COMPARISON OF MATERIAL TO DETERMINE BIAS IN THE CHEMISTRY LABORATORY

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We compared the results obtained from commercial control material, NST Serum 909, proficiency material and pooled patient samples for 17 routine chemistry analytes tested in 10 laboratories and plotted the relative bias for each material. Patient results were compared to each lab's reference intervals.

Objectives:

1. To observe the relative ability of each material to determine method-to-method bias.
2. To observe the importance of lab-to-lab bias in interpretation of patient results.

Methods:

1. Each laboratory tested each sample in duplicate over three consecutive days. Data was analyzed and graphs prepared.
2. Pooled patient samples were graphically compared to upper and lower reference intervals.

Conclusion:

1. Other materials do not provide the same information as pooled patient samples when determining lab-to-lab bias.
2. Bias and selection of appropriate intervals are important factors in the reporting of meaningful laboratory results.

MATERIAL AND METHODS

PATIENT POOLS

Serum samples were selected and pooled to give high and low values for each analyte. High and low pools were mixed to provide a mid-range value. Pools were aliquotted and frozen; fresh aliquots were thawed on each day of testing.

LIQUID QC 1,2,3

Dade Liquid Monitrol was used as recommended by the manufacturer.

PROFICIENCY

The average value from the past year's L.P.T.P. surveys (Laboratory Proficiency Testing Program, Ontario, Canada) was compared to the reference value.

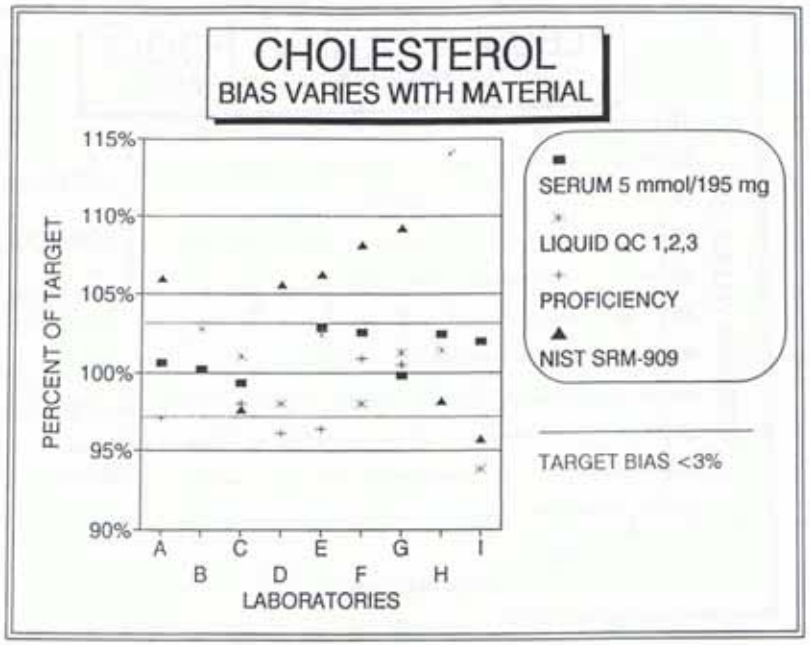
NIST SRM-909

Material was prepared and handled according to instructions from NIST.

Fresh aliquots of each sample were tested in duplicate on three days using routine reagents and calibration.

LAB	ANALYZER	REAGENT
A	KODAK	KODAK
B	HITACHI 717	B.M.C.
C	BECKMAN CX5	BECKMAN
D	TECHNICON RA-1000	SIGMA
E	TECHNICON RA-1000	SIGMA
F	COBAS MIRA	SIGMA
G	COBAS MIRA	SIGMA
H	COBAS MIRA	SYNERMED
I	COBAS MIRA	SIGMA

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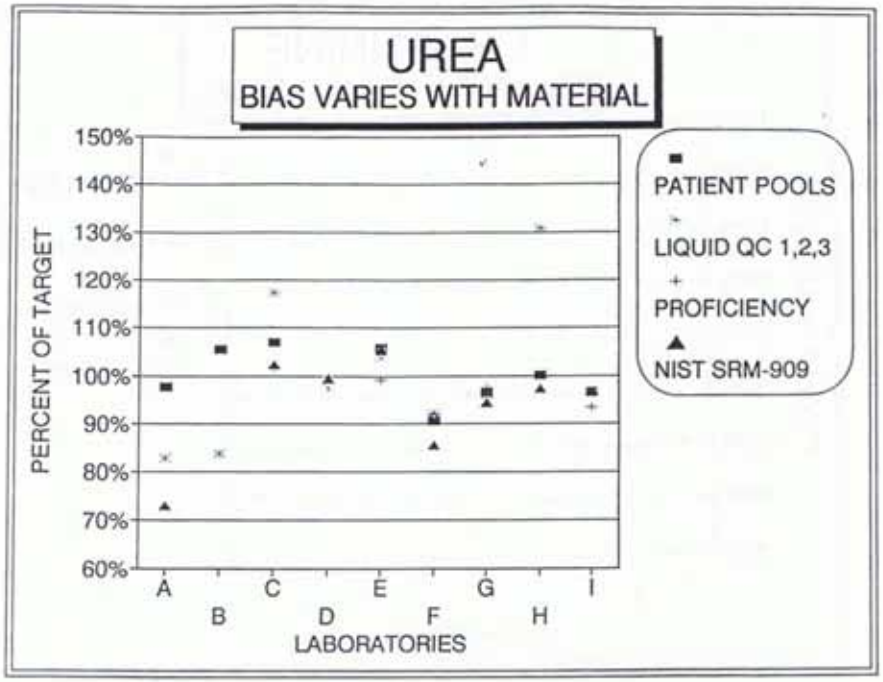


MAXIMUM & MINIMUM BIAS - ALL LABS

MATERIAL:	SERUM	Q.C.	P.T.	SRM-909
"TRUE" :	Core Lipid Lab, Toronto	Avg of All Labs	Reference Value	Reference Value
BIAS - MIN:	- 1%	- 6%	- 4%	0%
BIAS - MAX:	+ 3%	+ 3%	+ 1%	+ 9%

Individual testing materials produce variable results in relation to serum pools.

All laboratories showed acceptable bias with normal serum; most appeared unaceptable with other material.

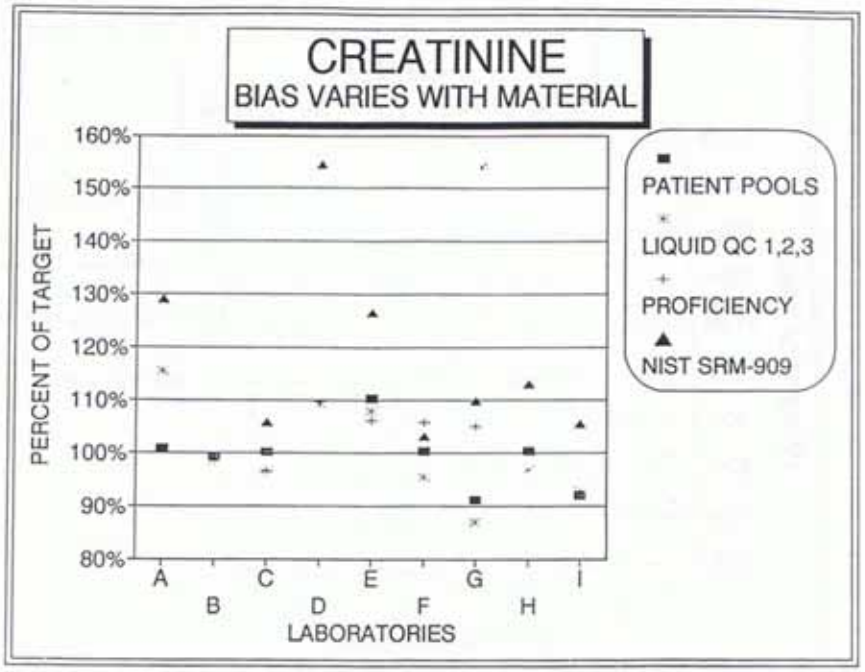


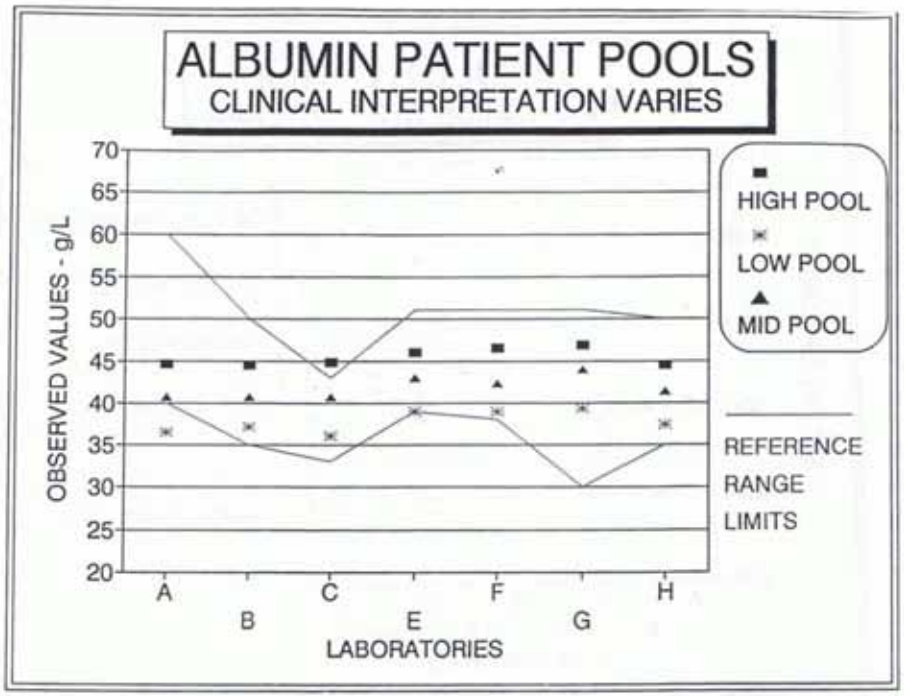
MAXIMUM & MINIMUM BIAS - ALL LABS

MATERIAL:	SERUM	Q.C.	P.T.	SRM-909
"TRUE" :	Avg of All Labs	Avg of All Labs	Reference Value	Reference Value
BIAS - MIN:	- 10%	-17%	- 8%	-27%
BIAS - MAX:	+ 7%	+31%	+ 2%	+ 5%

Estimates of bias vary within individual laboratories depending on material used.

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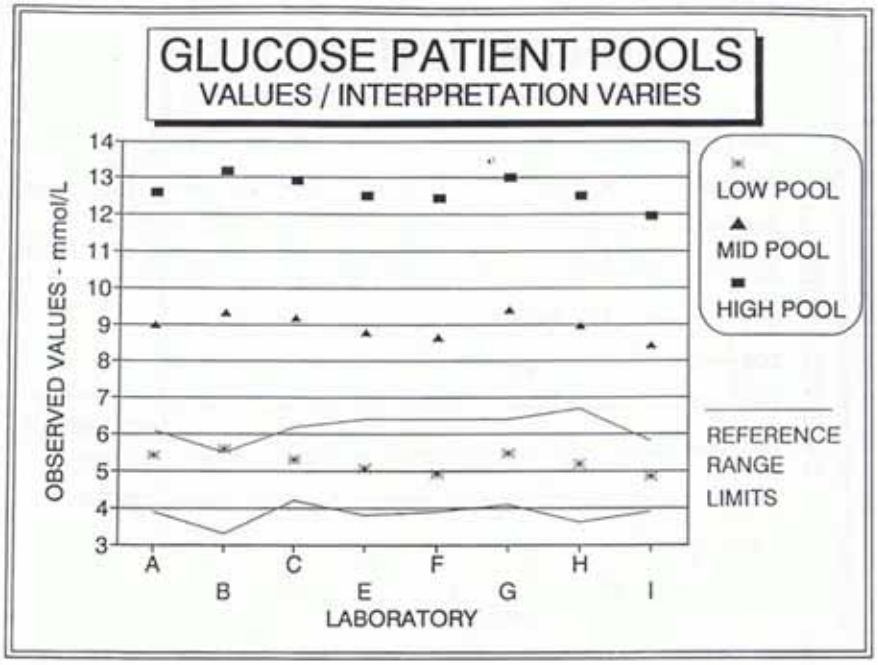
MAXIMUM & MINIMUM BIAS - ALL LABS

MATERIAL:	SERUM	Q.C.	P.T.	SRM-909
"TRUE" :	Avg of All Labs	Avg of All Labs	Reference Value	Reference Value
BIAS - MIN:	- 9%	-13%	- 3%	+ 3%
BIAS - MAX:	+10%	+16%	+ 10%	+54%

Variations between estimates of bias from serum pools and commercial/lyophilized material s are not consistent from lab to lab.

Although the absolute values reported on the three patient pools do not vary significantly among laboratories, reference intervals and therefore clinical interpretations do vary.

It is obvious that erroneous reference intervals are being used in some laboratories with potential for incorrect interpretation of clinical results.

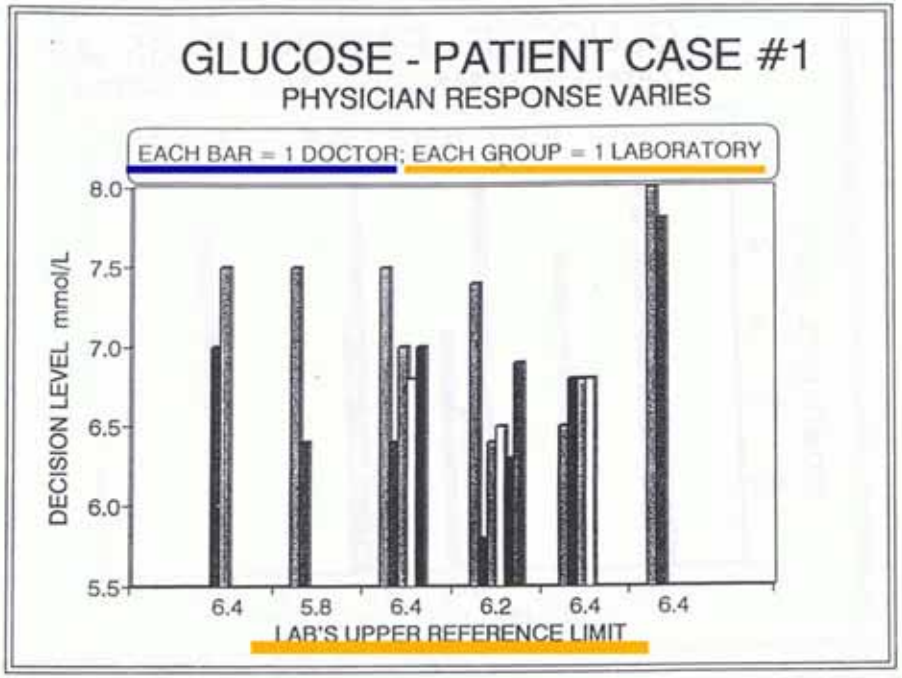


The variation in results in these labs is sufficiently wide if mirrored at decision levels to cause problems when arbitrary level s for clinical interpretation are used, eg.:

1) **7.8 mmol/L (140 mg/dL) fasting glucose level on two separate occasions is sufficient for a diagnosis of diabetes mellitus.**

2) **A level of ≥ 7.8 mmol/L one hour after a 50g oral dose of glucose requires further testing in a pregnant woman to determine whether she has gestational diabetes.**

Thus the same patient will/(will not) be diagnosed as having diabetes mellitus simply by presenting at a different laboratory.



"A 55 year-old man with no complaints is seen in your office as a new patient. Circle the lowest blood glucose value which would prompt you to repeat the fasting glucose and immediately undertake further investigation for the possibility of diabetes mellitus."
(5.8 , 5.9, 6.0, 6.1, 6.2, 6.3, 6.4, 6.5 ... >8.0)

Two clinicians would take no action until the fasting glucose was ≥ diagnostic levels for diabetes mellitis. Many would wait for inappropriately high levels before undertaking further investigation.

The decision to take action seems to bear little relation to the lab's upper level of the reference interval and there is no uniformity of decision levels among clinicians practising in the same institution.

CONCLUSIONS

1. Other materials do not provide the same information as pooled patient samples when determining lab-to-lab bias.

2. Bias and selection of appropriate intervals are important factors in the reporting of meaningful laboratory results.

COMMENTS

In order to provide appropriate patient care, we need:
(a) Accurate laboratory results;
(b) Precise laboratory results;
(c) Reliable reference ranges; and
(d) Uniform physician interpretation.

(a) Accuracy (absence of significant bias) is usually assumed without study.

(b) Laboratories have put most effort into the achievement of precise results. Current precision often exceeds clinical requirements.

(c) Reference ranges are frequently accepted without verification.

(d) Physician interpretation is seldom tested.

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has changed
in 20 years?