

Harmonization?

The solution:
Calibration 2000

Harmonization?

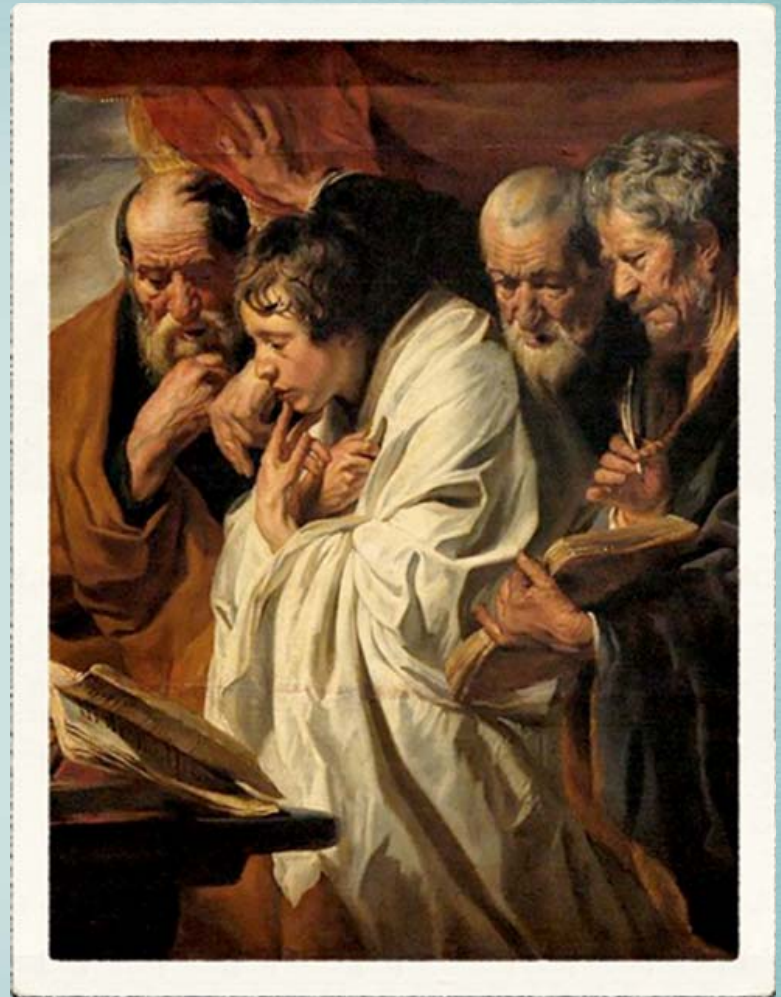


Four Evangelists
Jordaens 1625, Louvre

Gospel Harmony

Diatesseron

Tatian, 2nd century



Harmony in music

Pekka Kuusisto



Janine Jansen





Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek



Harmonization

The good message, the good music for
Laboratory Medicine

Calibration 2000

- Initiated 1998 (Jansen)
- Harmonization and Calibration
- Commutable materials
- Reference method targets where possible
- Biological variation for tolerance limits

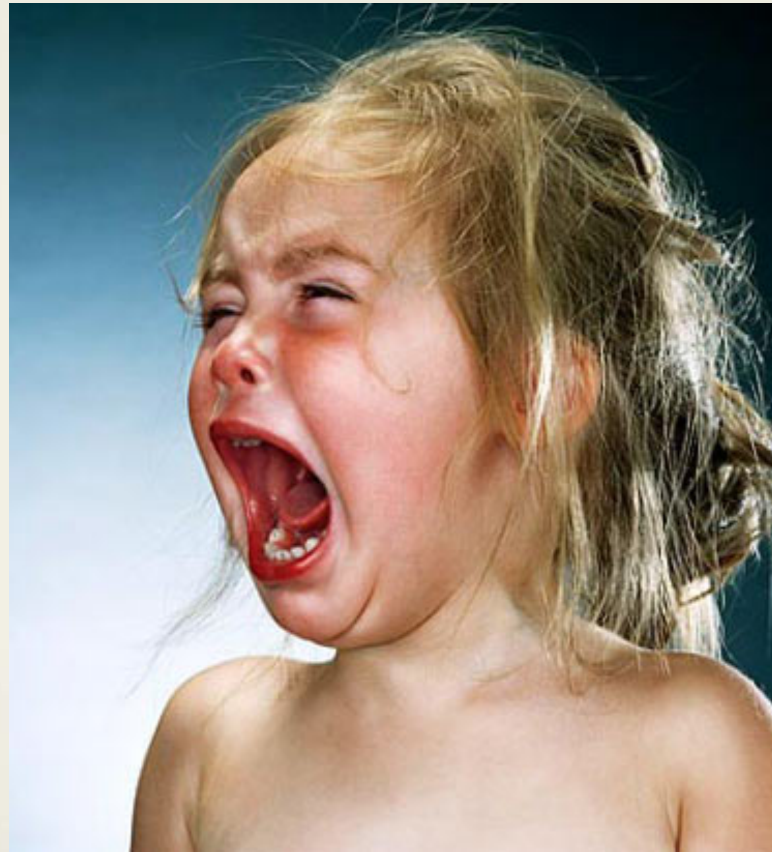
Calibration 2000

- Focus on harmonization
- Various disciplines
 - general chemistry
 - coagulation
 - hemocytometry
 - endocrinology/tumor markers
 - humoral immunology
 - cellular immunology
 - bacteriology/virology
 - histopathology



Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

NL Calibrated in 2000





Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

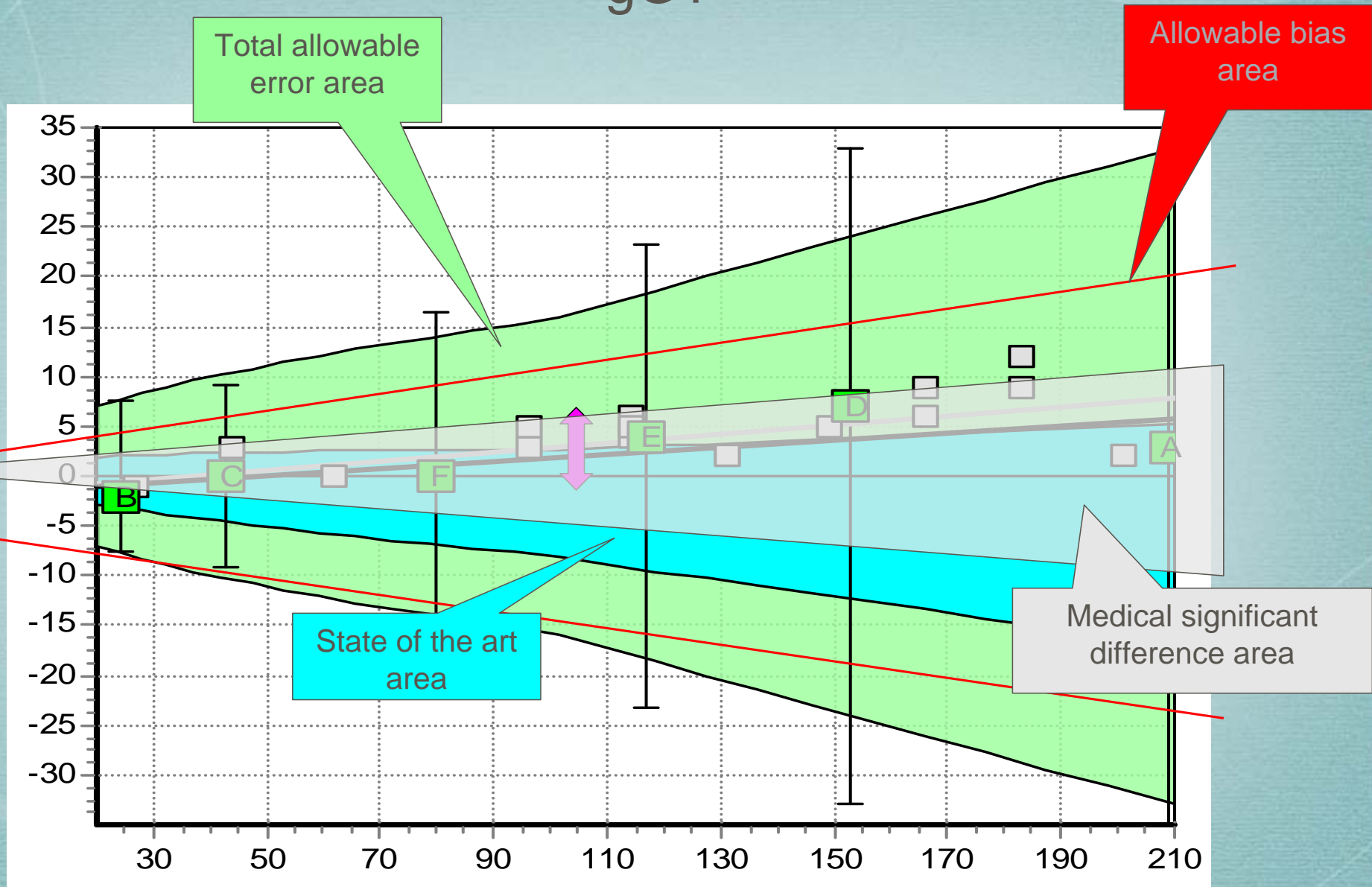
NL Calibrated in 2011



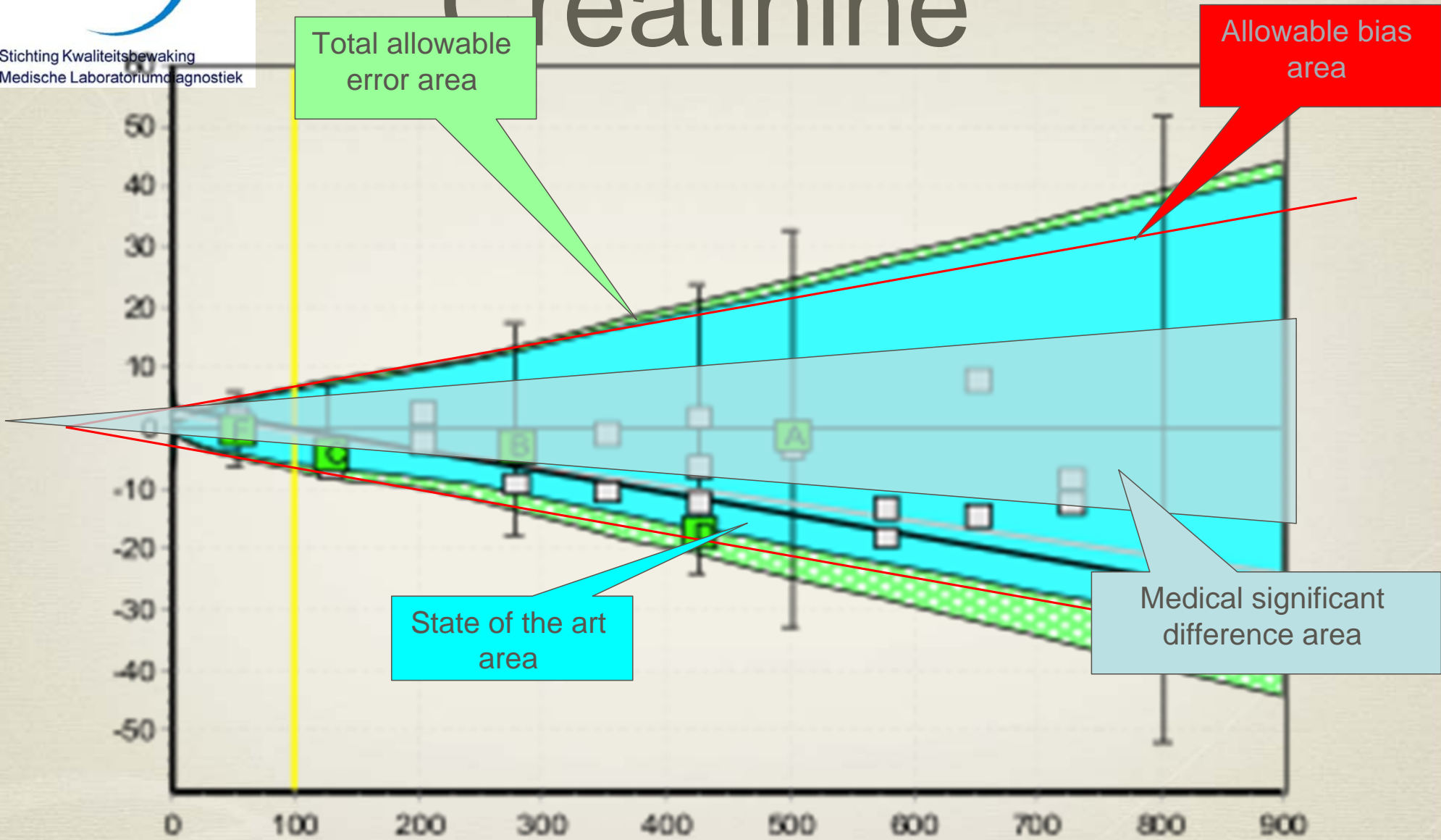
Calibration 2000 Results in 2011

- EQAS changed
- Harmonization of many analytes
- First step towards harmonized reference intervals
- Trueness verification
- IVD post marketing surveillance

gGT



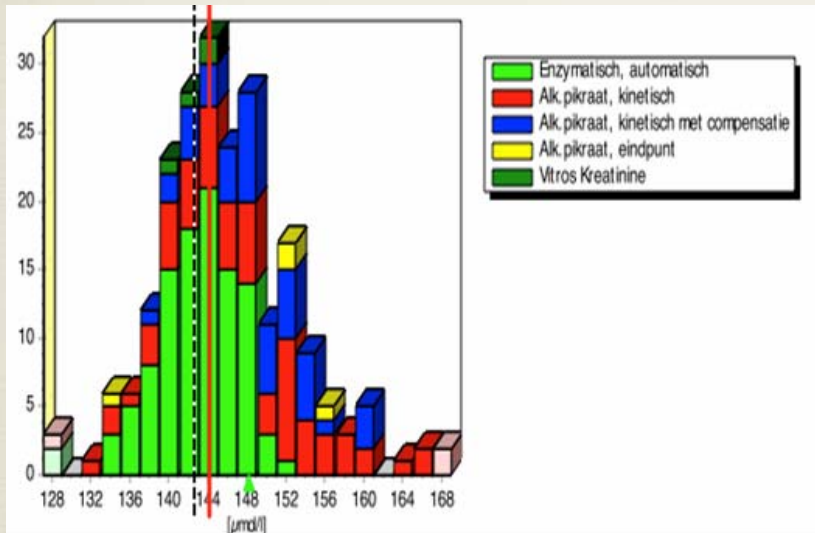
Creatinine



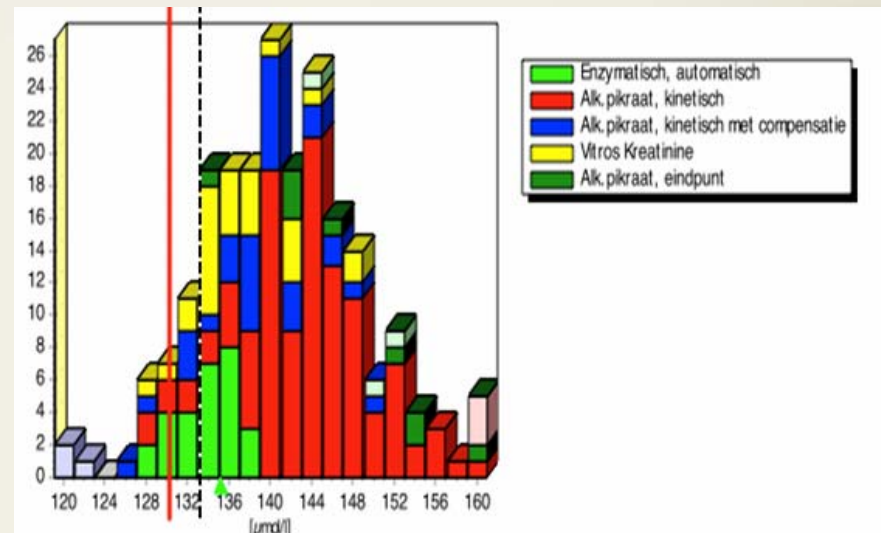
Harmonization of analytes: creatinine

Cobbaert

Kreatinine 2010.4E



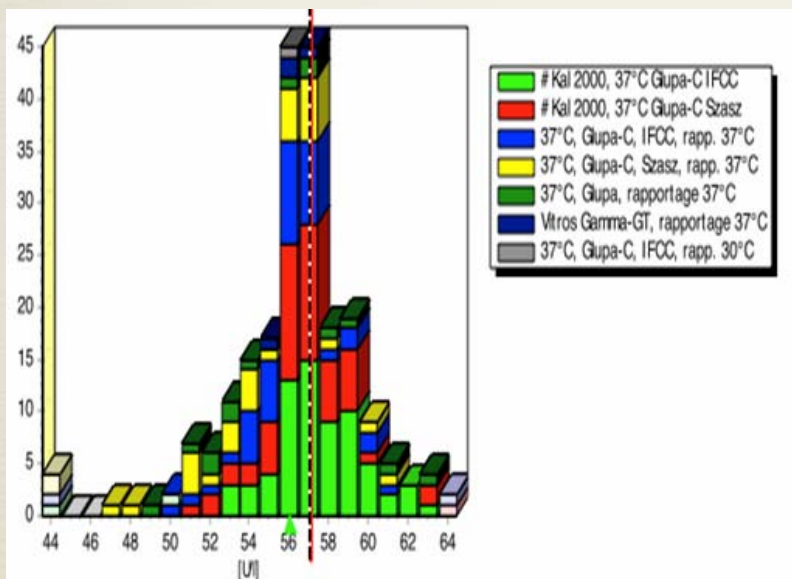
Kreatinine 2005.1C



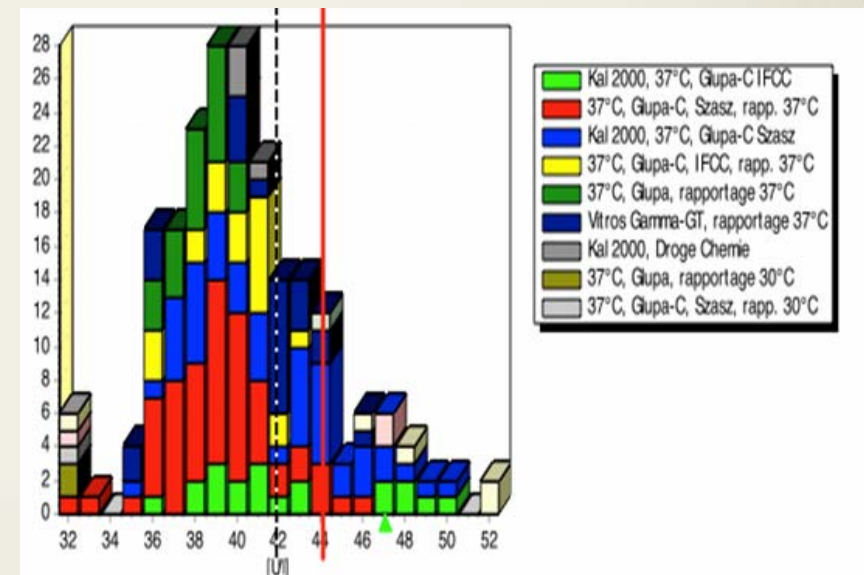
g-GT

Cobbaert

Gamma GT 2010.4 F

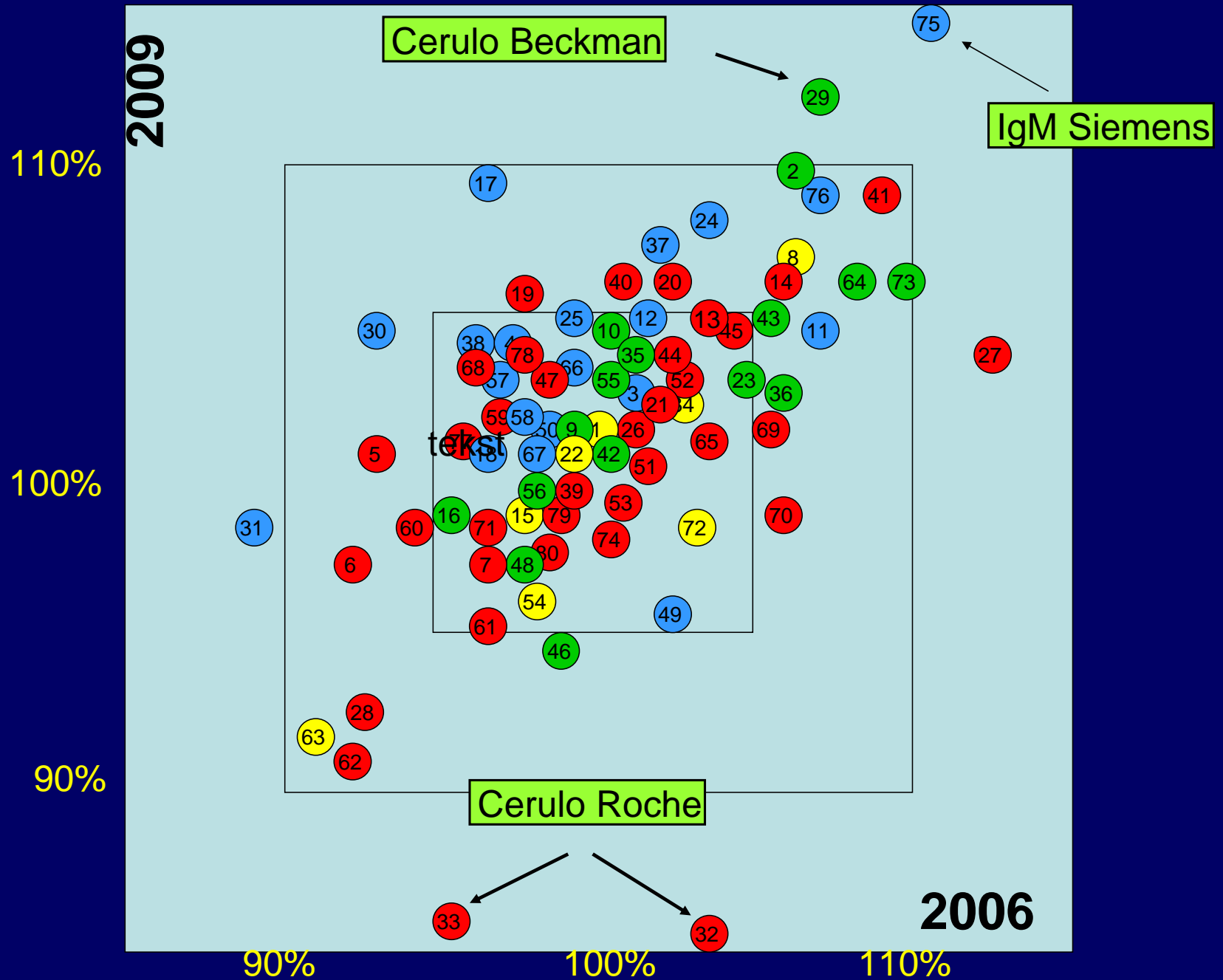


Gamma GT 2005.1 E



11 Proteins – All Methods

Weykamp, Haagen



Conclusions

75% less than 5% from Target

20% between 5 and 10% from Target

5% more than 10% from Target
Ceruloplasmine Roche (low) Beckman (high)
IgM Siemens BNII

General Conclusion

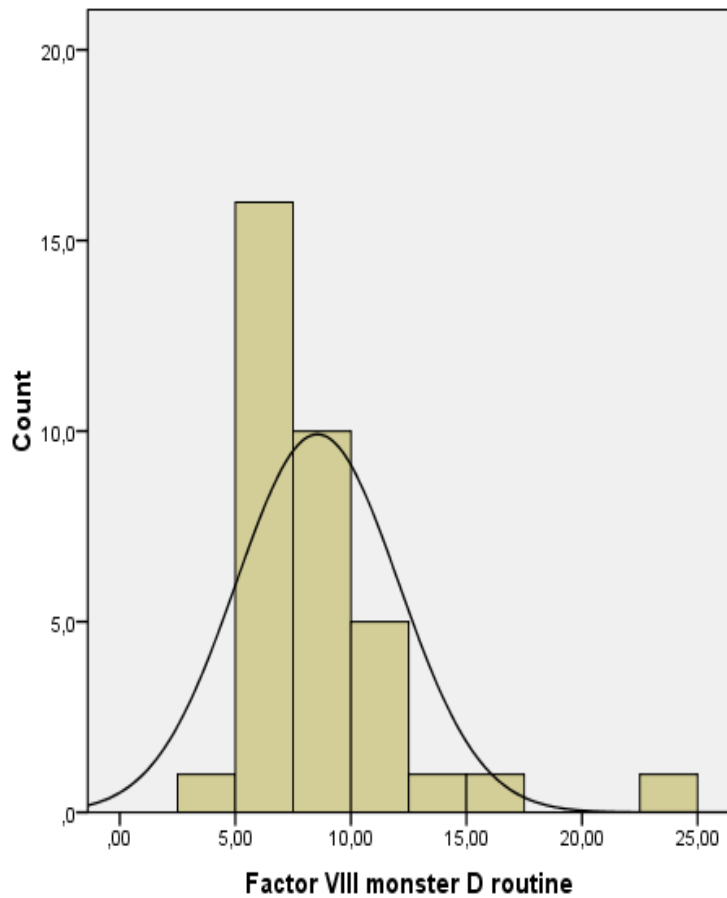
With commutable, stable, CRM-470 targeted EQA samples, the SKML can monitor:

- Performance of individual labs
- Performance of manufacturers
- Performance profession in general

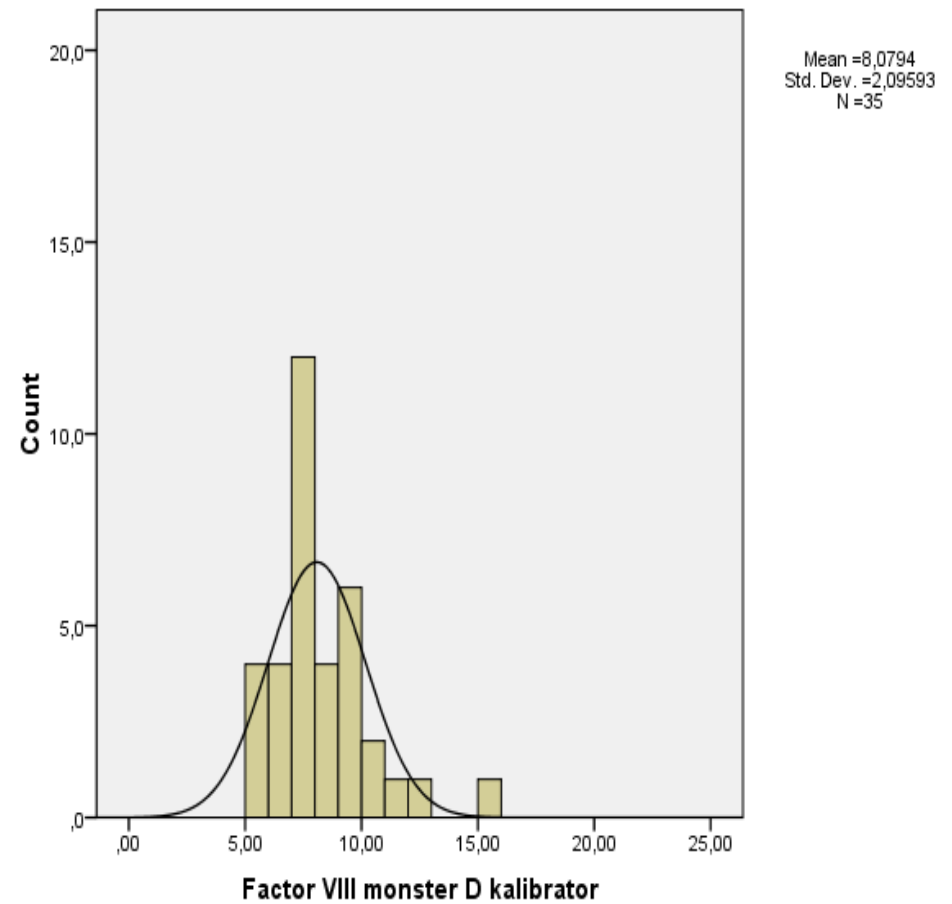
The (trend in) interlab CV is excellent to monitor Harmonisation

Factor VIII:C effect studie Besselaar

SD=3.5

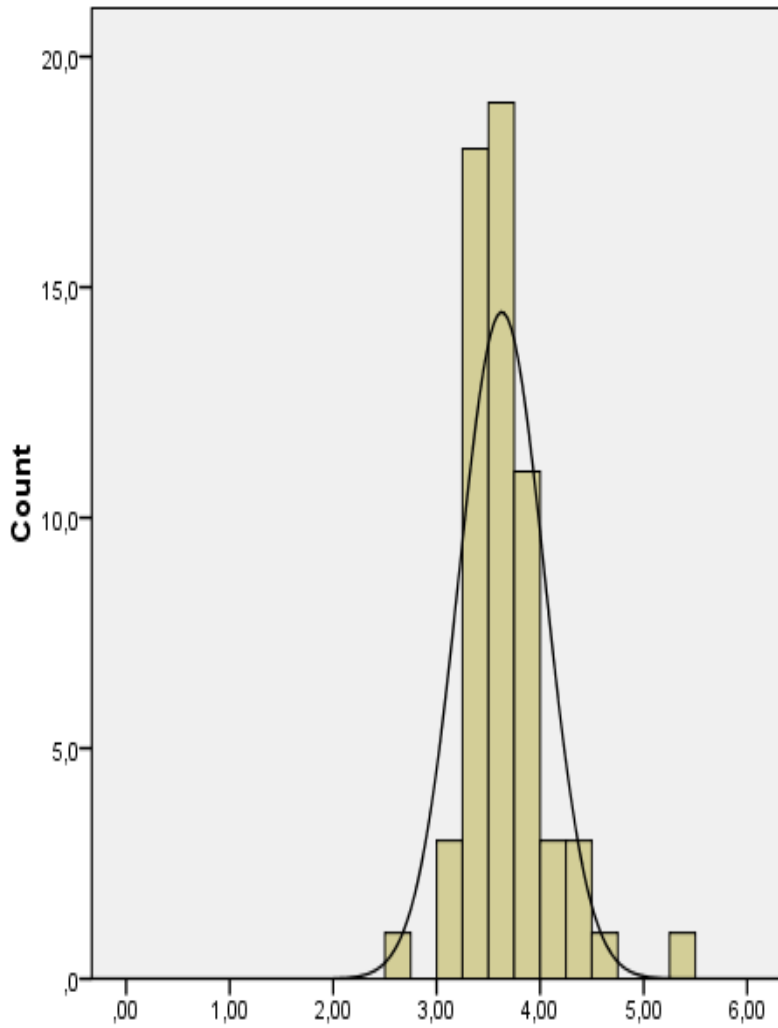


SD=2.1

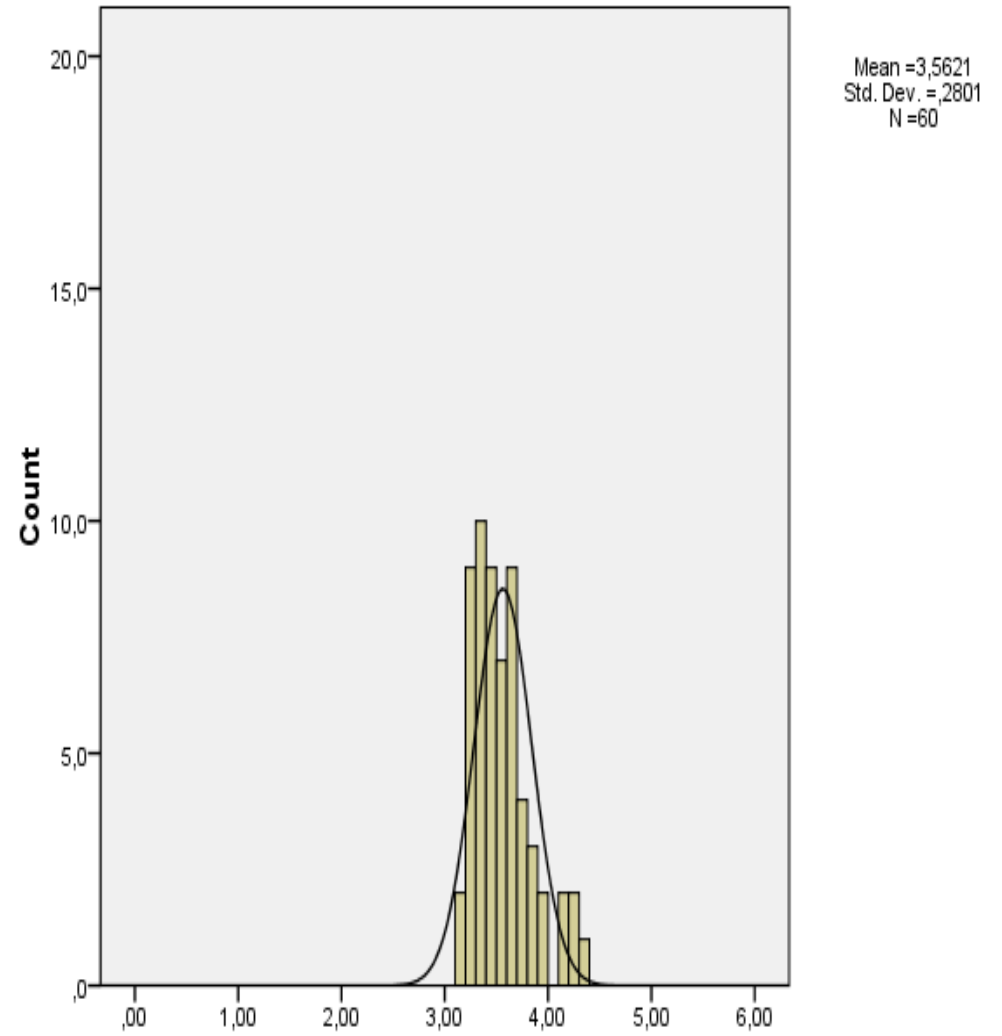


Fibrinogeen effect studie Besselaar

SD=0.41



SD=0.28

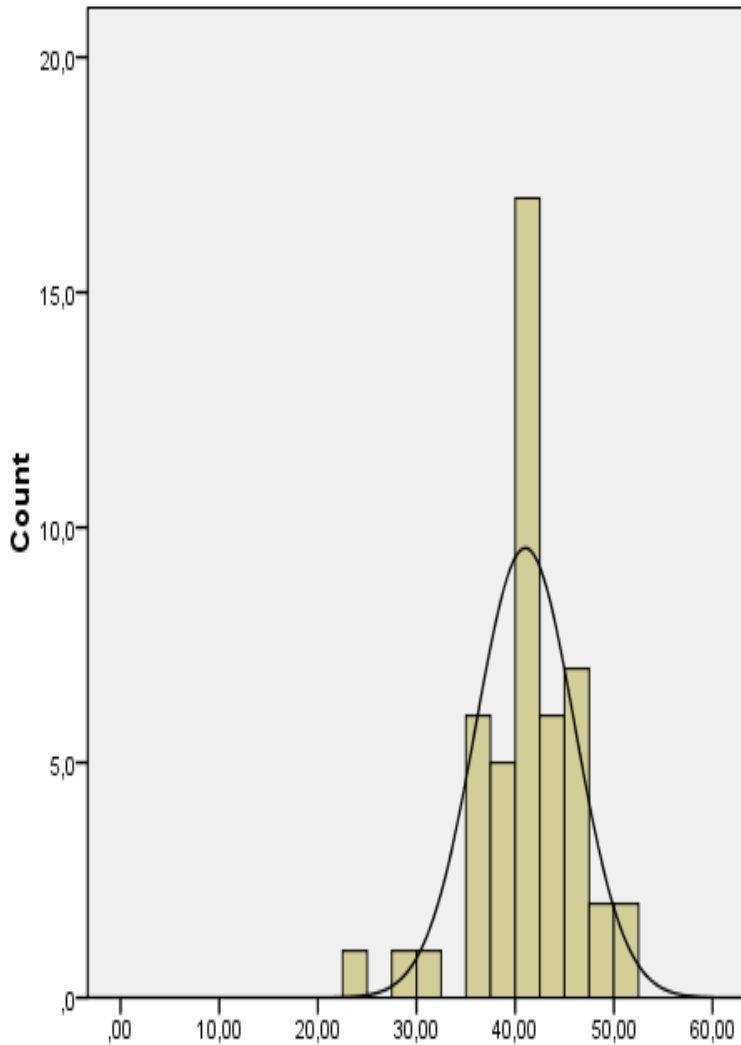


Sample D routine

Sample D calibrator

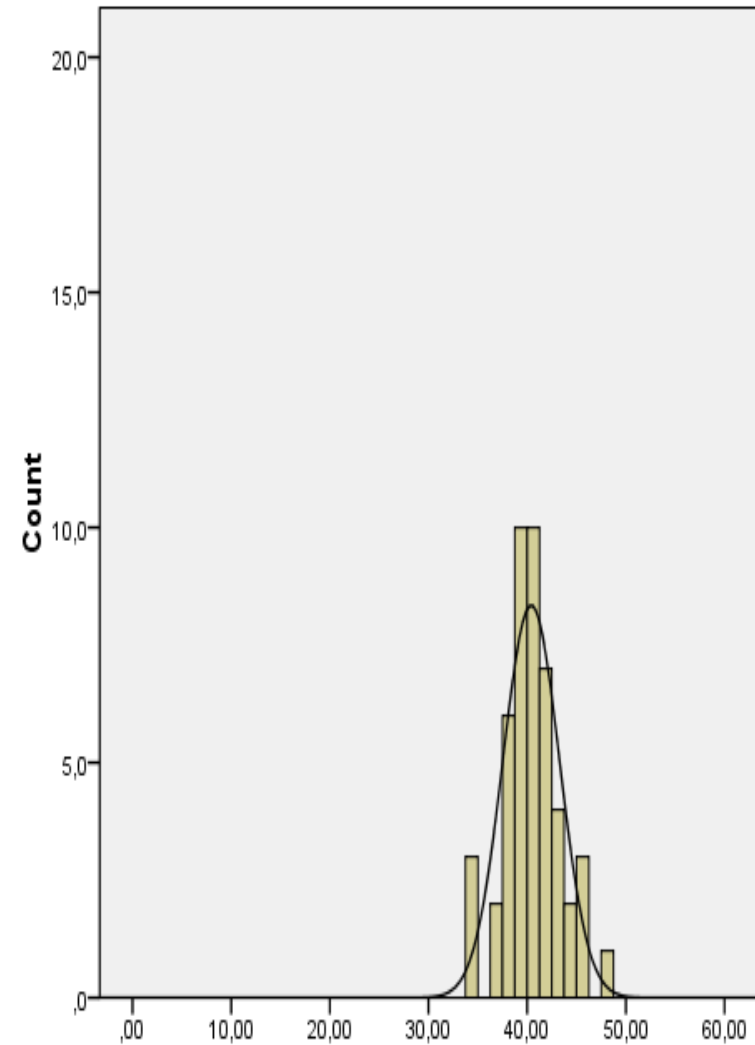
Antitrombine effect studie Besselaar

SD=5.0



Sample B routine

SD=2.9



Sample B calibrator

IVD Trueness verification

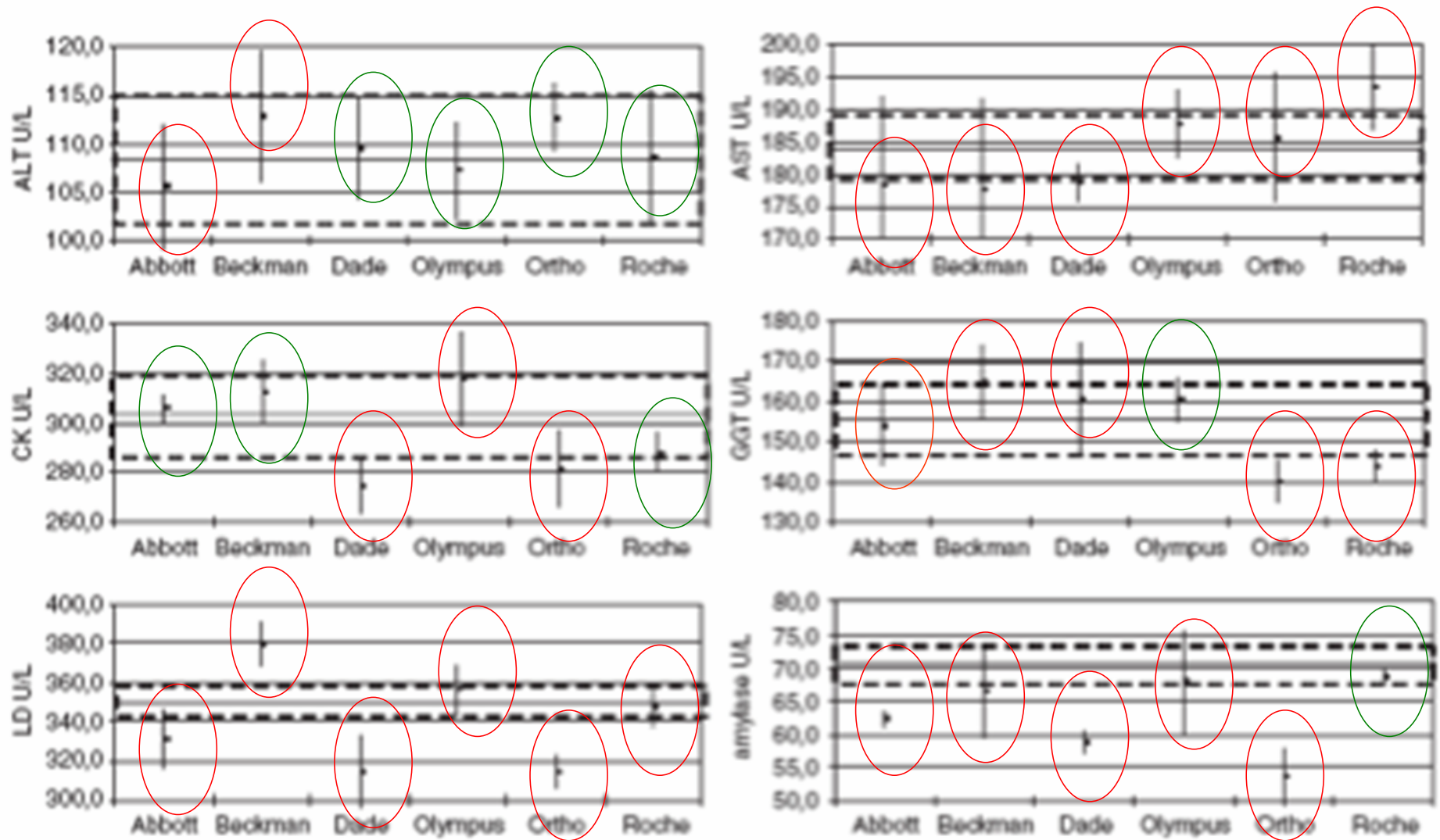
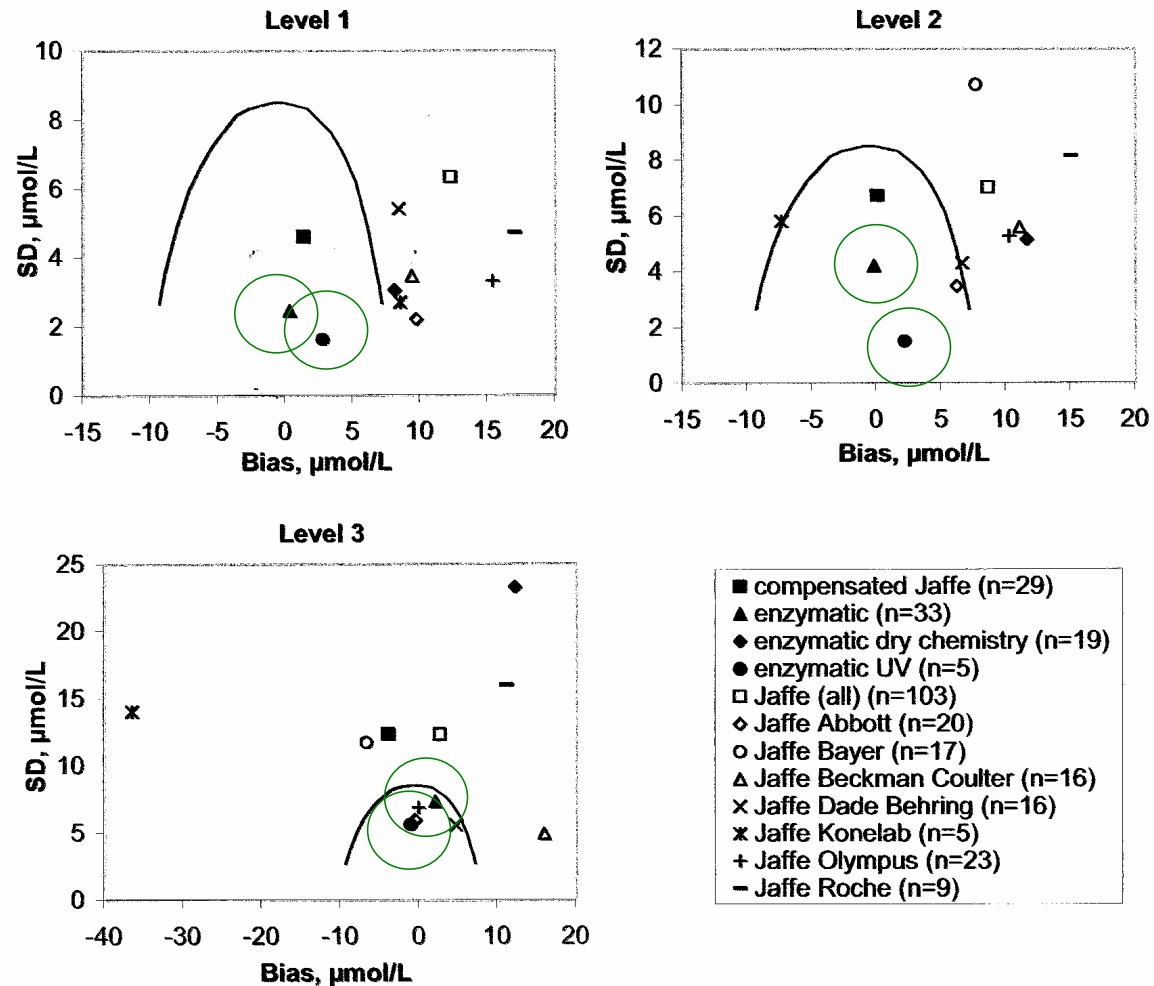


Fig. 1. Target value (fat line), mean \pm SD₉₅ (UL) for each company system, and the area (dashed) of maximum allowable SD₉₅ in absence of significant bias.

Creatinine Total error budget



Delanghe e.a. CCLM 2008, 46:1319

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Harmonization: Being as your neighbour?



Harmonization: Being as your neighbour!



Harmonization?

The first step to a solution:
Calibration 2000