Intra-type variability as a measure of the resilience to operator and environmental influences of POCT diagnostic devices

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Background

EU-IVDR requires from assays intended for "near-patient" use that

- the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary, after appropriate training and/or information;
- the risk of error by the intended user in the handling of the device, and, if applicable, the specimen, and also in the interpretation of the results, is reduced as far as possible.

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Background

- used by operators with less medical or laboratory technical qualification, competence and experience (similar in US and Australian Regulations)
- such assays should be characterized by high resilience to operator and environmental influences and therefore do not allow for intentional or unintentional modification of the test procedure

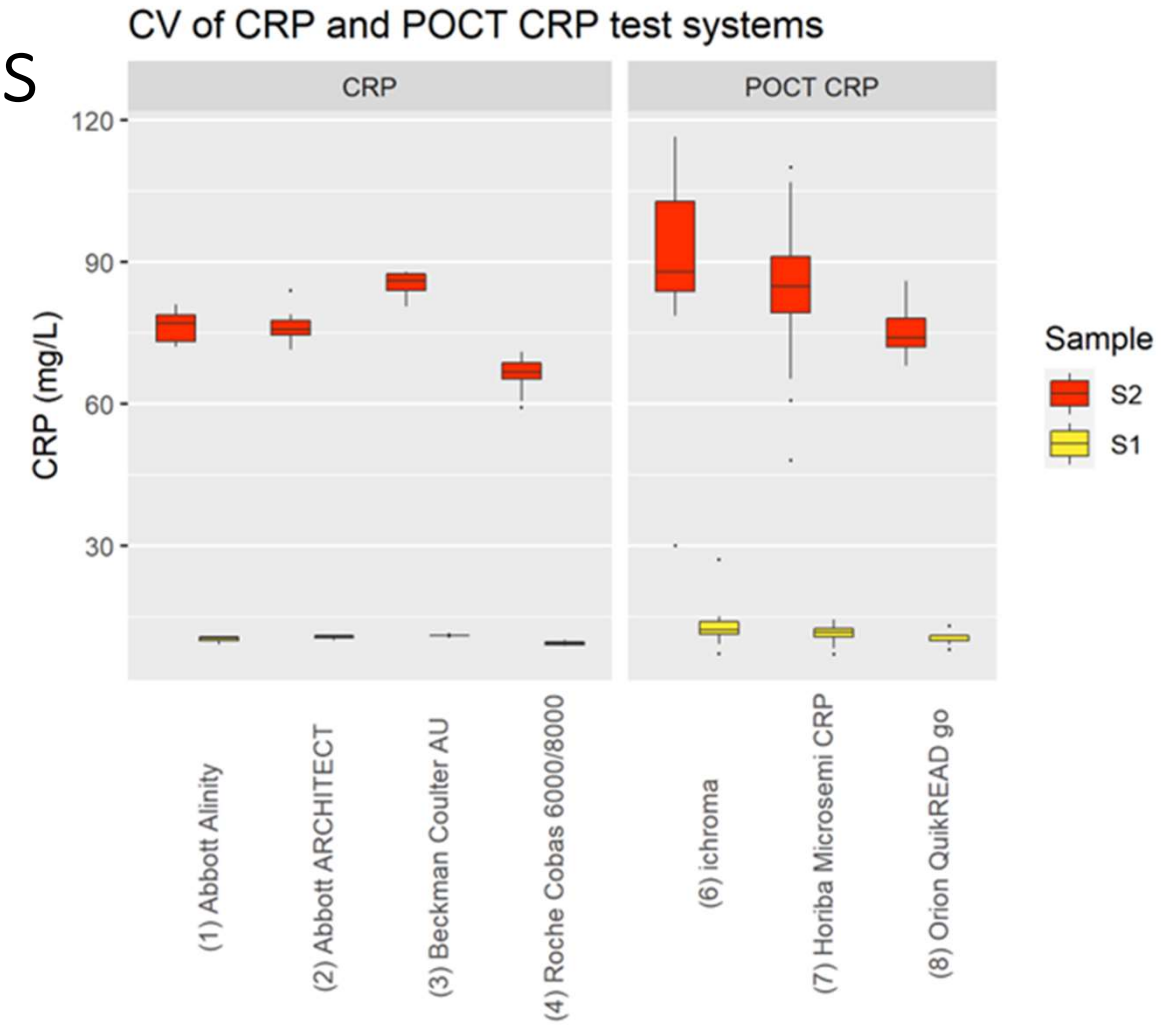
Background

It can be deduced that under whatever conditions and by whomever a device is operated, results with only little variance should be delivered.

Methods

EQA schemes involve multiple devices of the same type that almost simultaneously analyze the same samples, for which homogeneity and stability have been proven. Such schemes are therefore excellently suited for investigations on the variability.

Examples



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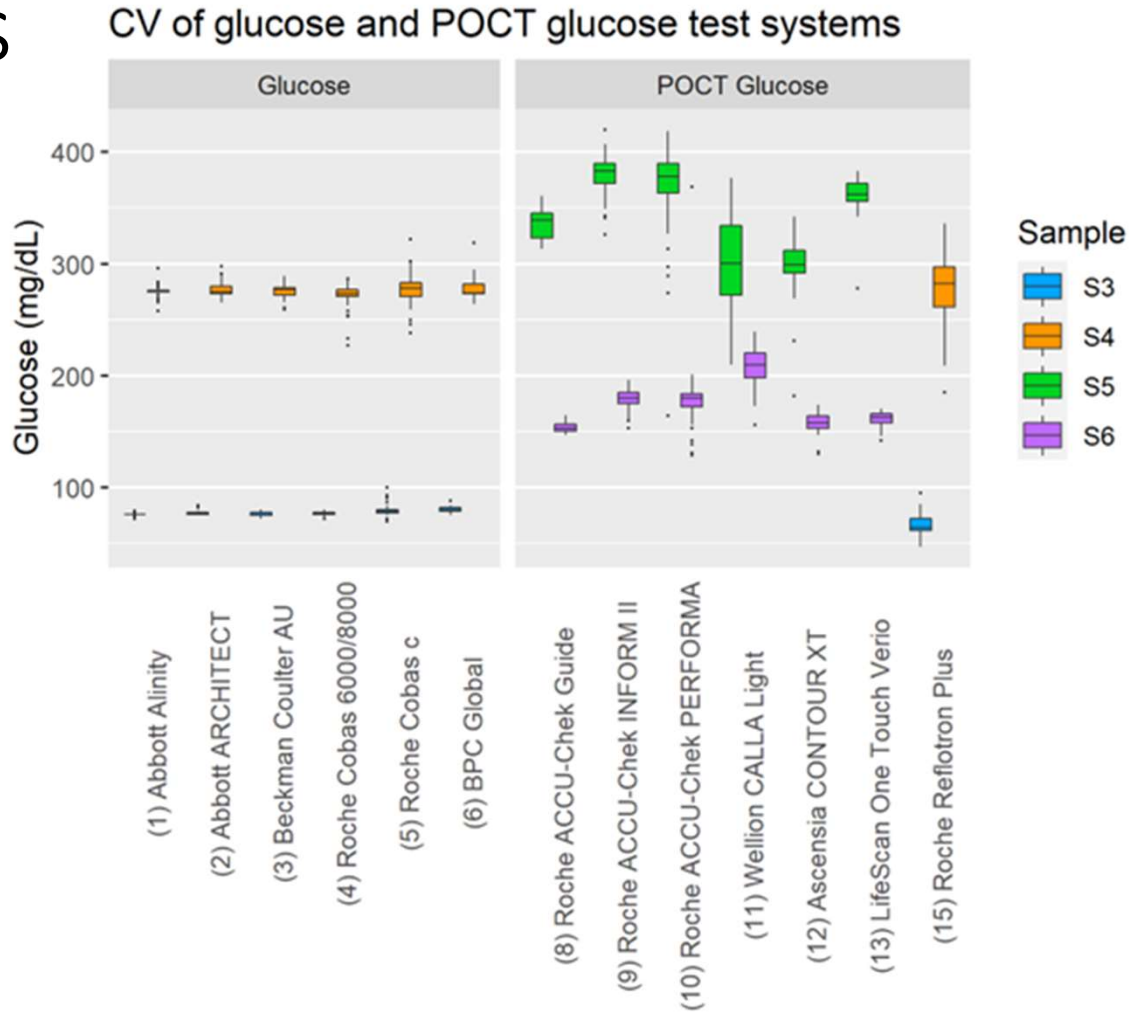
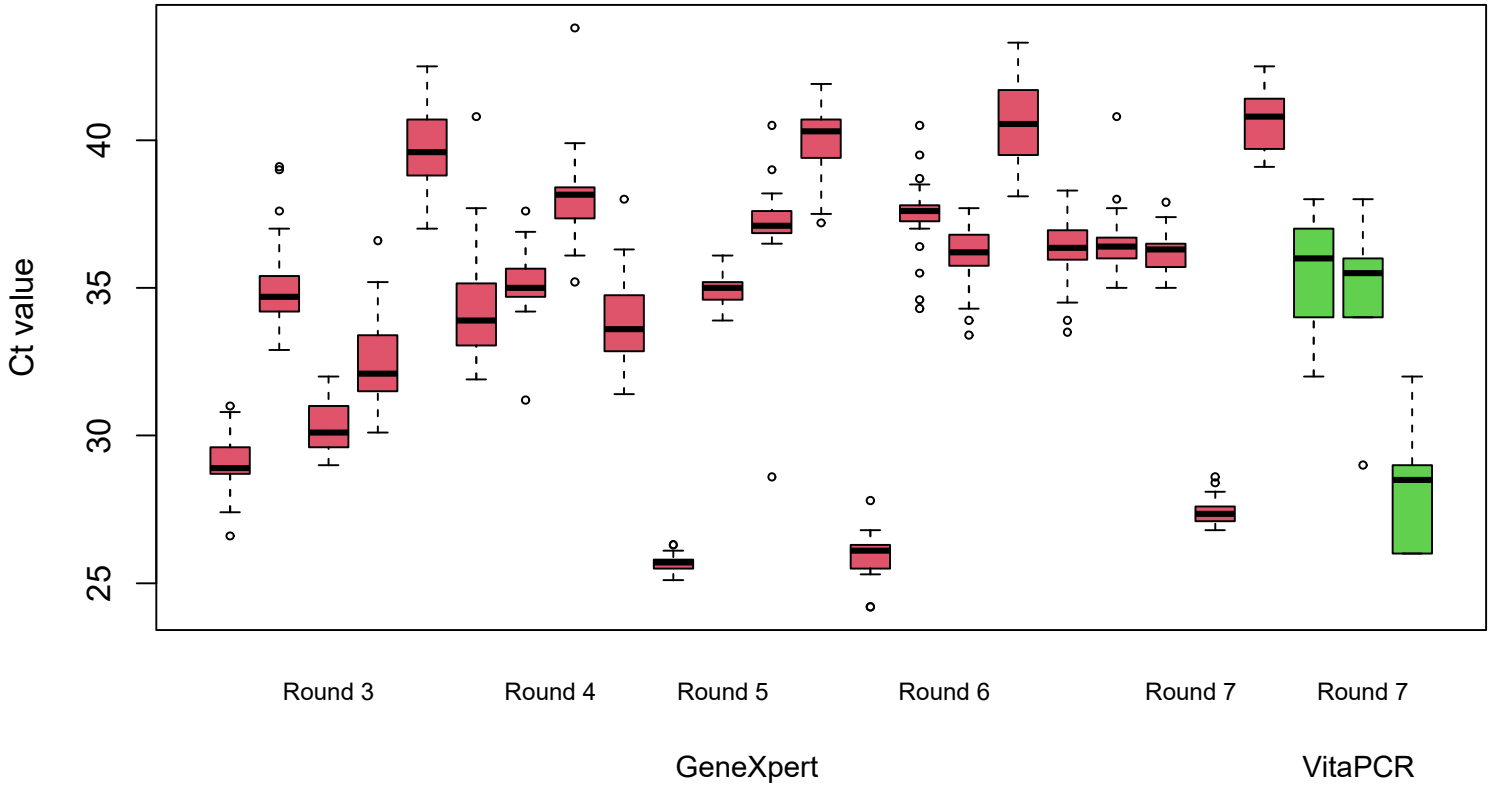
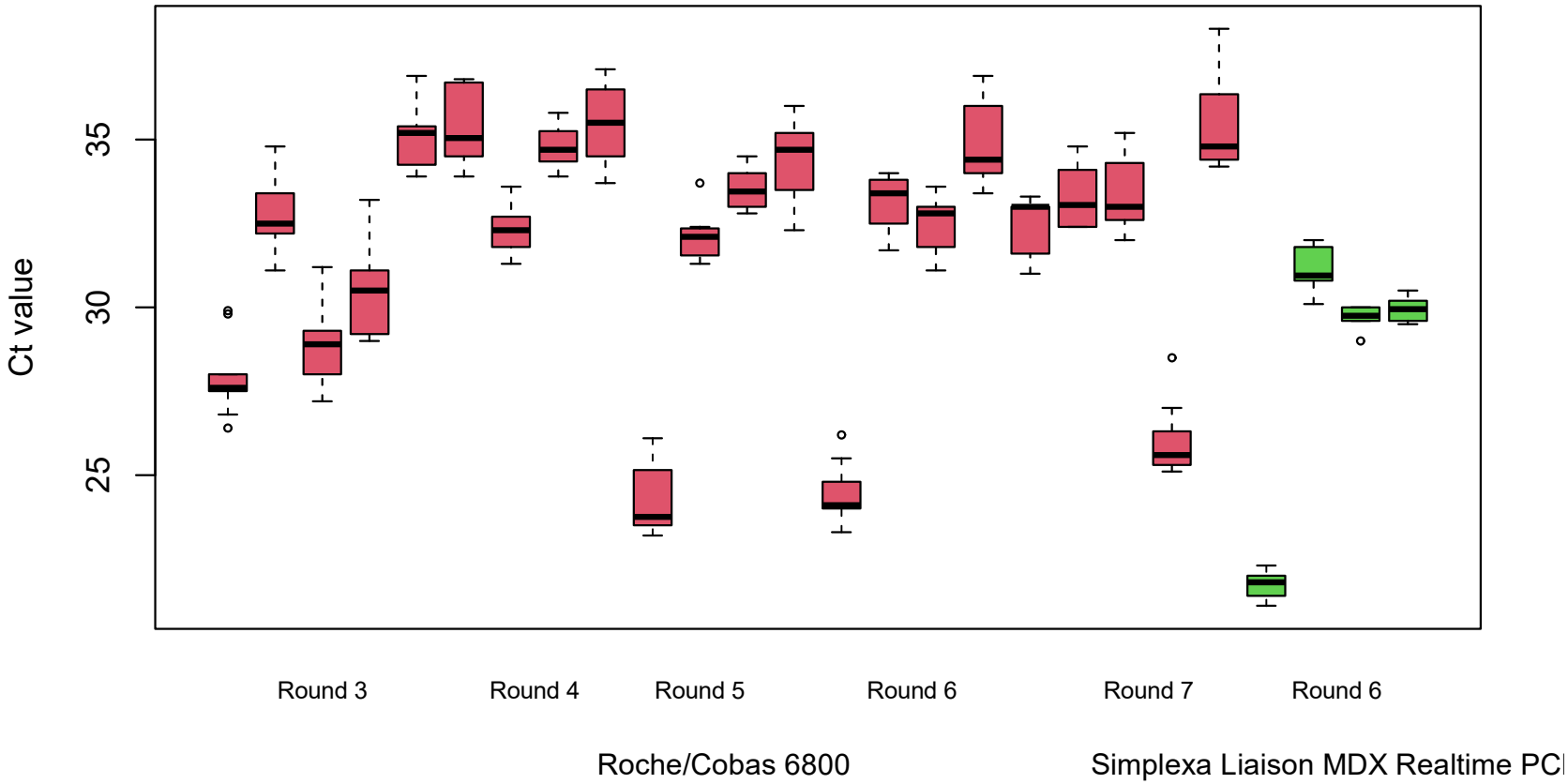
Examples



Examples


Ct value
25
30
35
40
Round 3
Round 4
Round 5
Round 6
Round 7
Round 7
GeneXpert
VitaPCR

Examples


Ct value
25
30
35
Round 3
Round 4
Round 5
Round 6
Round 7
Round 6
Roche/Cobas 6800
Simplexa Liaison MDX Realtime PCI

Hypothesis

The coefficient of variation (CV) of measurement results obtained from a larger number of identical devices from identical samples is a useful tool to give objective evidence on the resilience of test systems to external influences.

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Approach: Comparing EQA variability using multiple samples together

- Parametric model that describes relation between assigned values and standard deviations evaluates variability for multiple samples together

Characteristic function: $SD = \sqrt{a + b.CT^2}$

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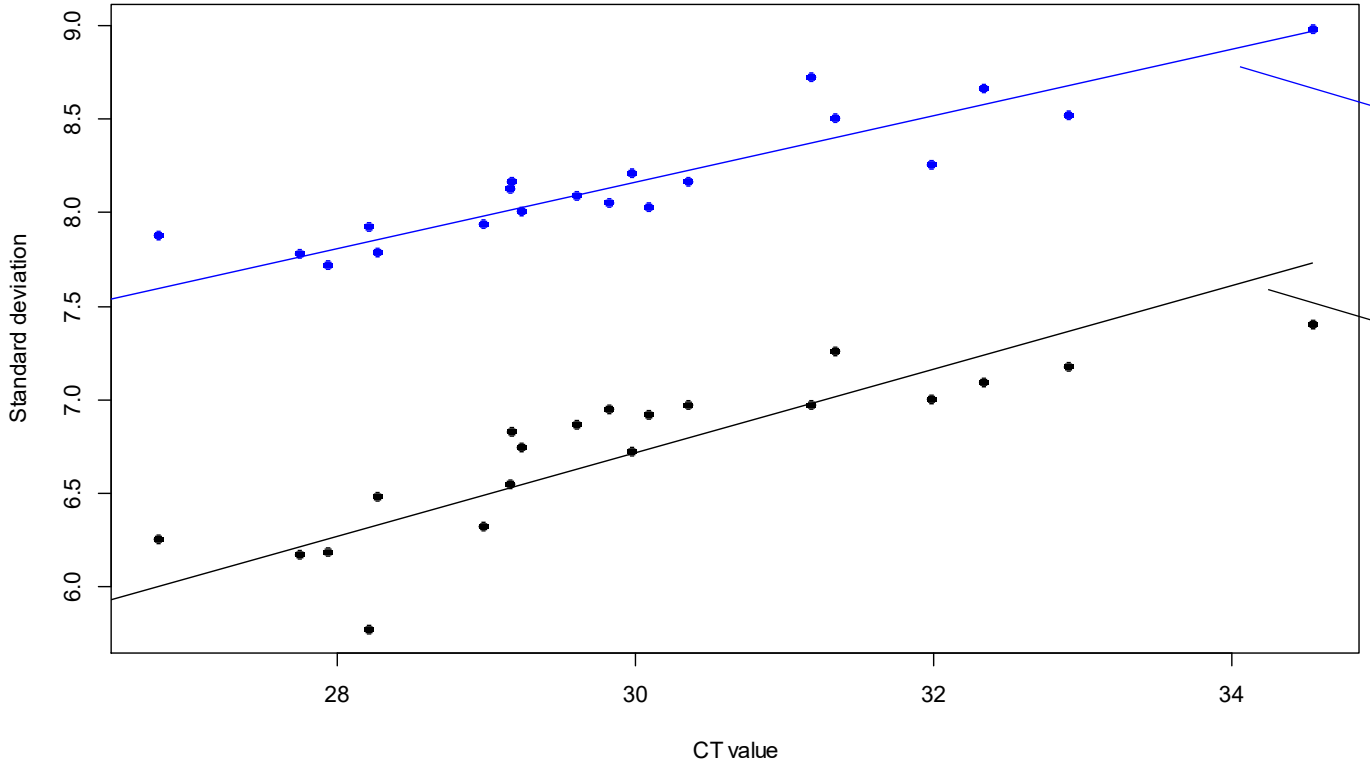

Higher variability
Higher a and/or b

Lower variability
Lower a and/or b

Thank you!

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