

Untitled study

Glucose (mg/dL) · Sigma metric × Criteria not met

3 of 3 questions judged · Minimum sigma at 100 mg/dL not met · Minimum sigma at 200 mg/dL and Minimum sigma at 300 mg/dL met

Study date Not recorded

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Minimum sigma at 100 mg/dL	≥ 4		3.20	× Not met ^a
Minimum sigma at 200 mg/dL	≥ 4		4.25	✓ Met
Minimum sigma at 300 mg/dL	≥ 4		4.00	✓ Met

^a Sigma is compared directly with the laboratory's minimum.

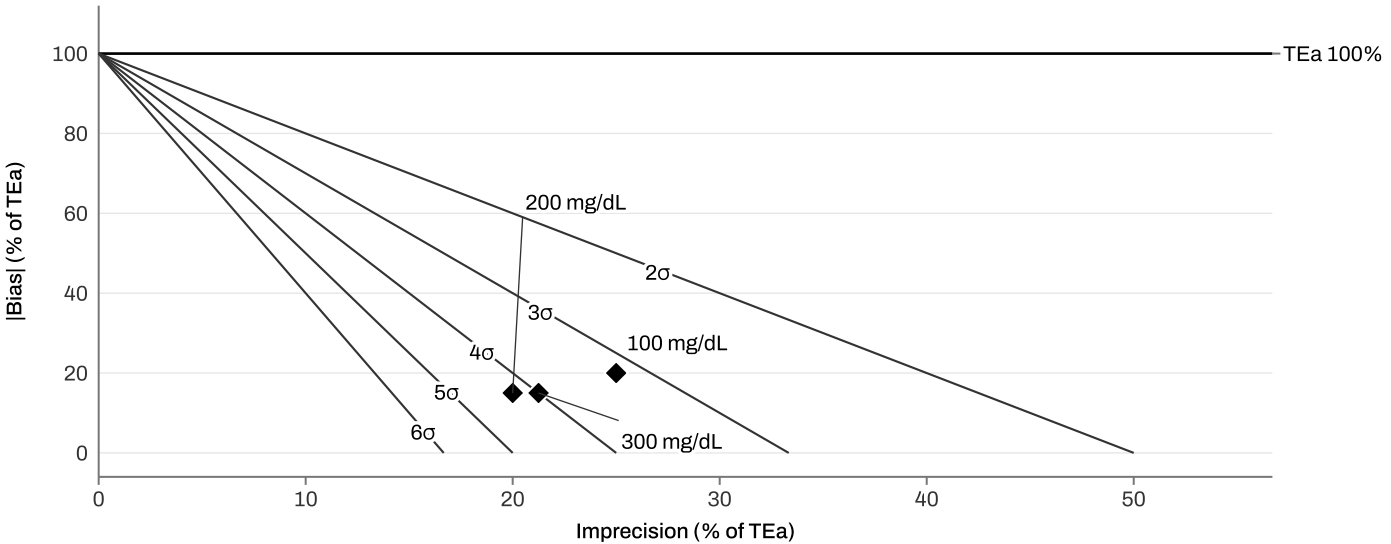


Figure 1. Method decision chart; lines mark 2σ to 6σ.

Table 2. Sigma by concentration ^{*1}

Concentration (mg/dL)	TEa (%)	Bias (%)	CV (%)	Sigma	Grade	Result
100	10	2	2.50	3.20	Fair	× Not met
200	10.00	1.50	2.00	4.25	Good	✓ Met
300	8	1.2	1.70	4.00	Good	✓ Met

Sigma = (TEa – |bias|) / CV, all at the stated concentration.

Study details

Entries 3

Signed off by

Date

A Data listing

Entry 1		
Concentration	100	
TEa	10	
TEa entered as	percent of the concentration	
Bias	2	
Bias entered as	percent of the concentration	
Imprecision	2.5	
Imprecision entered as	CV (%)	
Entry 2		
Concentration	200	
TEa	20	
TEa entered as	absolute, in the study unit	
Bias	-3	
Bias entered as	absolute, in the study unit	
Imprecision	4	
Imprecision entered as	SD, in the study unit	
Entry 3		
Concentration	300	
TEa	8	
TEa entered as	percent of the concentration	
Bias	1.2	
Bias entered as	percent of the concentration	
Imprecision	1.7	
Imprecision entered as	CV (%)	

1 Results

1.1 Inputs and evidence

Table 3. Inputs and their evidence

Concentration (mg/dL)	Input	Evidence
100	Bias	Peer-group mean
100	CV	Within-laboratory
200	Bias	Peer-group mean
200	CV	Within-laboratory
300	Bias	Comparison method
300	CV	Within-laboratory

Table 4. QC-rule starting design

Concentration (mg/dL)	Rules	Controls / run	Runs	Guidance
100	1:3s, 2:2s, R:4s, 4:1s, 8:x	4	2	Alternative: Two control measurements per run across four runs.
200	1:3s, 2:2s, R:4s, 4:1s	4	1	Alternative: Two control measurements per run across two runs.
300	1:3s, 2:2s, R:4s, 4:1s	4	1	Alternative: Two control measurements per run across two runs.

Two control levels. R:4s applies within a run.

Table 5. Concentration model

Concentration (mg/dL)	Bias source	Precision source	Range
100	—	—	Within source range
200	—	—	Within source range
300	—	—	Within source range

2 Study notes

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*1 Laboratory minimum sigma: 4.