	High	147.7	4
10	CRM-High	High	149.9	5

1 Results

1.1 Level plots

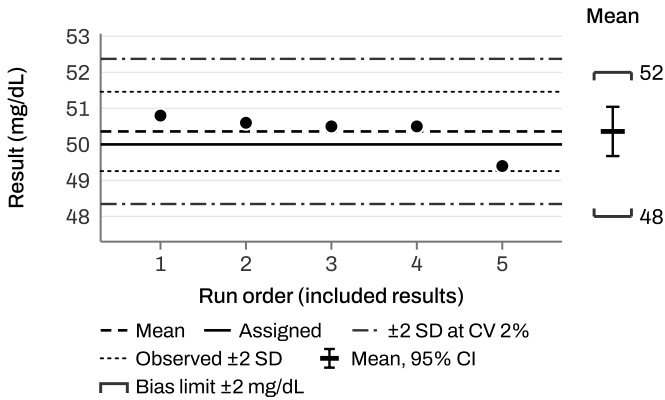


Figure 1. Level Low: results in run order.

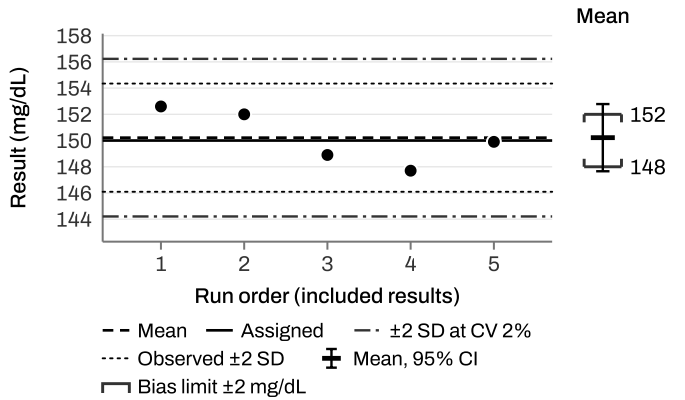


Figure 2. Level High: results in run order.

1.2 Additional estimates

Table 3. Median, range, SD, mean interval and uncertainty (mg/dL)

Level	Median	Lowest-highest	SD	Assigned-value uncertainty	Combined uncertainty	Bias 95% interval with assigned-value uncertainty	Mean 95% CI
Low	50.50	49.4–50.8	0.550	0.5	0.557	–1.19 to 1.91	49.68–51.04
High	149.90	147.7–152.6	2.06	—	—	—	147.66–152.78

Standard uncertainties; the combined uncertainty adds the measurement's to the assigned value's.

2 Study notes

Level Low

1. Assigned-value uncertainty was propagated into a combined standard uncertainty; the combined interval reflects measurement and assigned-value uncertainty.