

Commutability

Improving definitions & How to deal with

JCTLM 2013

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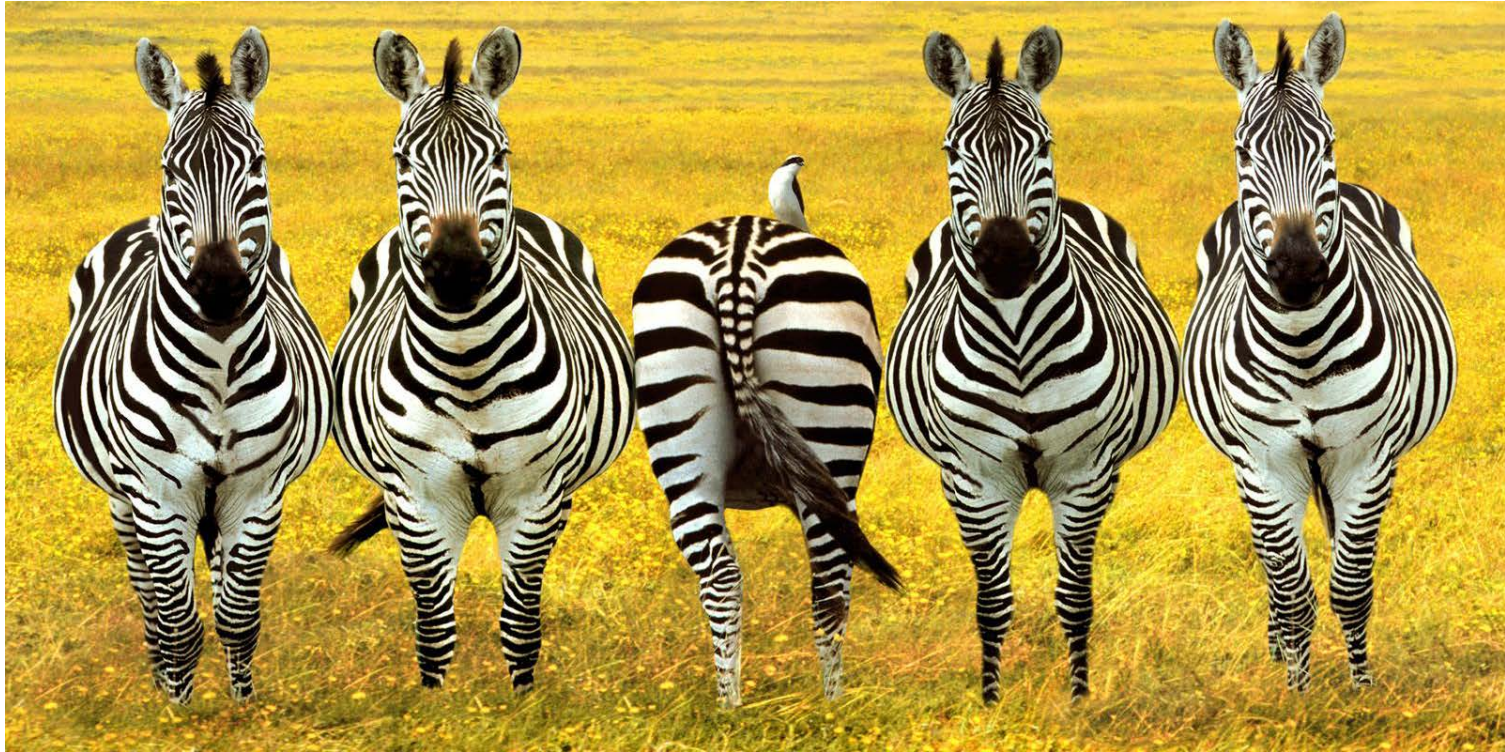
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STT

Consulting

Introduction

Reference materials, calibrators,
quality control samples



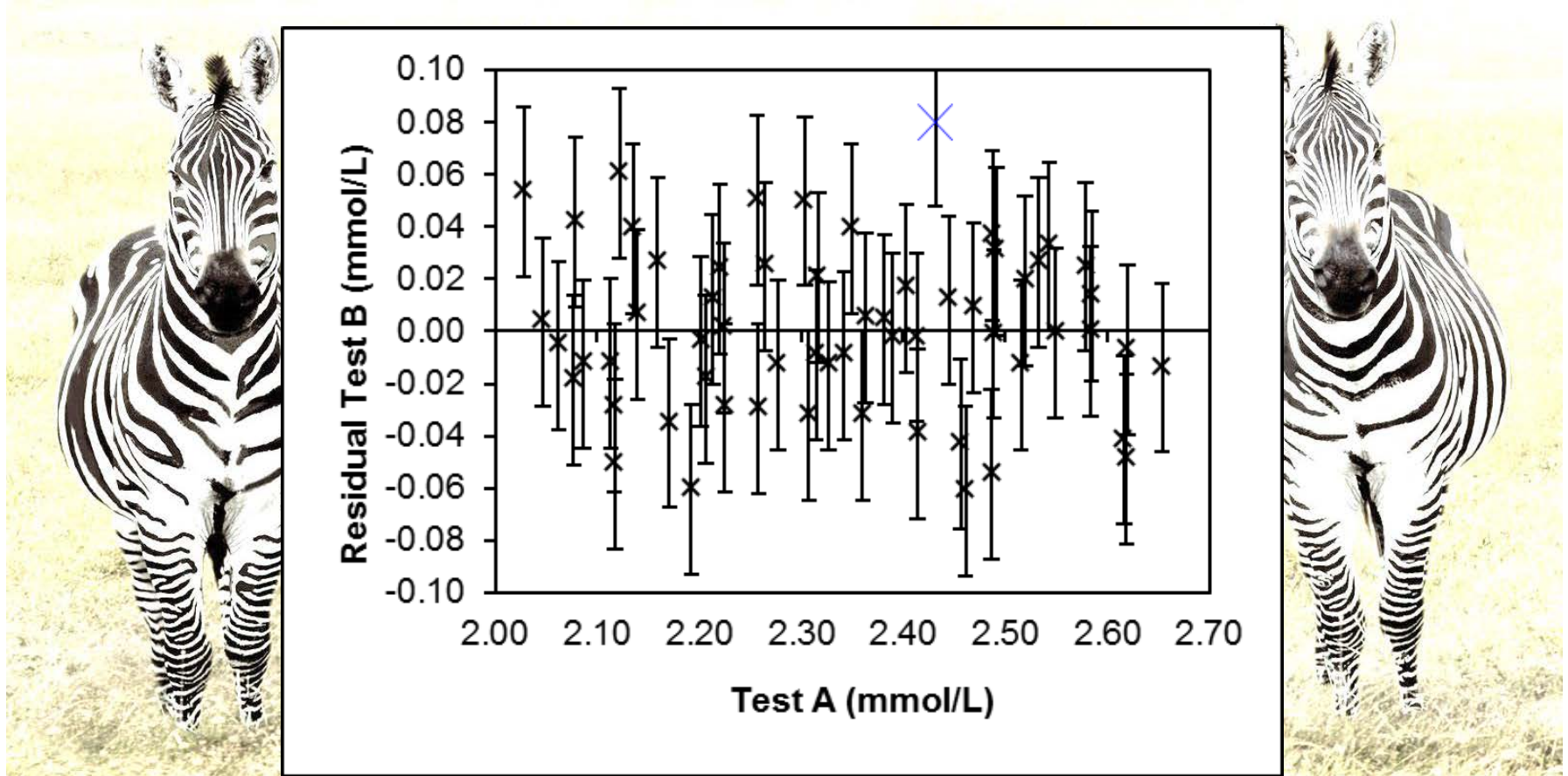
Different from patient samples?

How do we know?

How to deal?

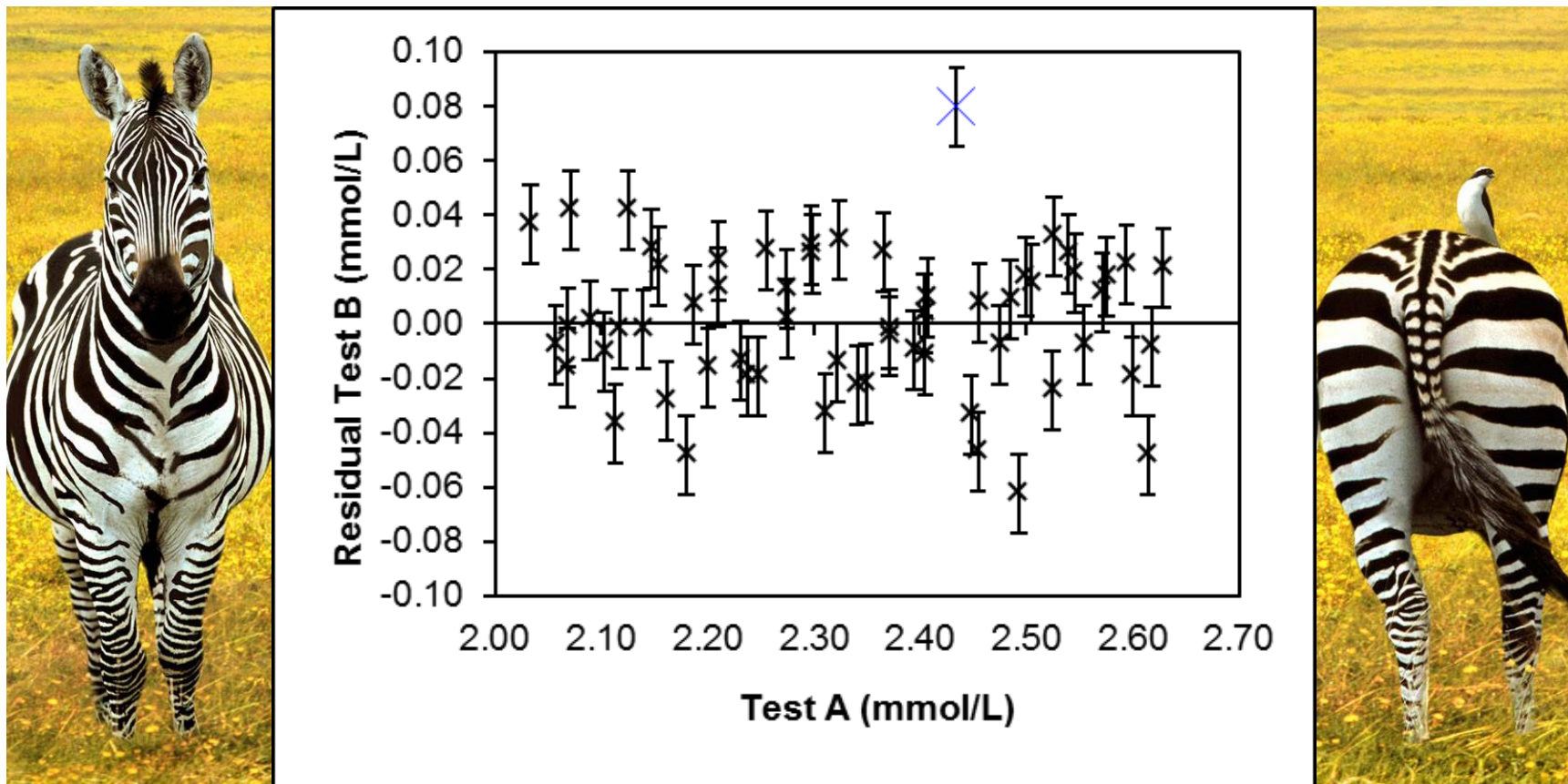
What about patient samples themselves?

1 replicate



Yes, patient samples too!

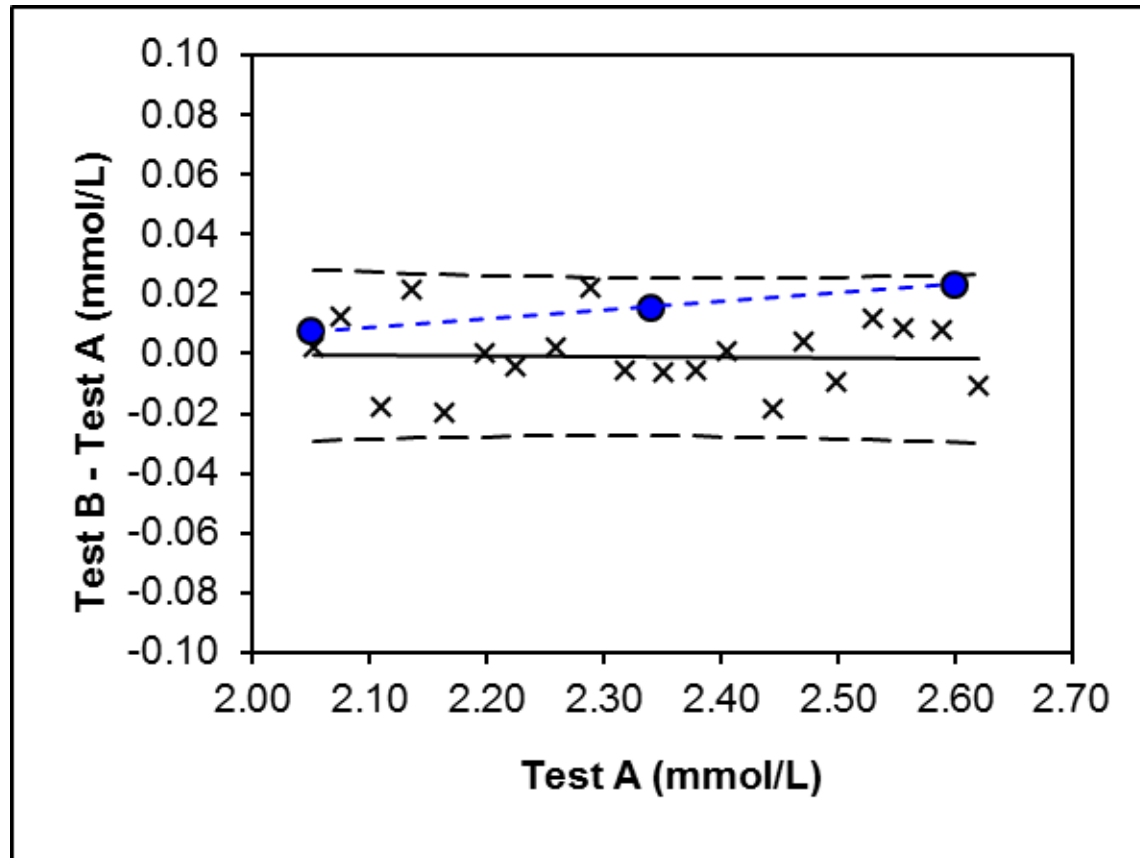
5 replicates, reduced CI



Reasons: drug interference, antibodies

Related samples (calibrators)

One by one commutable!



Calibration line non-commutable!
Statistics will be elaborated!

Other surprises?

Classical experiment

Measure a minimum of 20 native samples and test samples in one run in replicate (EP 14, $n = 3$) with at least two measurement procedures

General interpretation

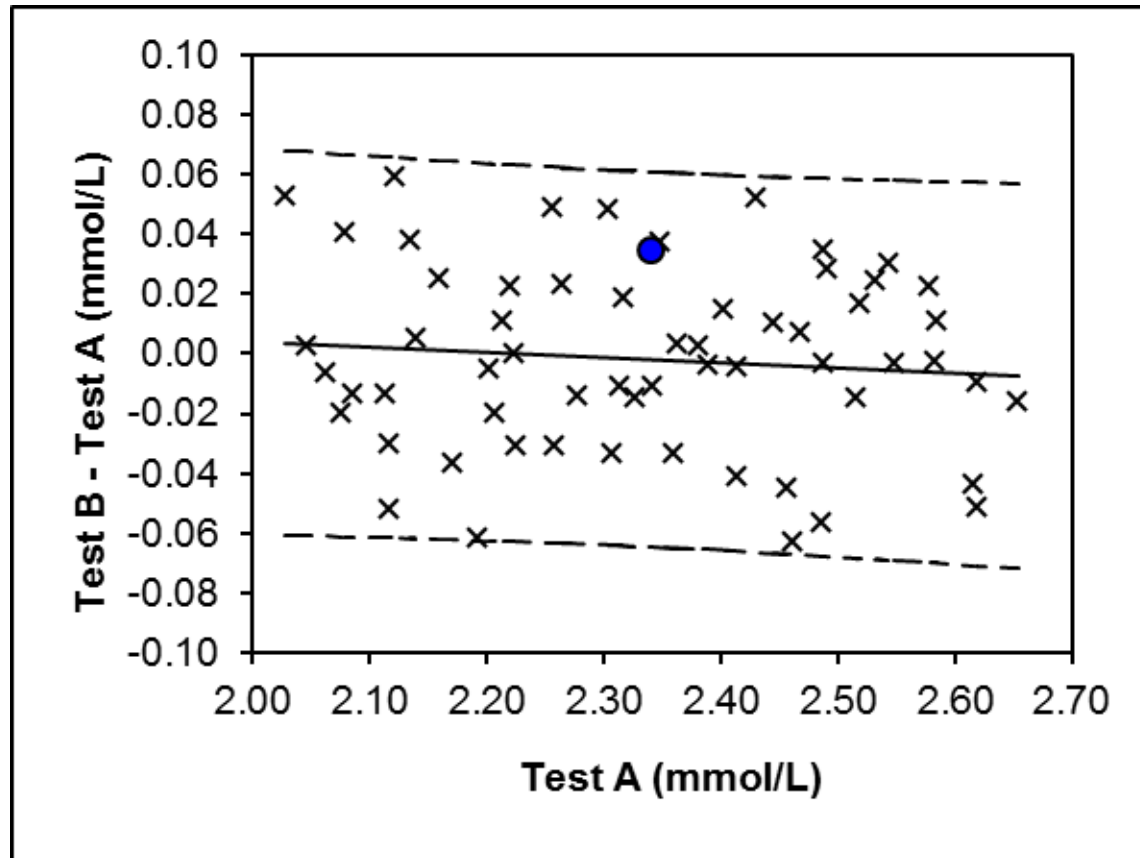
“Compare the behaviour of the test samples with the native samples”

EP 14 interpretation

Test samples should be within the prediction limits of the regression based on the native samples

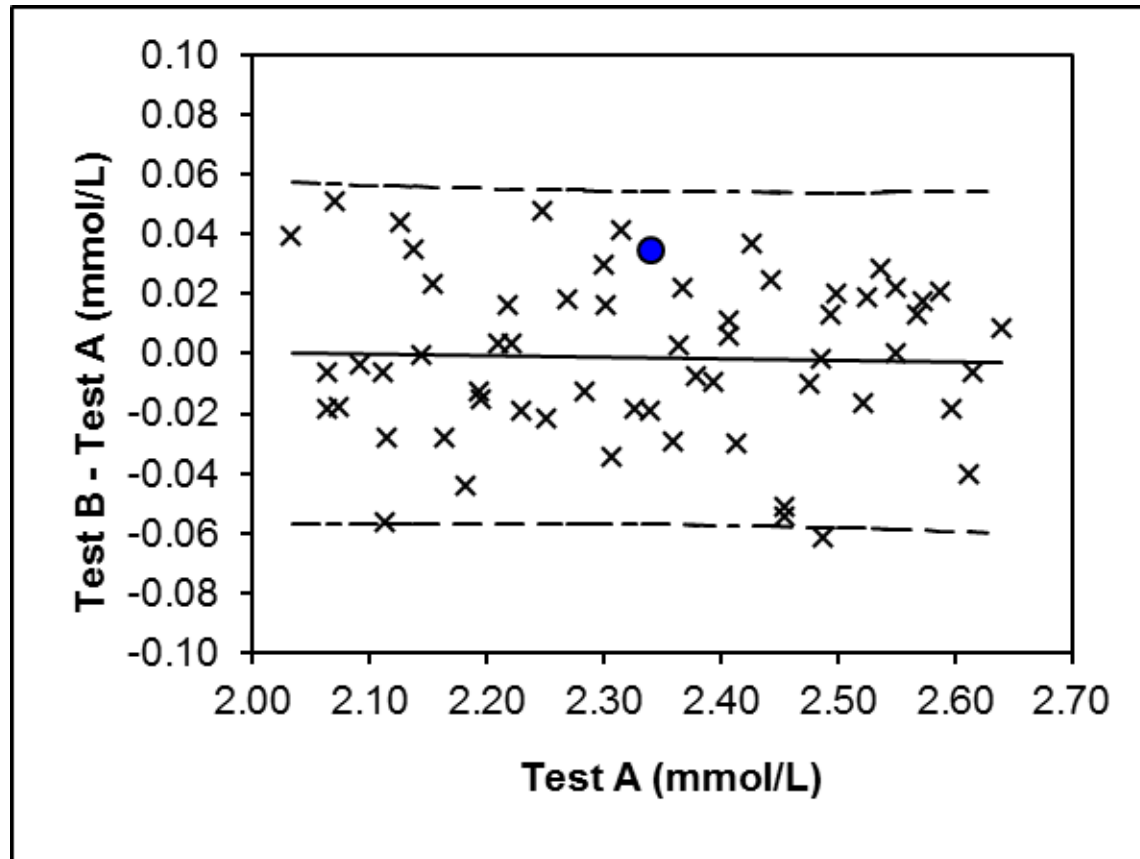
Statistical test (Prediction Interval)

1 replicate



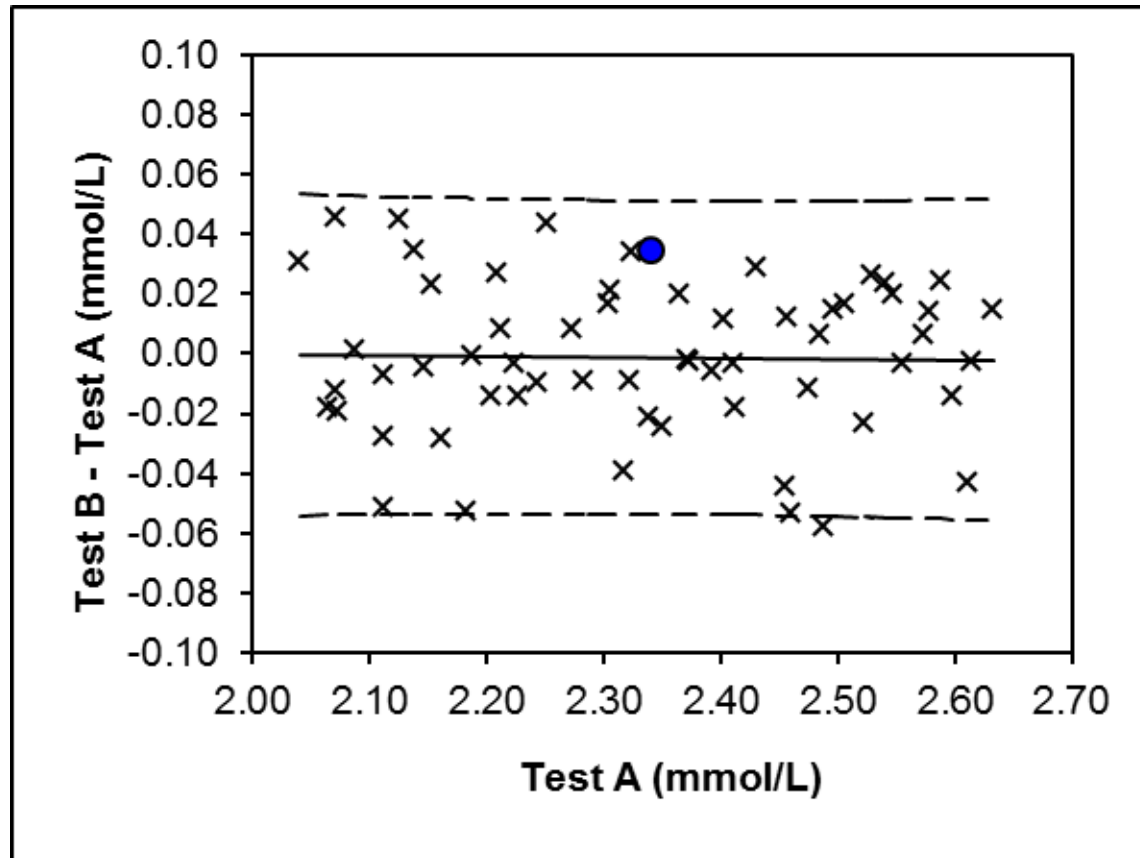
Statistical test (Prediction Interval)

2 replicates



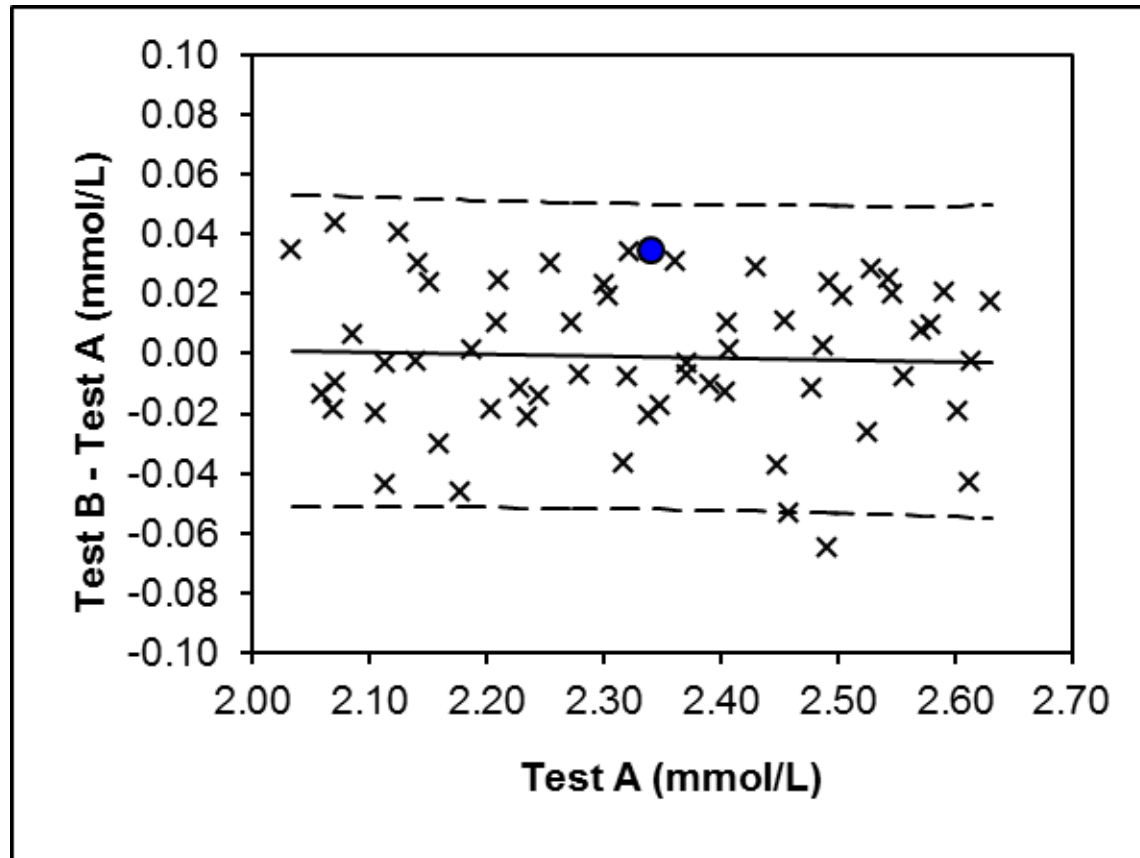
Statistical test (Prediction Interval)

3 replicates



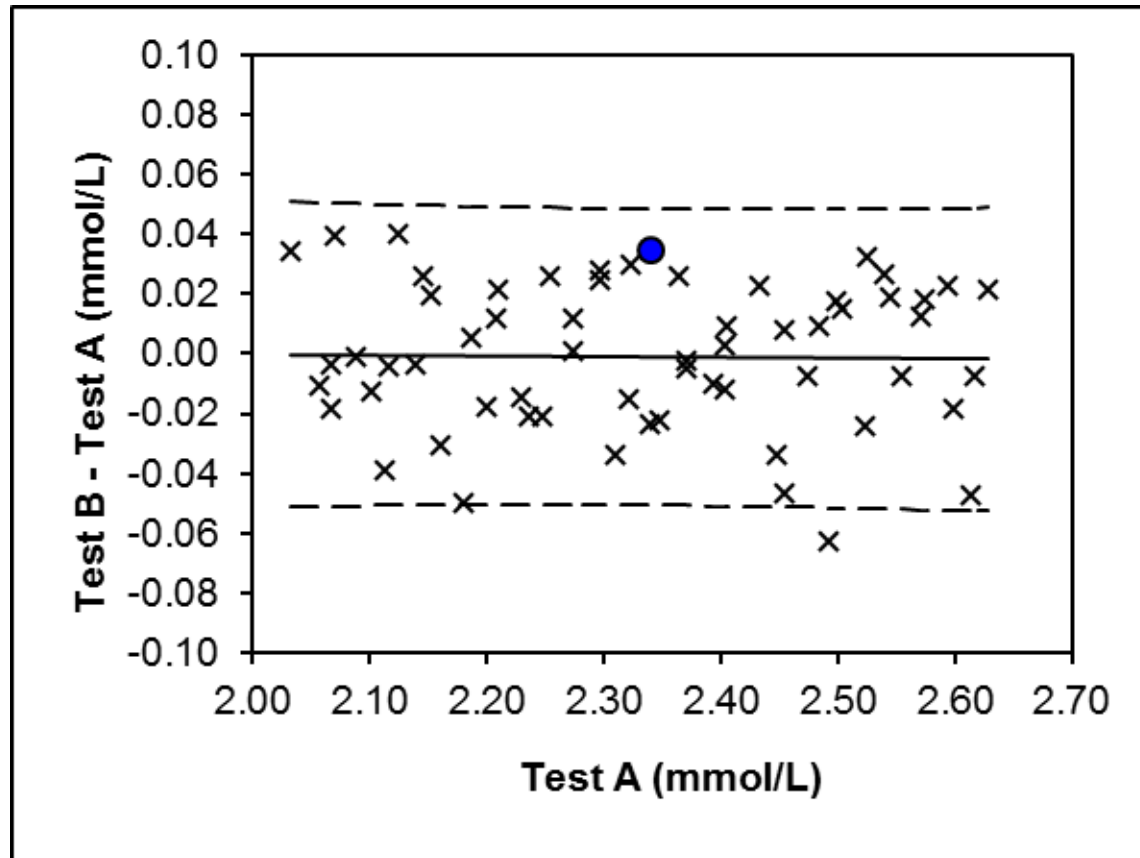
Statistical test (Prediction Interval)

4 replicates



Statistical test (Prediction Interval)

5 replicates



Random, Sample-related effects

Importance of sample-related effects for commutability testing according to the EP14 protocol.

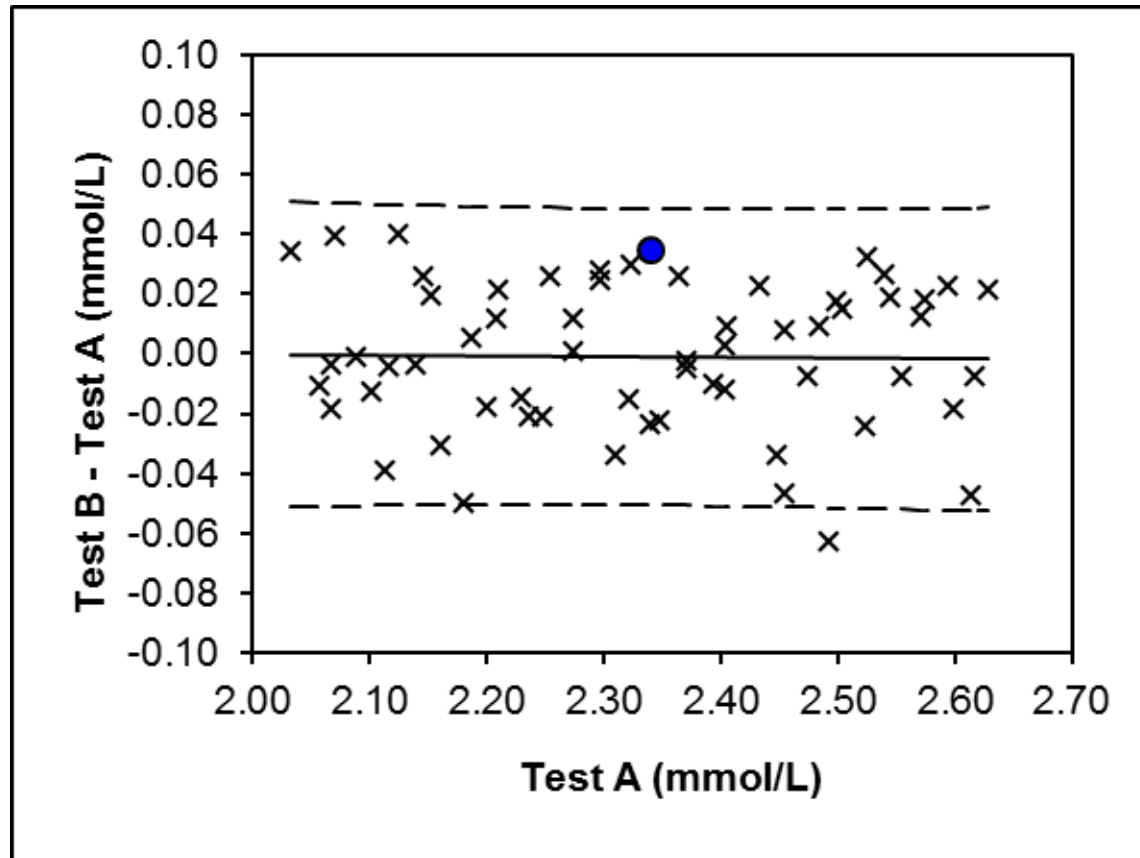
Stöckl D, Stepman HC, Van Houcke SK, Thienpont LM.

Clin Chim Acta 2010;411(17-18):1378-9



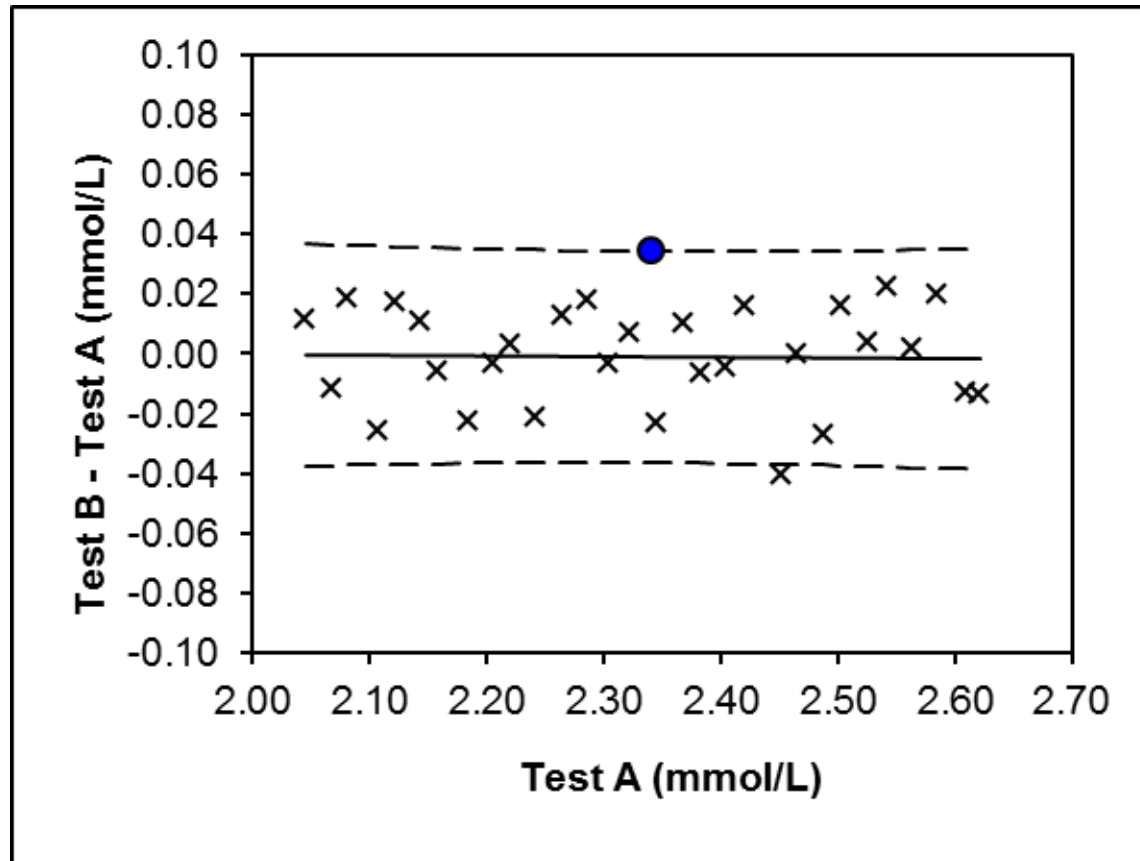
Solution for sample-related effects

5 replicates, 60 samples



Solution for sample-related effects

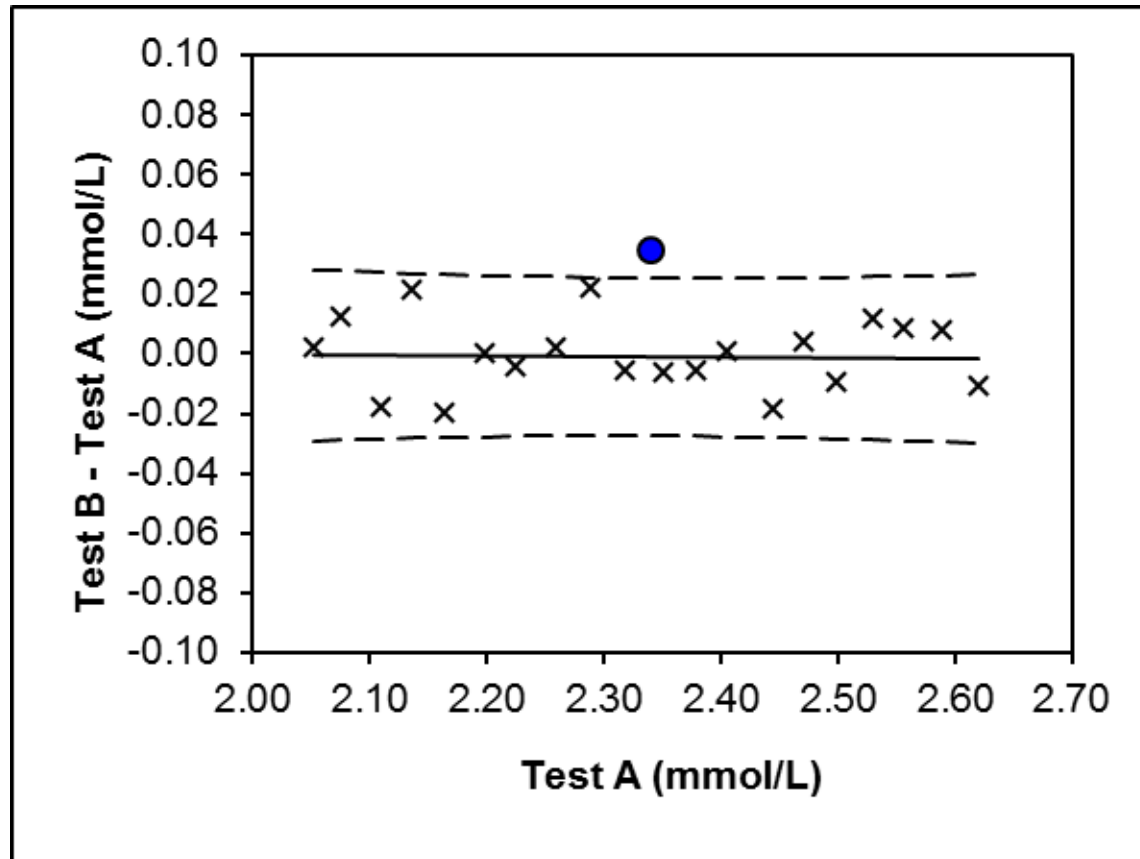
5 replicates/ 2 samples virtual pooling



60 samples → 30 "samples"

Solution for sample-related effects

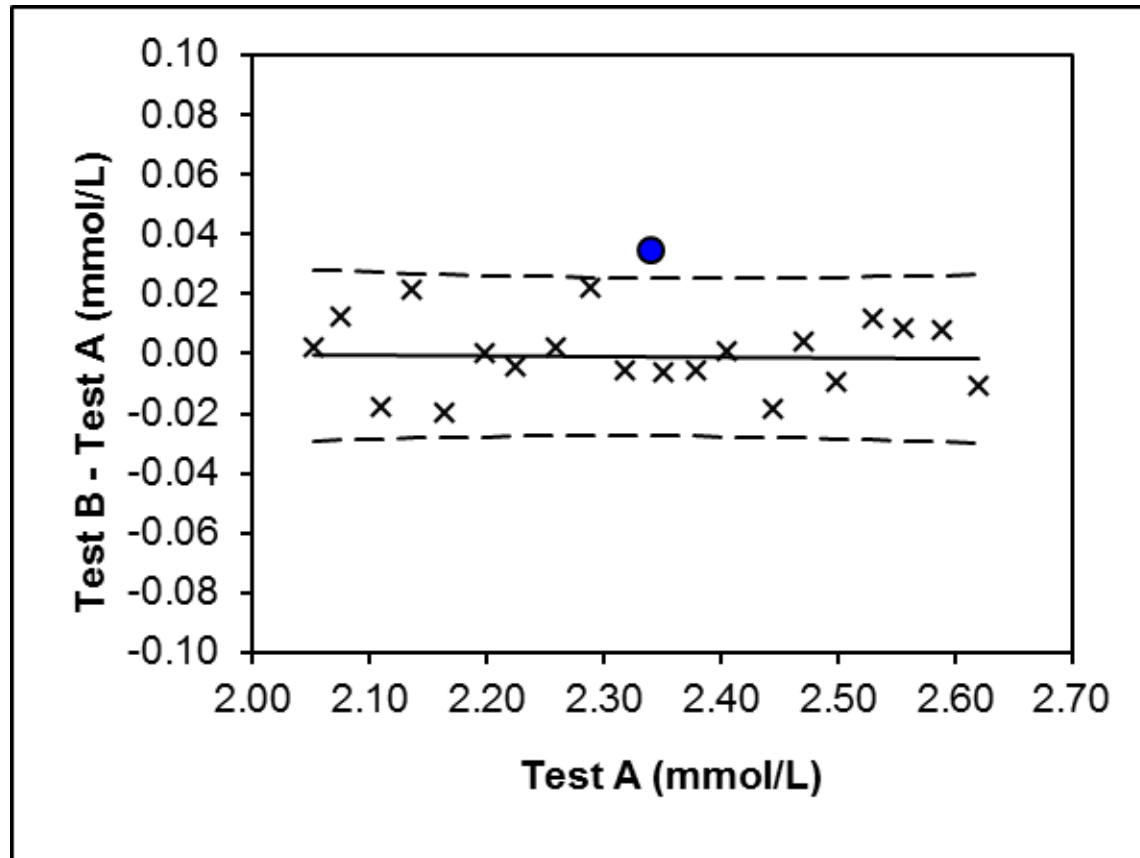
5 replicates/ 3 samples virtual pooling



60 samples → 20 "samples"

Commutability extent?

Difference = 1.5%



Should be <0.5%; It's calcium!

Rule of thumb: 1/3 of bias from biology!

Commutability extent?

Can we reach the desired extent?

Table 1 Prediction intervals (%) and commutability data (\$) for the EQA sera #1 & #2																
	Calcium				Magnesium				Albumin				t-Protein			
	PI#1	#1	PI#2	#2	PI#1	#1	PI#2	#2	PI#1	#1	PI#2	#2	PI#1	#1	PI#2	#2
Abbott Architect	0.4	0.6	1.1	1.4	3.4	ok	4.6	5.0	3.1	ok	4.5	5.1	0.6	0.7	1.0	ok
Ortho Vitros	0.5	ok	1.3	ok	2.0	ok	2.6	5.4	2.0	ok	2.9	7.2	1.7	ok	2.6	ok
Roche Modular	0.5	0.5	1.1	ok	0.6	0.6	0.8	ok	0.8	ok	1.2	ok	0.5	ok	0.8	ok
Roche Cobas	0.3	0.3	0.7	ok	1.1	ok	1.5	ok	0.9	ok	1.3	ok	0.6	ok	1.0	ok
Siemens Advia	0.4	0.4	0.9	ok	1.3	ok	1.8	2.5	2.9	ok	4.3	ok	0.5	0.6	0.8	0.8

\$For each EQA sample the deviation (%) from the regression line for the native samples was calculated.

PI#1, PI#2: prediction interval (%) at the concentration of EQA sample #1 and #2.

£ok: EQA material is commutable, because its deviation is smaller than the prediction interval.

Yes, we can!

- Via EQAS &
- All Procedure Trimmed Mean

Commutability assessment by use of external quality assessment surveys – A means to reduce the uncertainty in the commutability decision

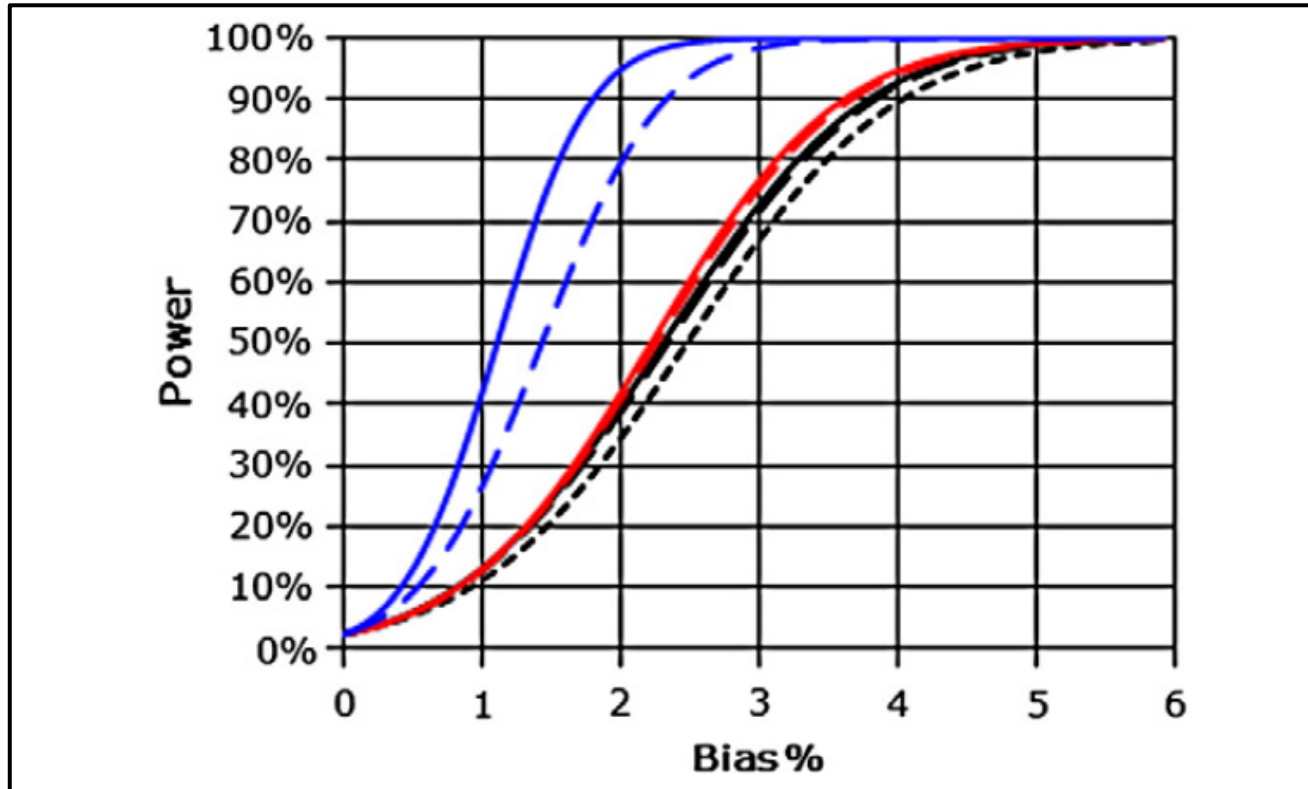
Sofie K. Van Houcke¹, Pål Rustad², Hedwig C.M. Stepman¹, Thomas H. Røraas³, Sverre Sandberg³, Linda M. Thienpont¹

**Klinisk Biokemi
i Norden**

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Plan your commutability experiment!

Sample-size calculations



Statistical power for commutability testing in the presence of random, sample-related effects by use of the EP14 protocol. Røraas TH, Van Houcke SK, Stöckl D, Thienpont LM.

Clin Chim Acta. 2012 Oct 9;413(19-20):1710-1

Fig. 1. Power curves illustrating influence of virtual pooling of samples and replication (both CV_a and $CV_{sr} = 1\%$) (from left to right): 100 (60) samples, 3 replicates, 5 (3) pooling [blue solid (long dashed) line]; 20 samples, 15 (9) replicates, no pooling [red solid (long dashed) line]; 100 (60, 20) samples, 3 replicates, no pooling [black solid (long, short dashed) line].

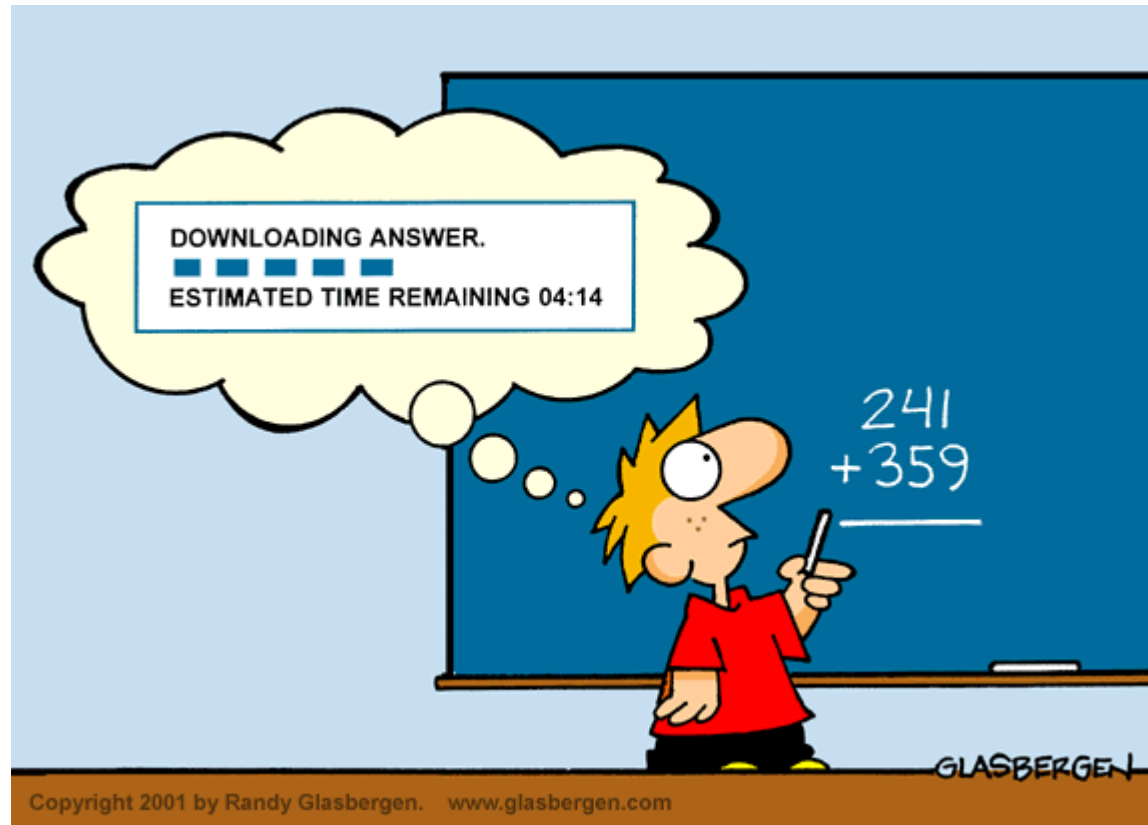
Commutability decision?

Work with
Preset specifications!

Limit the magnitude
of the prediction interval, for example!

>Sample size calculations
at given power!

How to deal with it?



How to deal with it?

Avoid it!



How to avoid it in calibration?

Bjorkhem I, et al. Assay of cortisol with a radioimmunoassay method calibrated by isotope dilution-mass spectrometry. Scand J Clin Lab Invest 1983;43:433-7.



"The calibration standards used in the RIA method ... were replaced by a series of human serum samples, in which the concentration of cortisol had been determined by the reference ID-MS method".

How to avoid it in assessment?

MASTER COMPARISONS

EQA with panels of fresh frozen single donation (commutable) sera

VIRTUAL EQA-1 (Percentiles)

Mid- to long-term monitoring of patient percentiles across laboratories and manufacturers

EDUCATION

Conceptual and statistical education about analytical quality in the medical laboratory

VIRTUAL EQA-2 (IQC monitoring)

Mid- to long-term monitoring of IQC data across laboratories and manufacturers



