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Laboratory Issues: CLIA Blood Lead Acceptability Limits

Robert L. Jones, PhD

Inorganic Toxicology Laboratory
Division of Laboratory Sciences
National Center for Environmental Health
Centers for Disease Control and Prevention

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Mention of company or product names does not constitute endorsement by the National Center for Environmental Health (NCEH), Centers for Disease Control (CDC), or the Public Health Service.

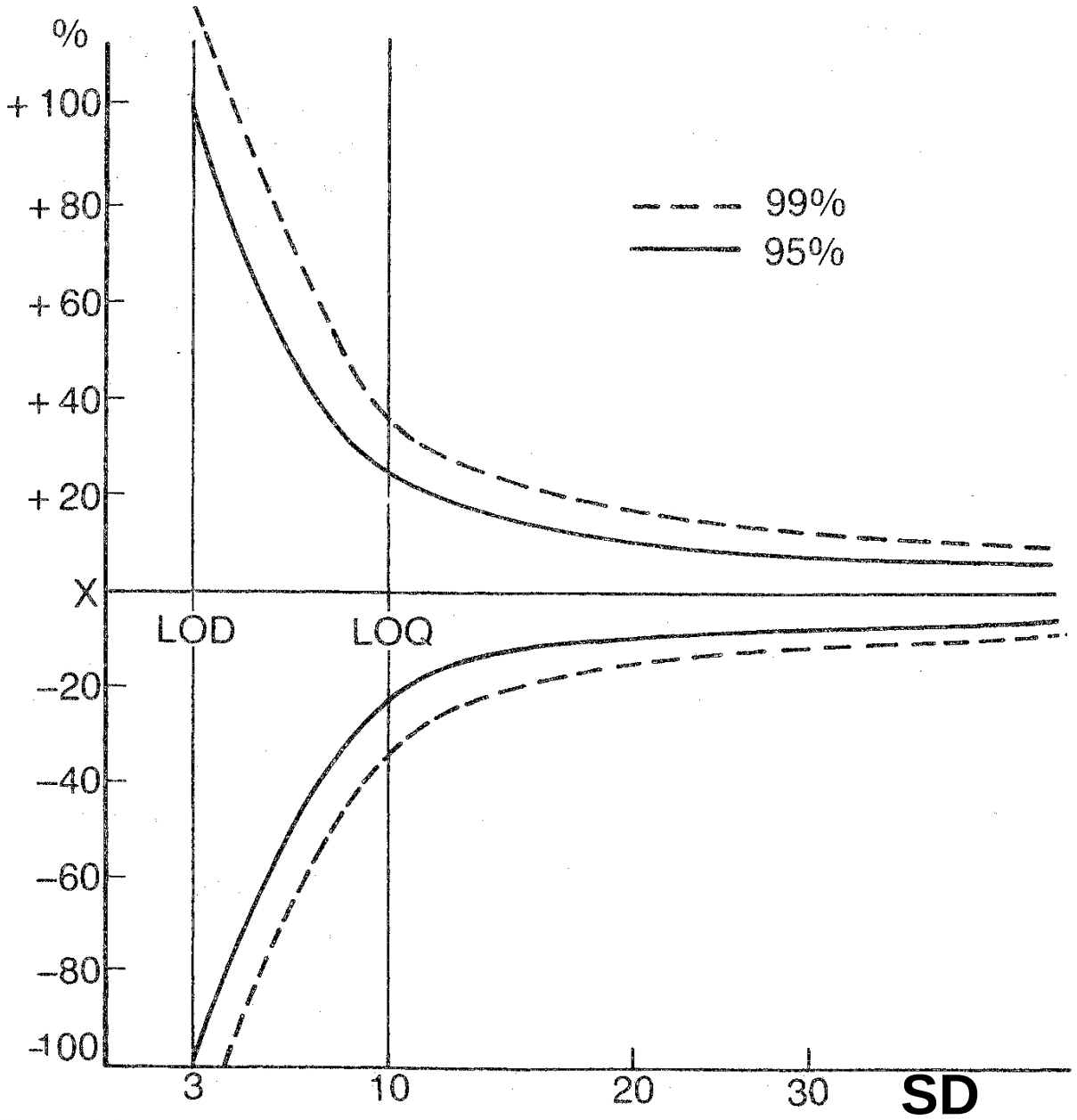
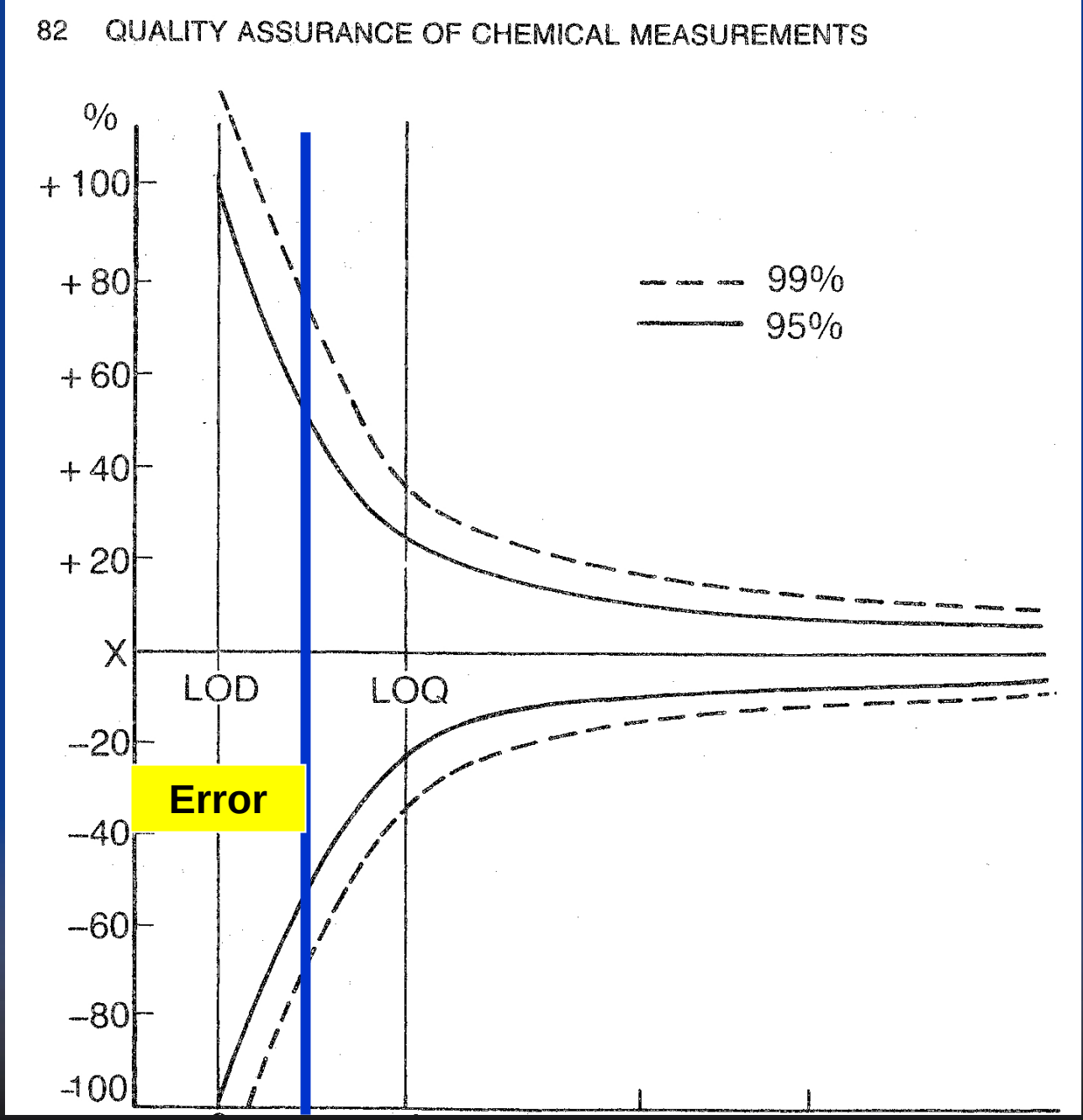
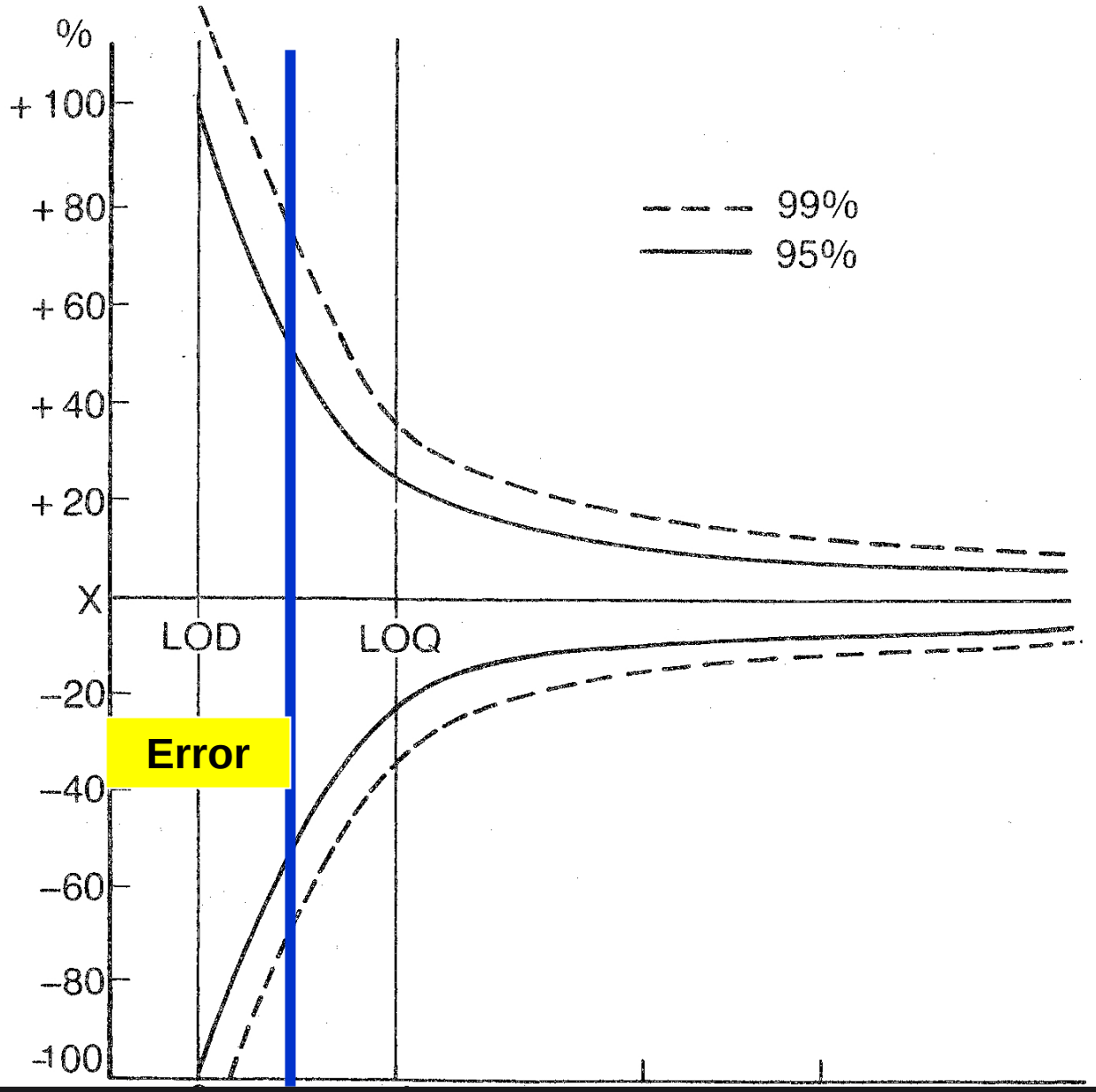


Figure 9.3. Uncertainty of measurement close to the limit of detection.


%
+ 100
+ 80
+ 60
+ 40
+ 20
X
–20
–40
–60
–80
–100
99%
95%
LOD
LOQ
Error
1
2
3
ug/dL


%
+ 100
+ 80
+ 60
+ 40
+ 20
X
–20
–40
–60
–80
–100
99%
95%
LOD
LOQ
Error
2
4
6
ug/dL

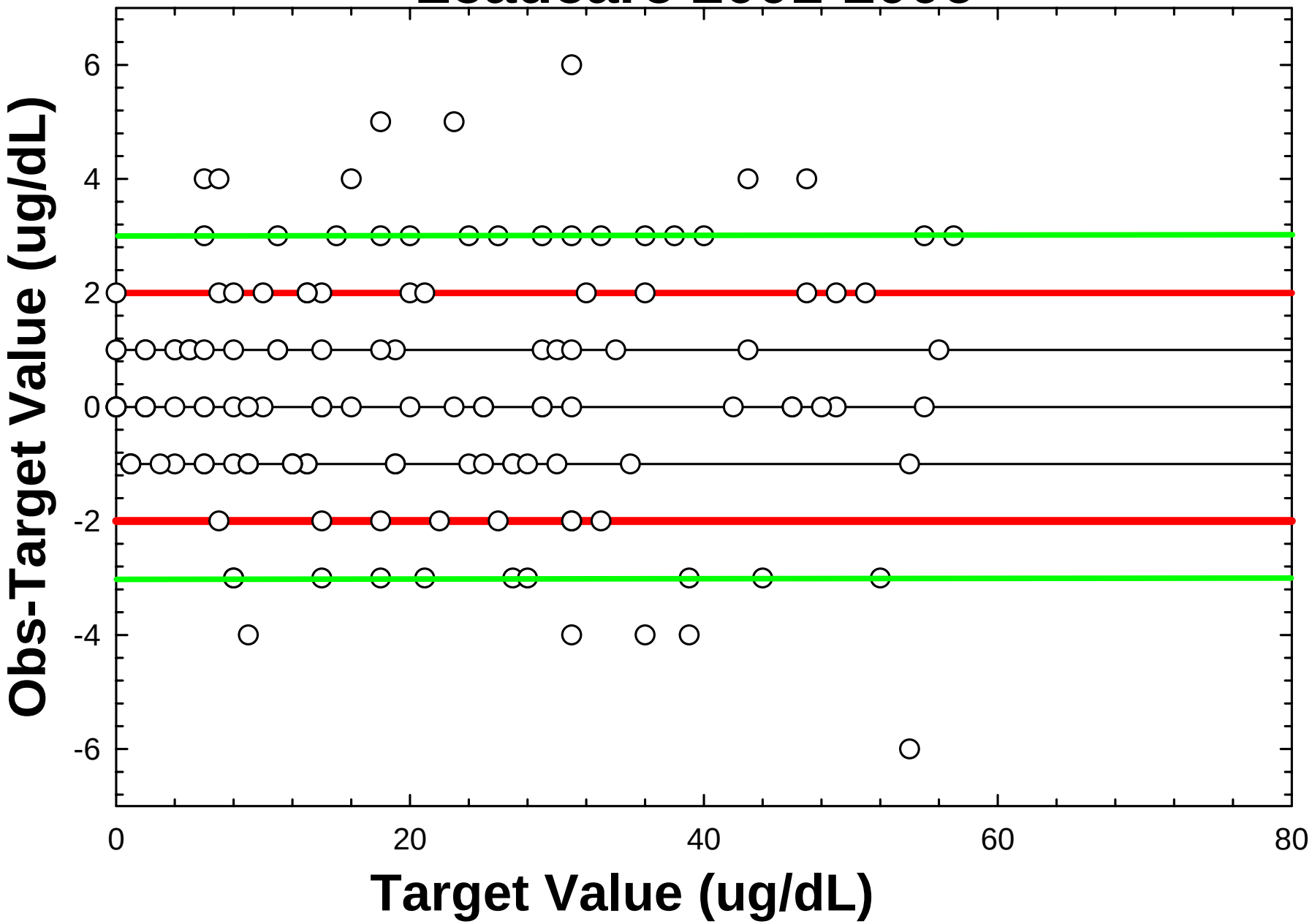
LOD Issues:

LOD = 1, 0 to 2 ug/dL precision range

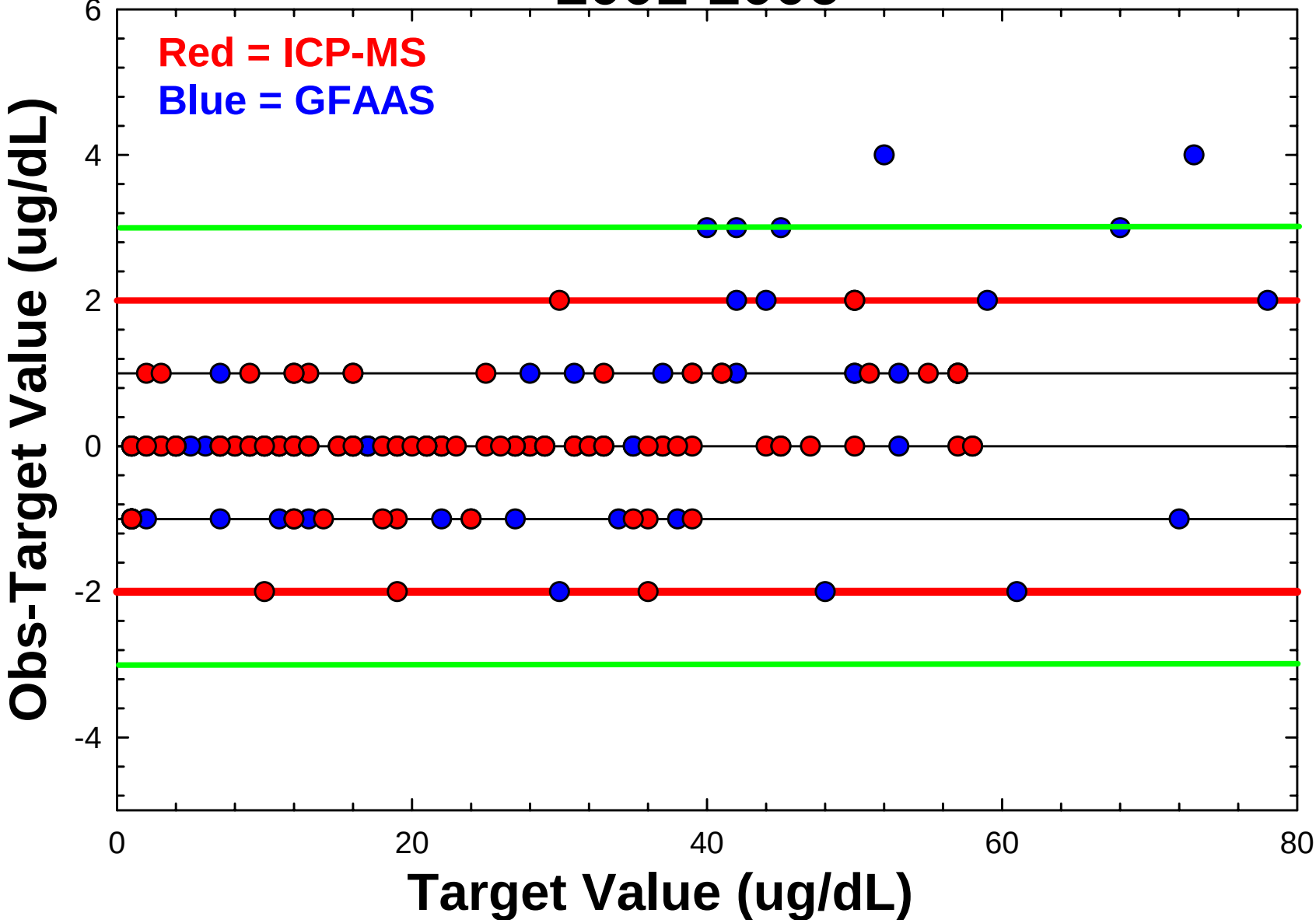
Only way to pass PT challenge is

Bias = 0.0

WI Blood Lead PT Results
Leadcare 2001-2006



WI Blood Lead PT Results
GFAAS and ICP-MS
2001-2006



PT Results Conclusions:

LeadCare

± 3 a possibility with some failures

± 2 would result in multiple failures

GFAAS

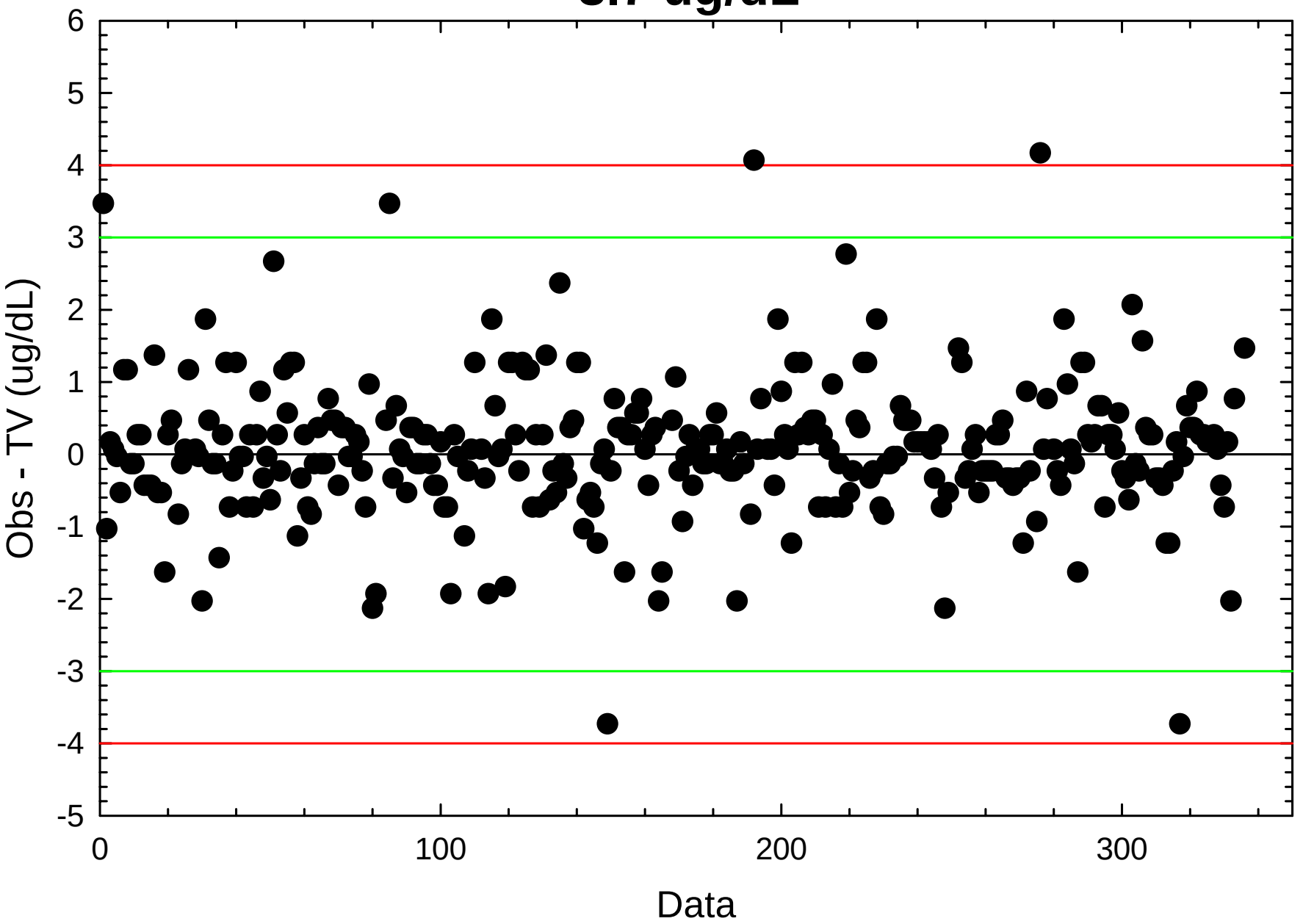
± 3 a possibility with minimal failures

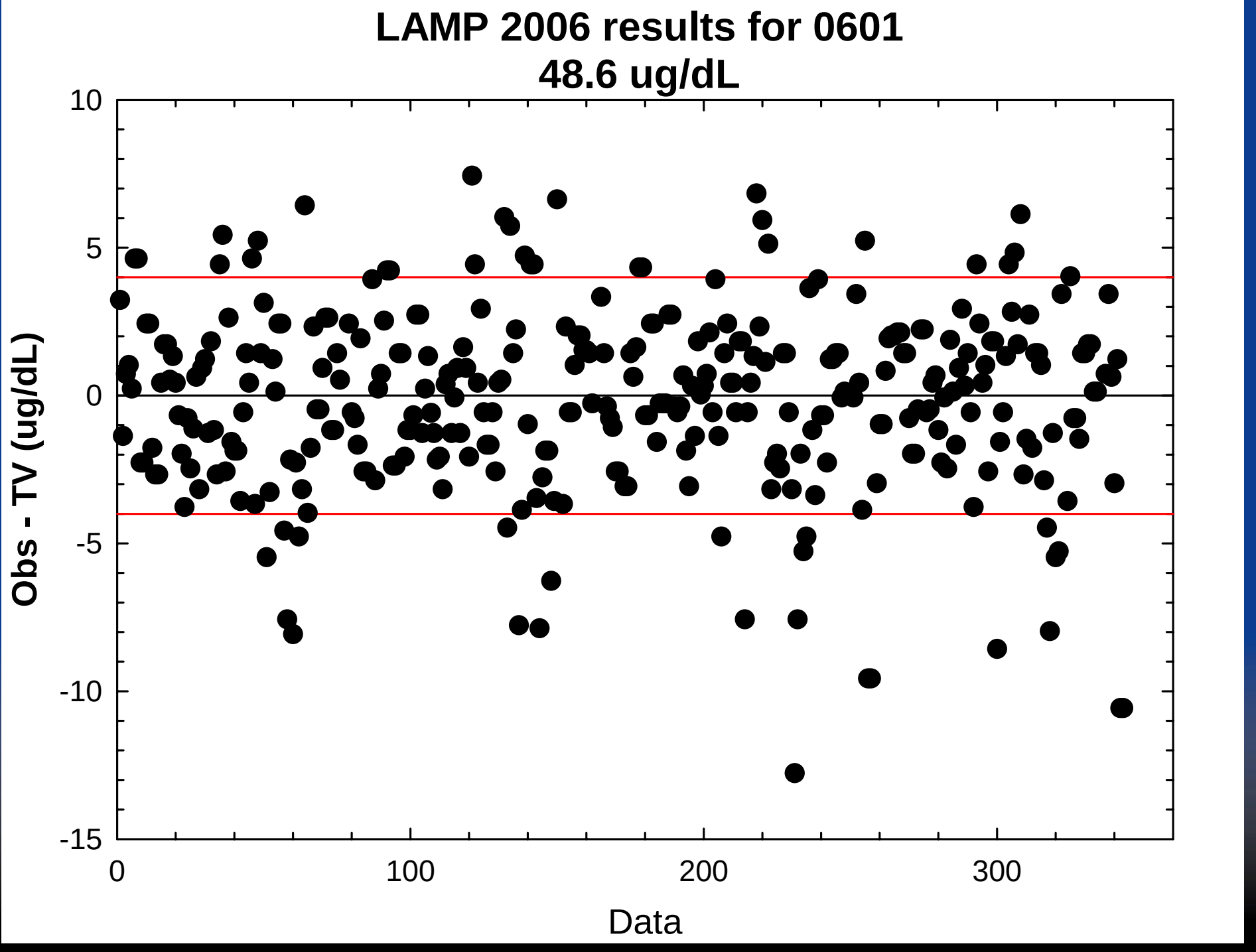
± 2 would result in multiple failures

ICP-MS

± 3 a possibility with no/minimal failures

± 2 would result in minimal failures


LAMP 2006 results for 0601
3.7 ug/dL
Obs - TV (ug/dL)
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
0
100
200
300
Data


LAMP 2006 results for 0601
48.6 ug/dL
Obs - TV (ug/dL)
10
5
0
-5
-10
-15
0
100
200
300
Data

LAMP Results:

All Instrumentation

Low Concentration:

± 3 a possibility with minimal failures

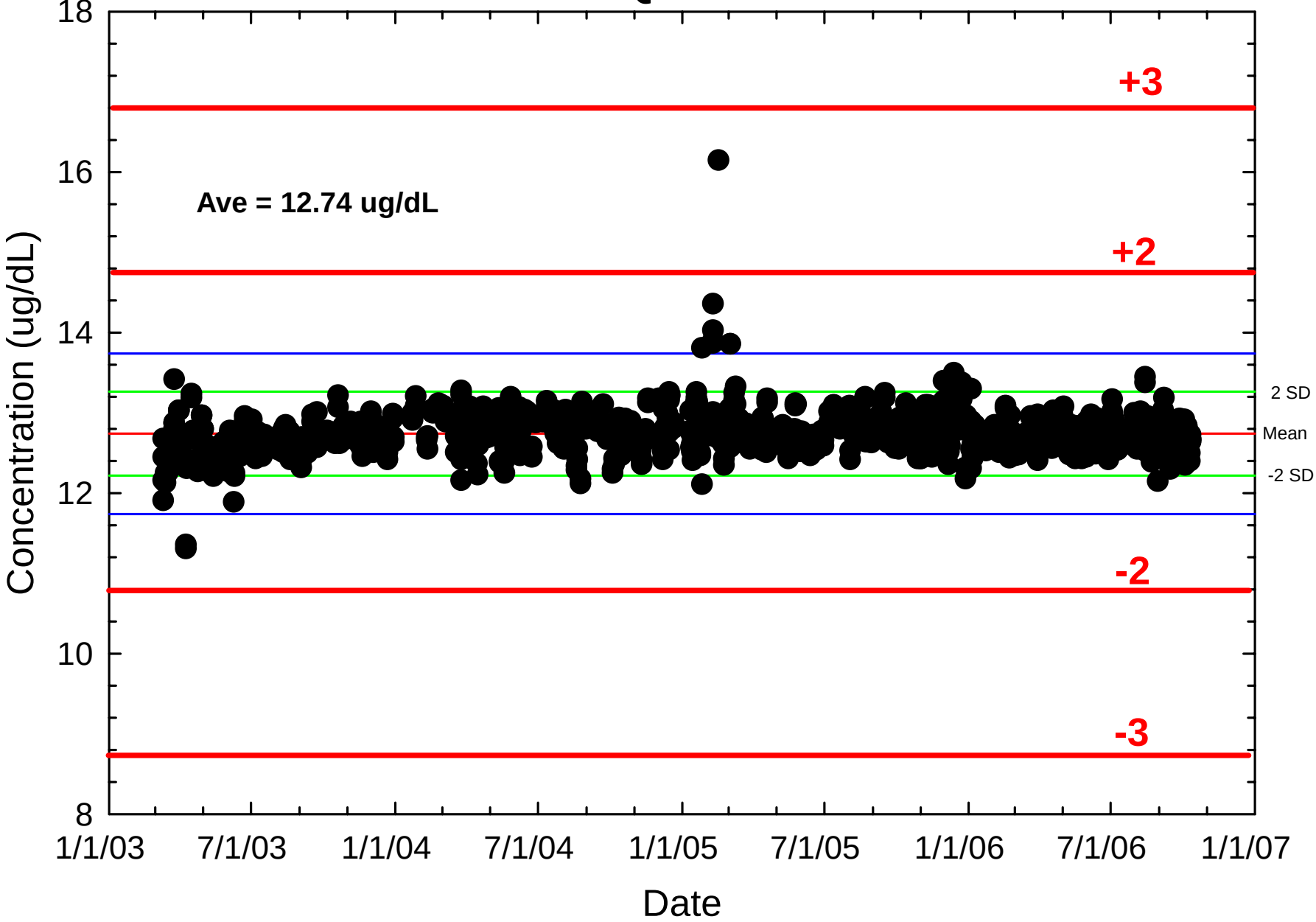
± 2 would result in multiple failures

Hi Concentration:

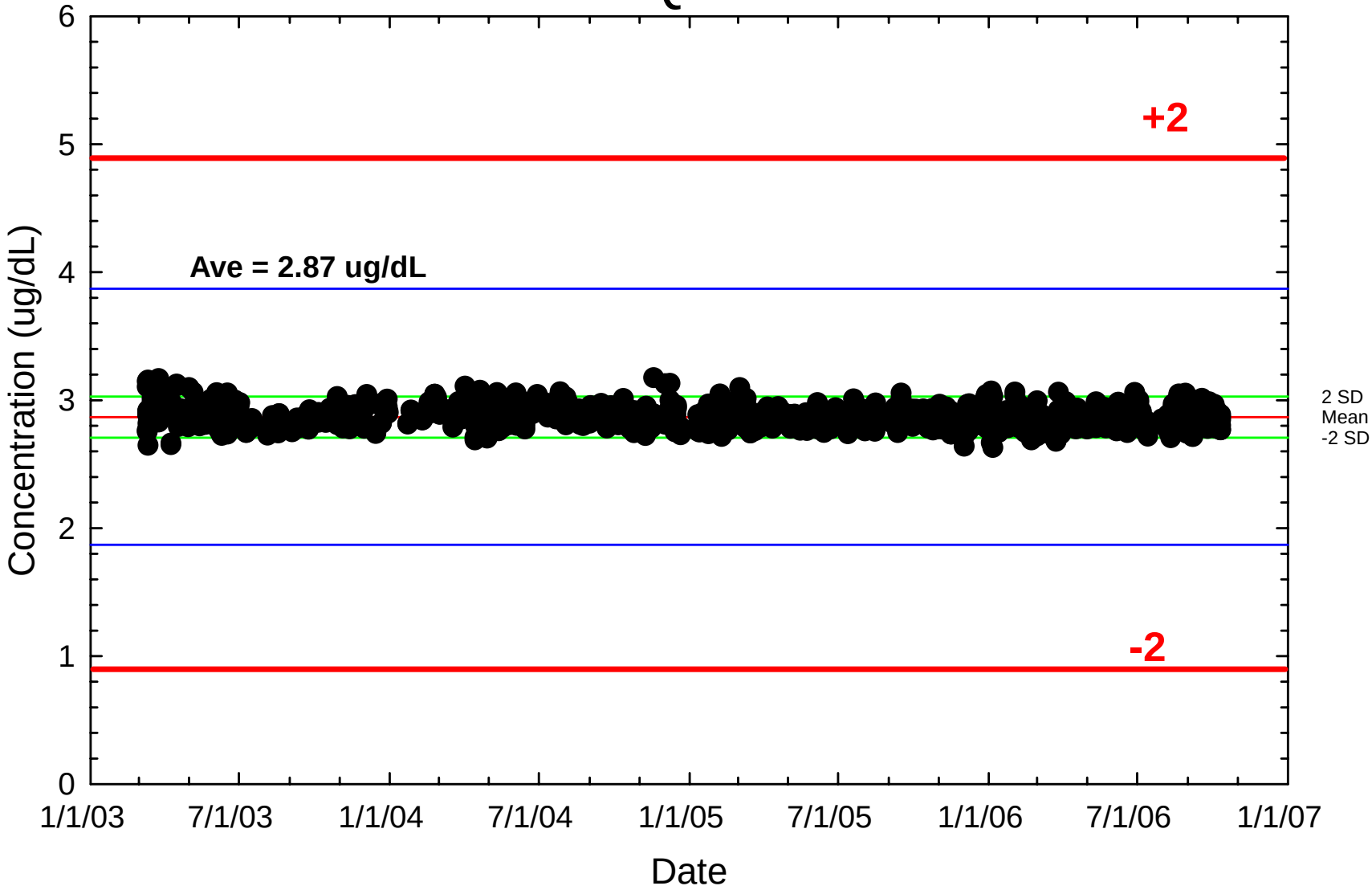
± 3 would result in multiple failures

± 2 would result in significant failures

ICP-MS Blood Lead
Bench QC data



ICP-MS Blood Lead
Bench QC data



CDC Bench QC Results:

GFAAS

± 2 a possibility with no/minimal failures

ICP-MS

± 2 a possibility with no/minimal failures

Bench QC samples generated with extreme measures

Cost of analysis ~$80/sample

Range ($70-$90)

Conclusions for ± 1 ug/dL:

LODs must be < 1 ug/dL for ± 1 limits

PT sample Homogeneity would need to be < 0.1 ug/dL

PT Sample Target value would need to be set with a precision < 0.05 (cost >> $1000) to determine per concentration

PT Sample containers would all need to be acid washed: cost > $1 per sample

PT samples would need to be transported frozen = $$$

Conclusions:

± 3 a possibility with minimal failures

± 2 a possibility with significant failures

Analytical accuracy and precision is only one factor, the entire PT sample generation would need to be considered as well.

Thank you

Questions

Discussions

Contact Info

Robert L. Jones, PhD

Centers for Disease Control and Prevention

4770 Buford Hwy

Mailstop F-55

Atlanta, GA 30341

RLJones@cdc.gov