EQA - The Czech Experience

B. Friedecky, J. Kratochvila, M. Budina

SEKK, Czech Republic

Provider of proficiency testing schemes no. 7004 accredited by CAI according to ISO/IEC 17043

web: www.sekk.cz

e-mail: sekk@sekk.cz

Milano 2015

City of halved horse and of Czech EQA office

City emblem originated due to participation of Barons from Pardubice on the siege Milano by army of Friedrich Barbarossa in the 12th century

Pardubice

Arnošt (Ernest) of Pardubice
Vilém (William) from Pernstein

ERNEST

- First Czech (Prague) archbishop (1343 – 1364)
- Diplomat on behalf Charles IV (Roman emperor)
- First chancellor of Charles University (14th Century)

WILLIAM

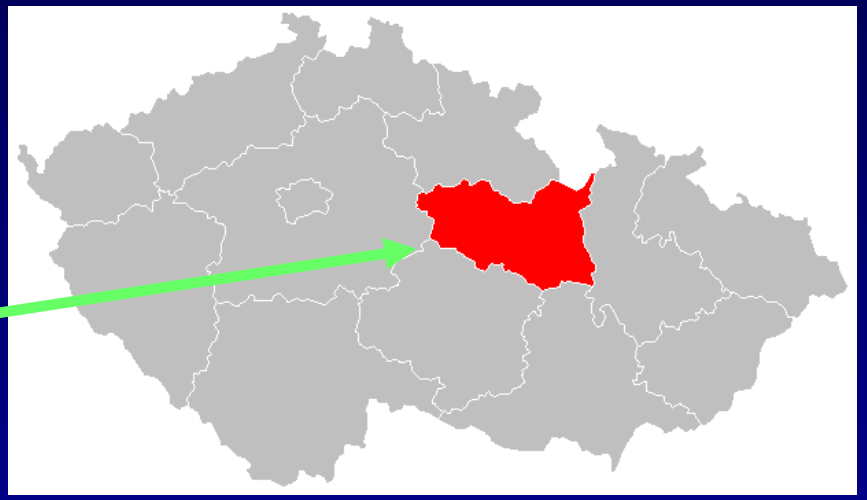
- Huge economy development of district
- Unbelievable (for beginning 16 century) religion tolerance

Dominator

- Dominik Hašek
- Ice hockey goalkeeper
- Six times winner of Vezin trophy in NHL

Pardubice-settlement of SEKK

- Cca 100 000 inhabitants
- Capitol of district
- University city
- Only 1 hour from Prague by train
- Big chemical factories Explosia (SEMTEX)…



EQA in the Czech Republic

- **Mandatory**: insurance companies require participation (both of laboratories and professional POCT users)
- **Professional supervision**: Czech Medical Chamber and Czech Medical Association it‘s professional societies
- **Technical background and organisation**: accredited provider according to ISO 17043

SEKK - Systém Externí Kontroly Kvality

- **Software**: developed by SEKK
- **Arrangement:** approx. 63 programmes → 150 rounds (surveys) per year from majority parts of laboratory medicine; over 1800 participants (CZ and SK mostly)
- **Web pages:** www.sekk.cz (partially also in English), freely available
- **Archive of results:** and statistics free (5 years history) in English freely available

Assigned values

- According to ISO 17043:
- CRV – certified reference values if possible and available (unfortunately not available for most analytes) – cooperation with RfB Bonn, ERL for Glycohemoglobin Winterswijk and others
- **Mostly used CVP** has 2 important subcategories:
- Robust mean of all results (**no grouping** if possible)
- Grouped results → (robust mean of group)
- Grouping according ISO 13528

Criteria for the evaluation of the results

D_{max} = maximal accepted difference of participant‘s result from assigned value

- D_{max} are periodically revised
- In case of necessity (new clinical guidelines, conclusion of Task Forces IFCC) are D_{max} revised more frequently
- 2016-year for revision/verification of D max values

How to make criteria (D_{max})?

D_{max} = bias + 2.5 * LTR

for standardized method without dividing to groups

D max = 2,5 * LTR(Grp)

for non standardized methods (results divided into to peer groups)

bias = average of its absolute value in the last 2 years
LTR = long-term (2 years) reproducibility of all results
LTR(Grp) = long-term (2 years) reproducibility in groups

How to make criteria (D_{max})? Applying requirements of IFCC working group or clinical international guidelines

Here we aim to do in near future:

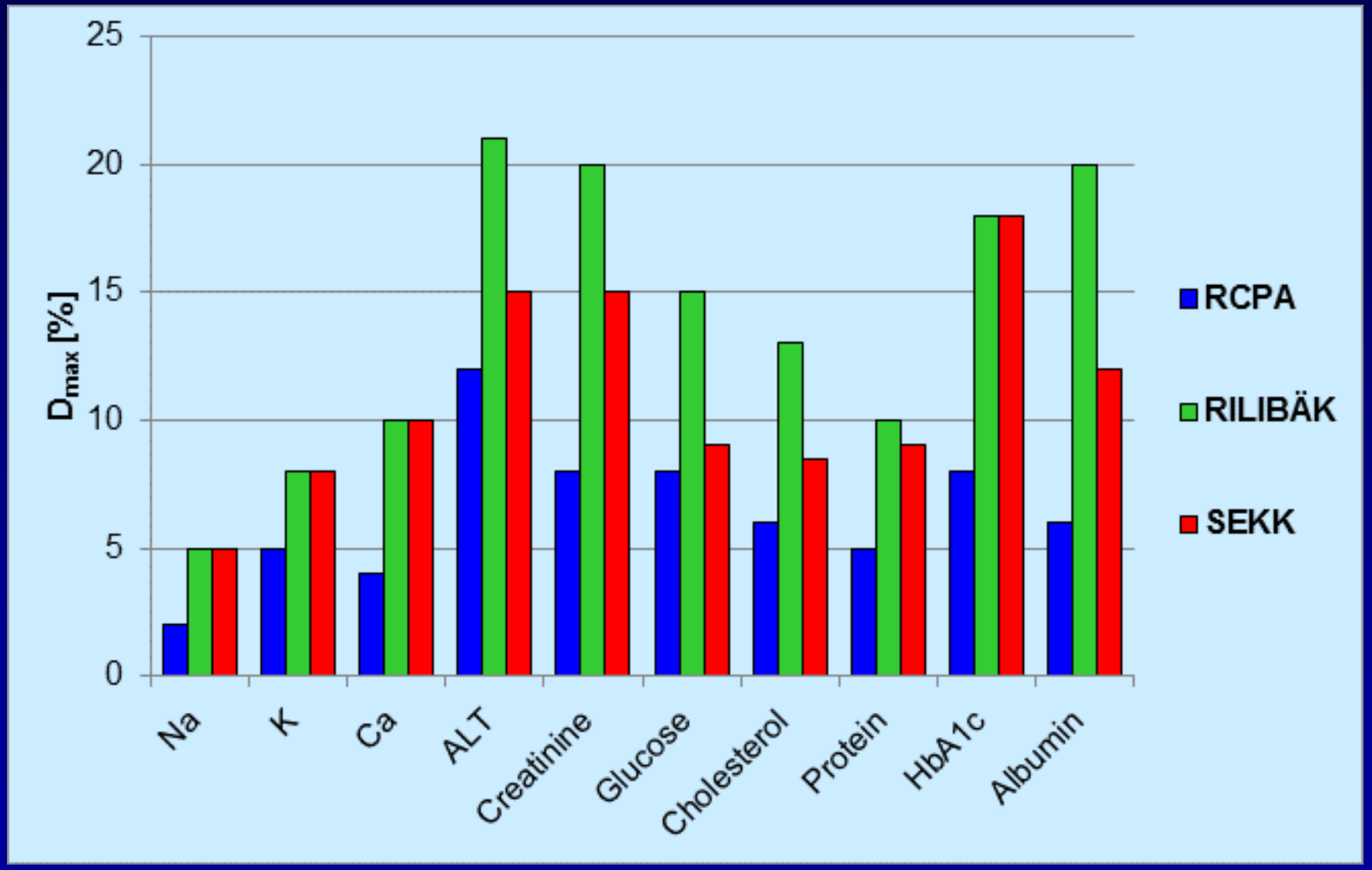
HbA_{1c}

decrease D_{max} from 18 % to 15 % and later to 10 % in harmony with „Task Force IFCC 2014´“

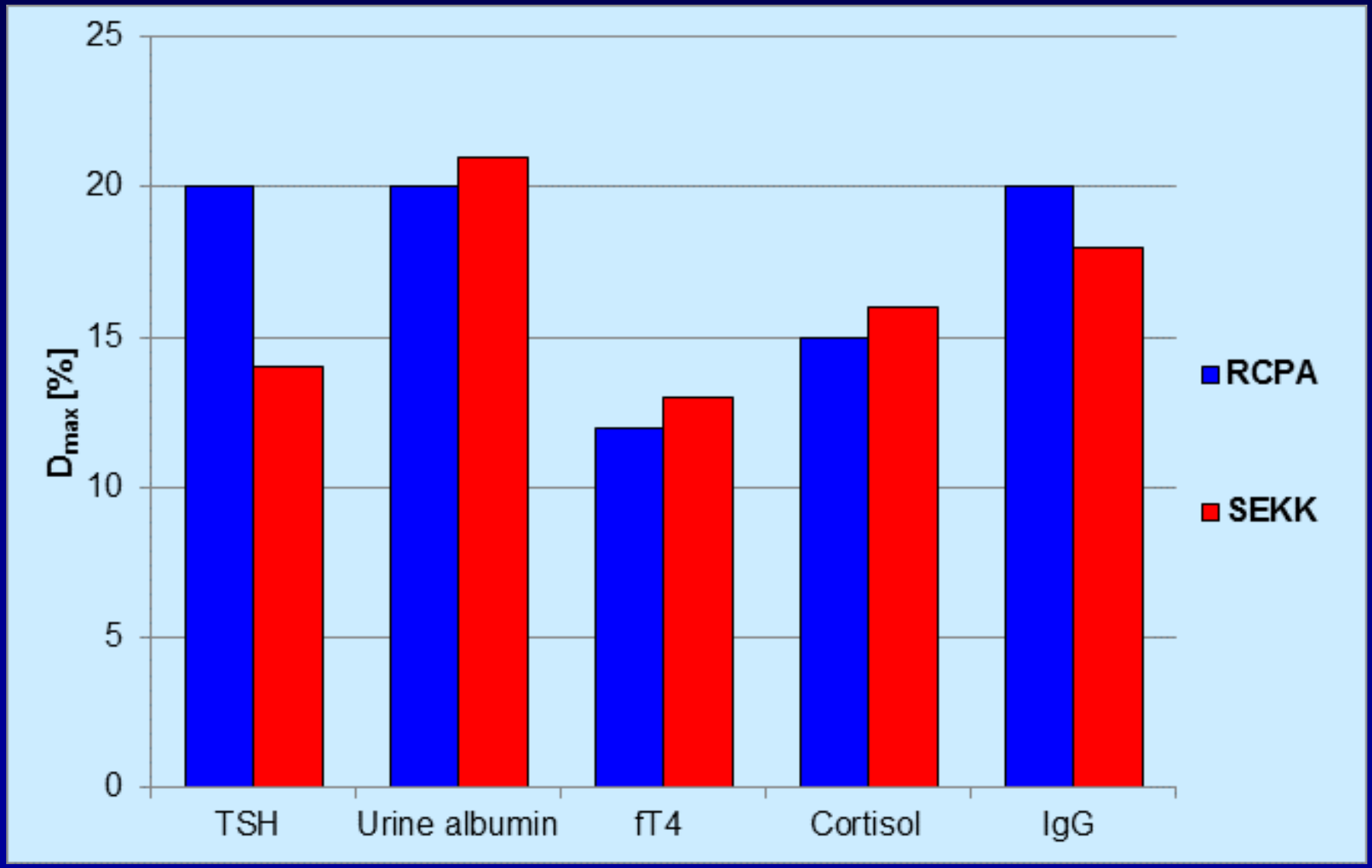
cTnI/T

apply requirement from guidelines for myocardial infarction: 20 %

Comparison of acceptable limits (D_{max}) for standardized/harmonized analytes



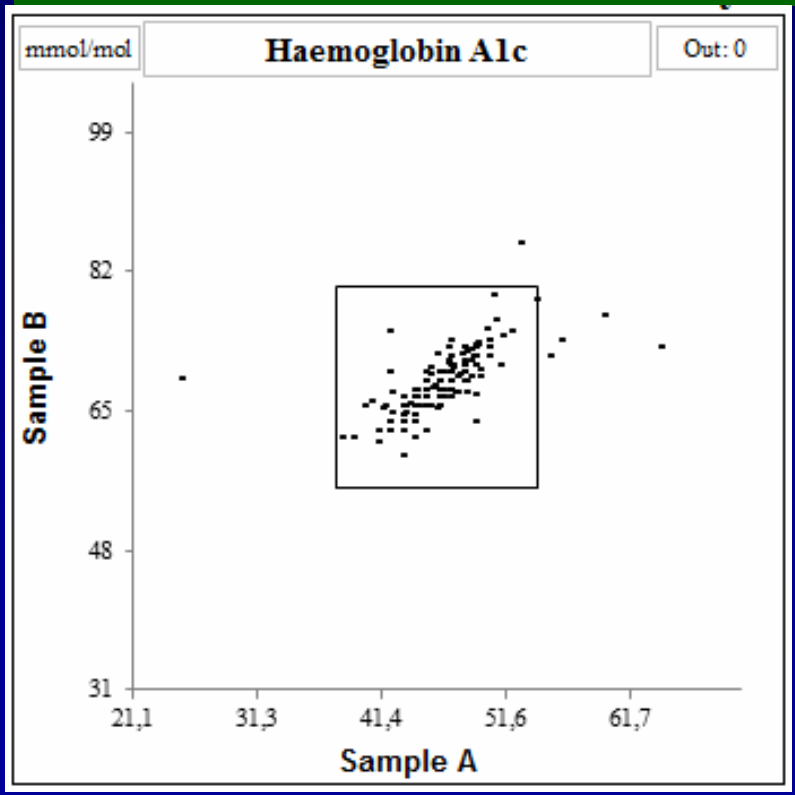
Comparison of acceptable limits (D_{max}) for some non standardized analytes



HbA_{1c} – different level of harmonization in labs and POCT

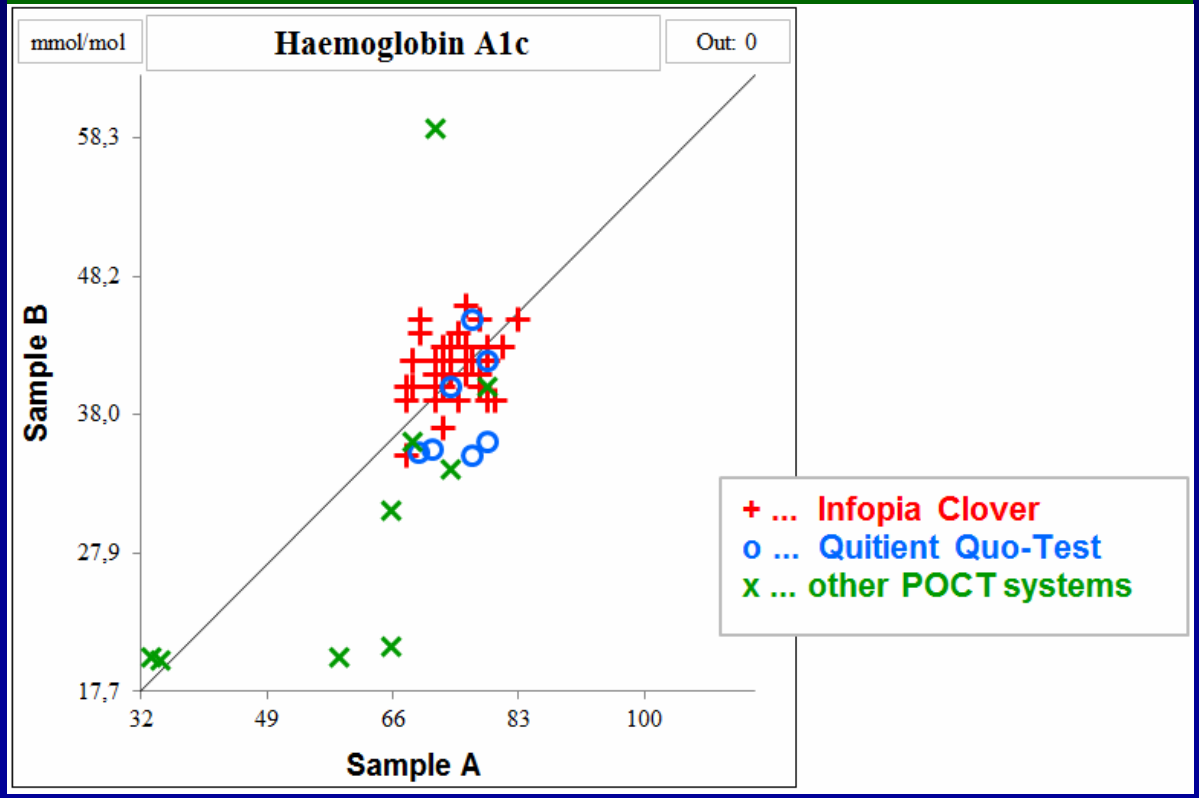
Laboratories

n = 275, no grouping
CRV from ERL
CV: 5 %
success: 98 %

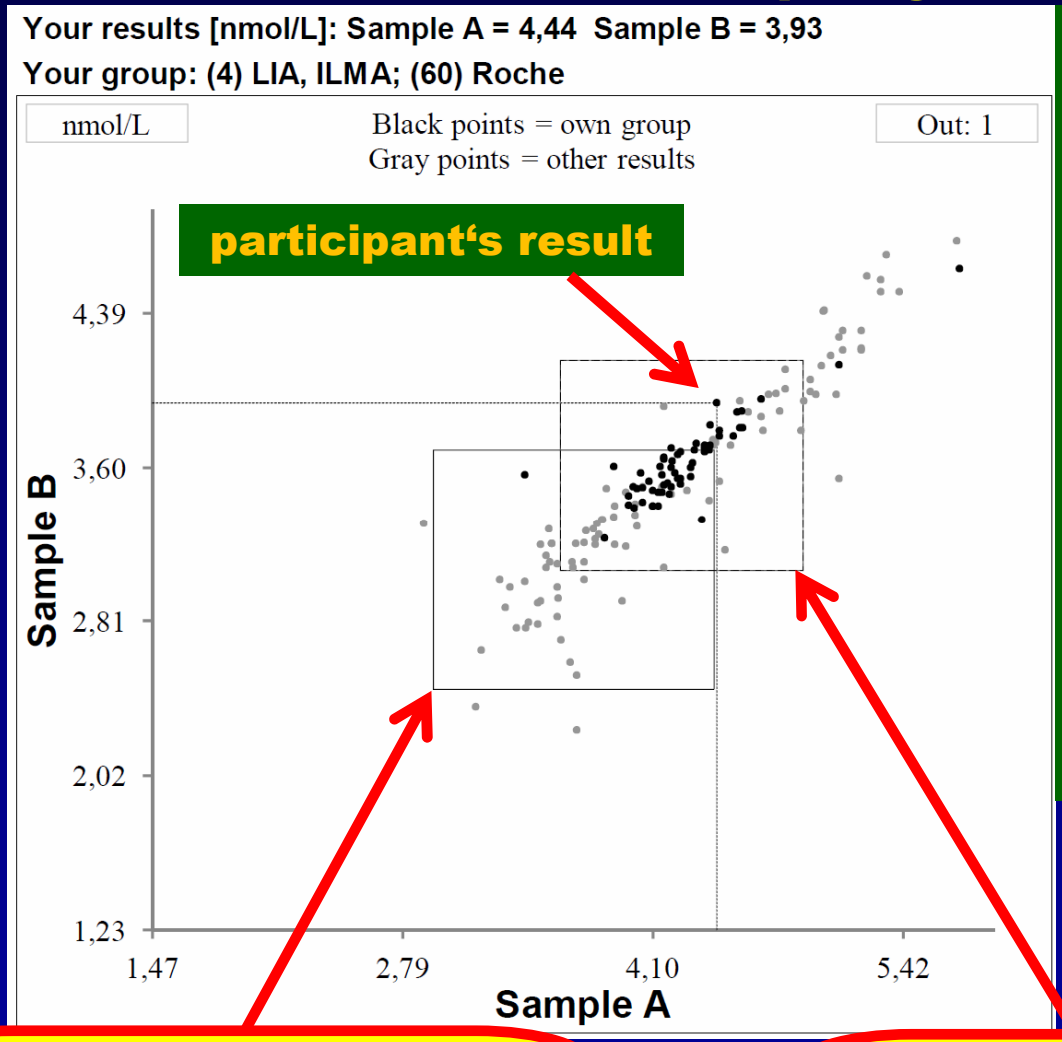


POCT

n = 56, groups based on systems
AV: robust means of groups
CV: 10 % (total), 7 % (in groups)
success: 90 – 100 % in groups



Using two different D_{max} values in endocrinology programs



Comment

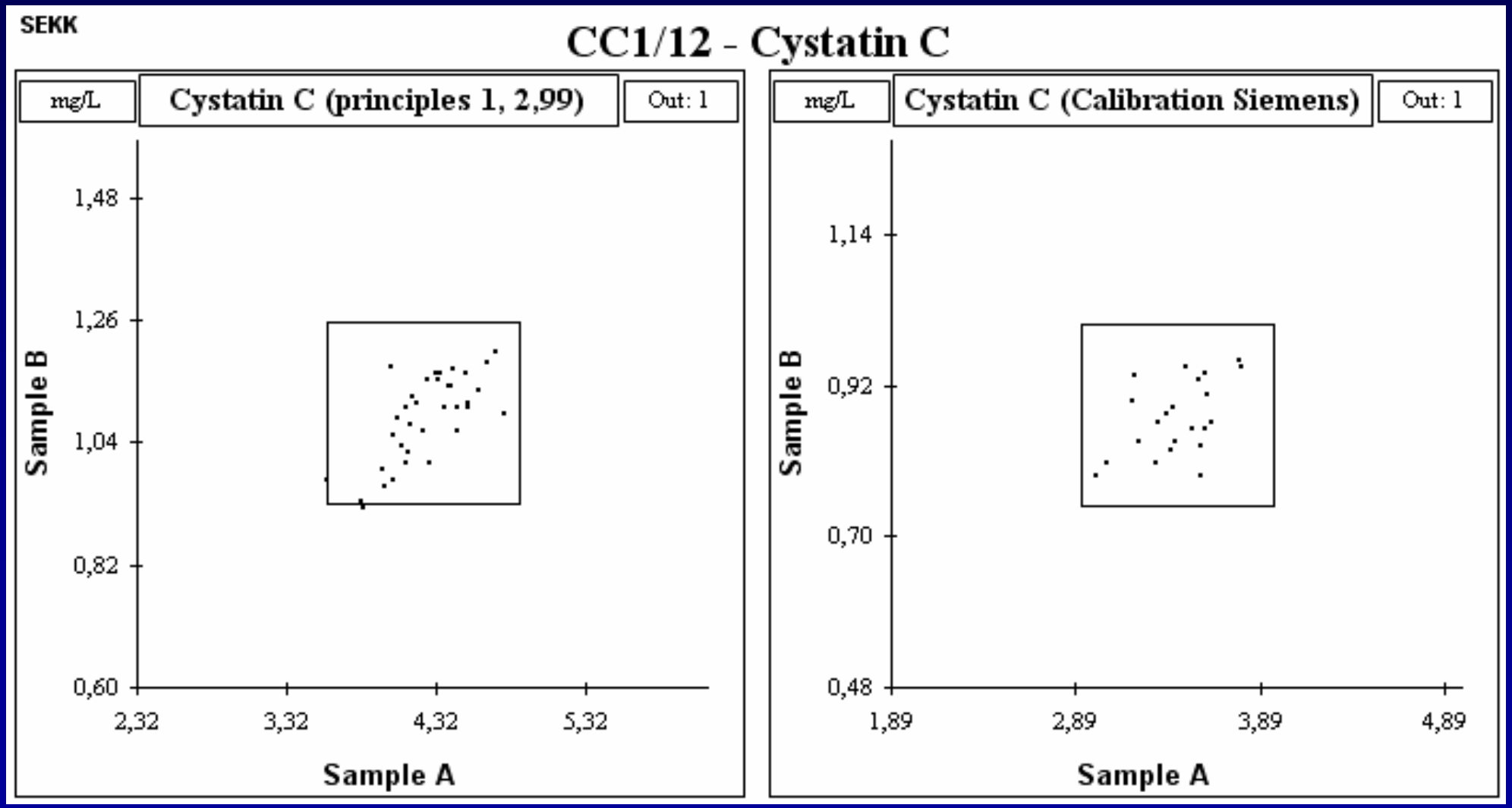
- **Analyte T3 total**
- The bias of Roche group is clearly visible.
- Participant‘s result evaluation: it is not traceable, but it is comparable to the results of its own group (Roche)
- **Conclusion: participant succeeded**

traceability criterion: AV (CRV) ± 20 %

comparability criterion: AV (group mean) ± 15 %

Cystatin C before standardisation

2012 (CC1/12) – 2 separate groups-2 different calibrations



Current state (CC2/15), calibration by ERM DA 471

One group now

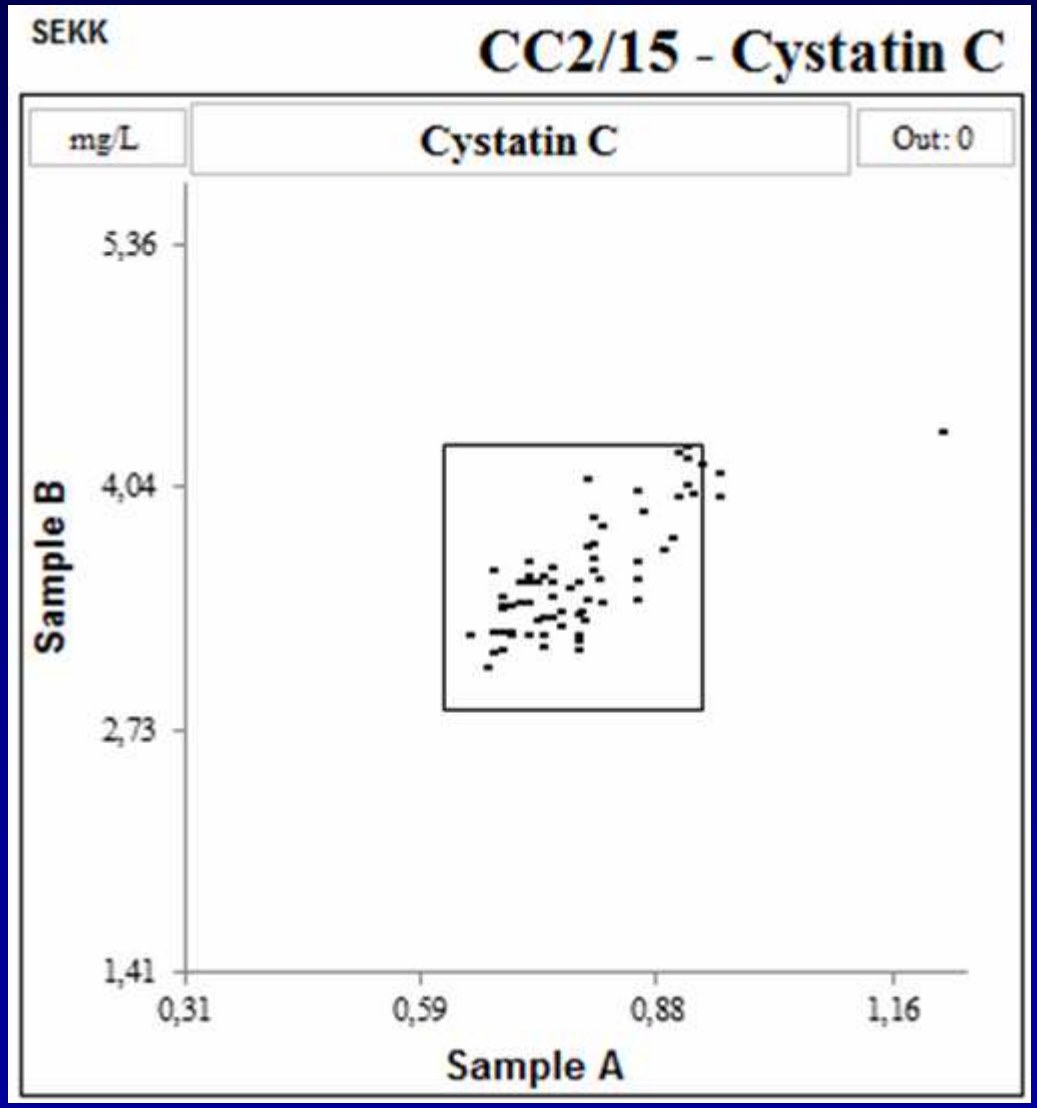
CV (2012) = 14%

CV (2015) = 10%

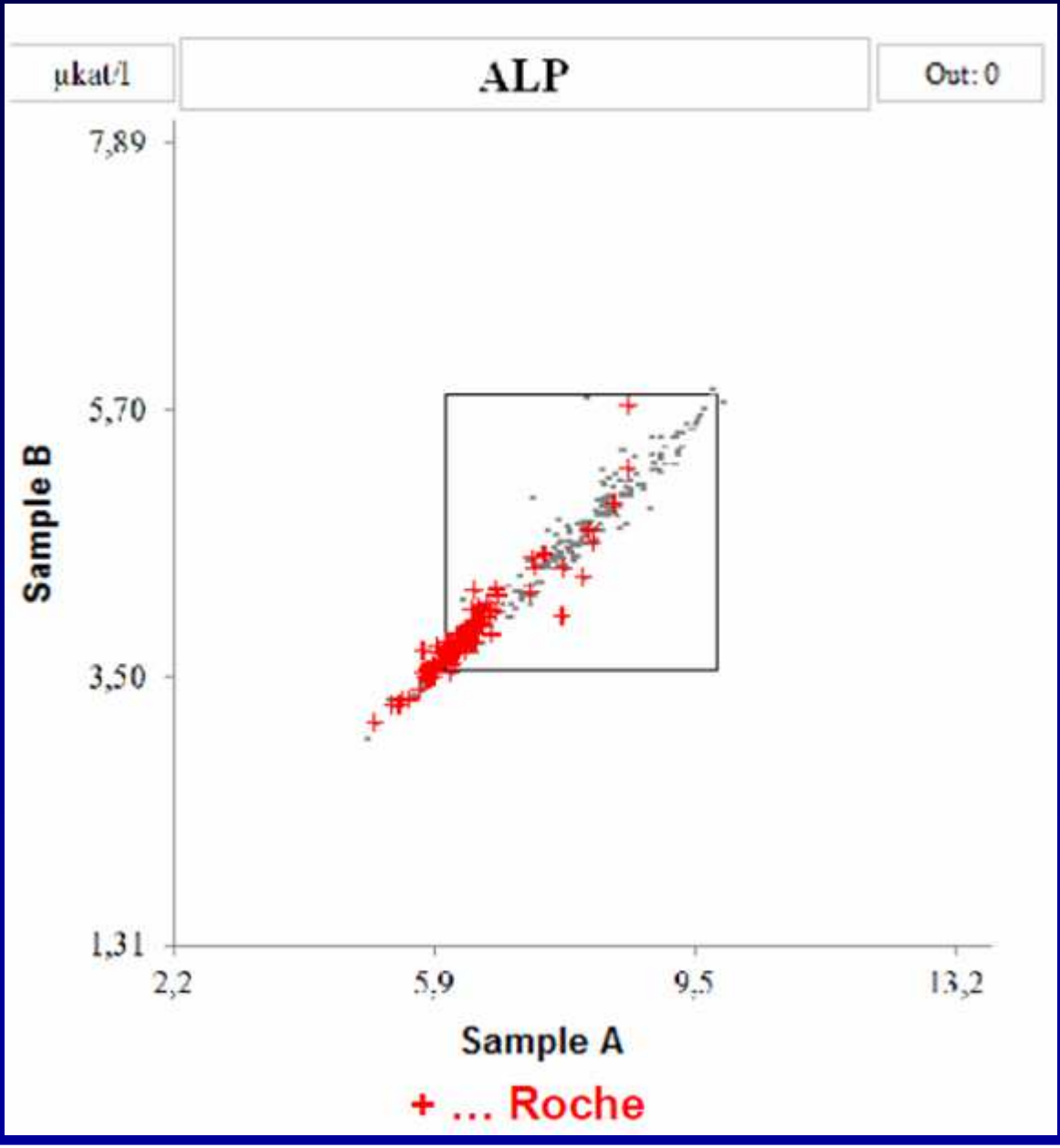
D_{max} **(2012) = 20%**

D_{max} **(2015) = 16%**

Improvement after standardization, but process is not finnished



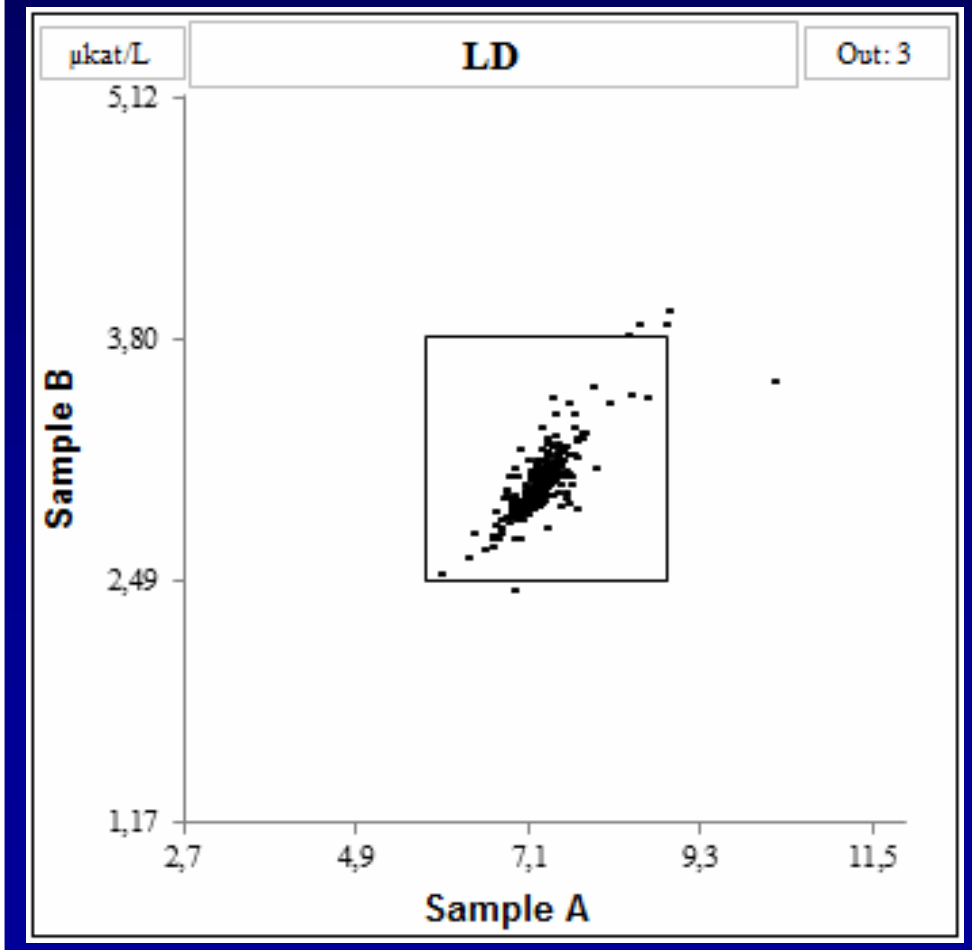
ALP standardisation (AKS4/15)



- CRV measured in RfB Bonn
- Only one group of non-harmonised results (1 producer)

LD standardisation

SEKK: strict standardisation, see Youden plot bellow (AKS4/15)



Compare to:

- LD evaluation in Empower 2014 Master Comparison (here difference LD IFCC vs LD pyruvate = 210%
- RIQAS 2012: only 21% of methods bound to the IFCC principle

What is the influence of the sample matrix to the bias value in standardized measurements?

We inspected the biases of peer groups based on the manufacturer of kit in the data of:

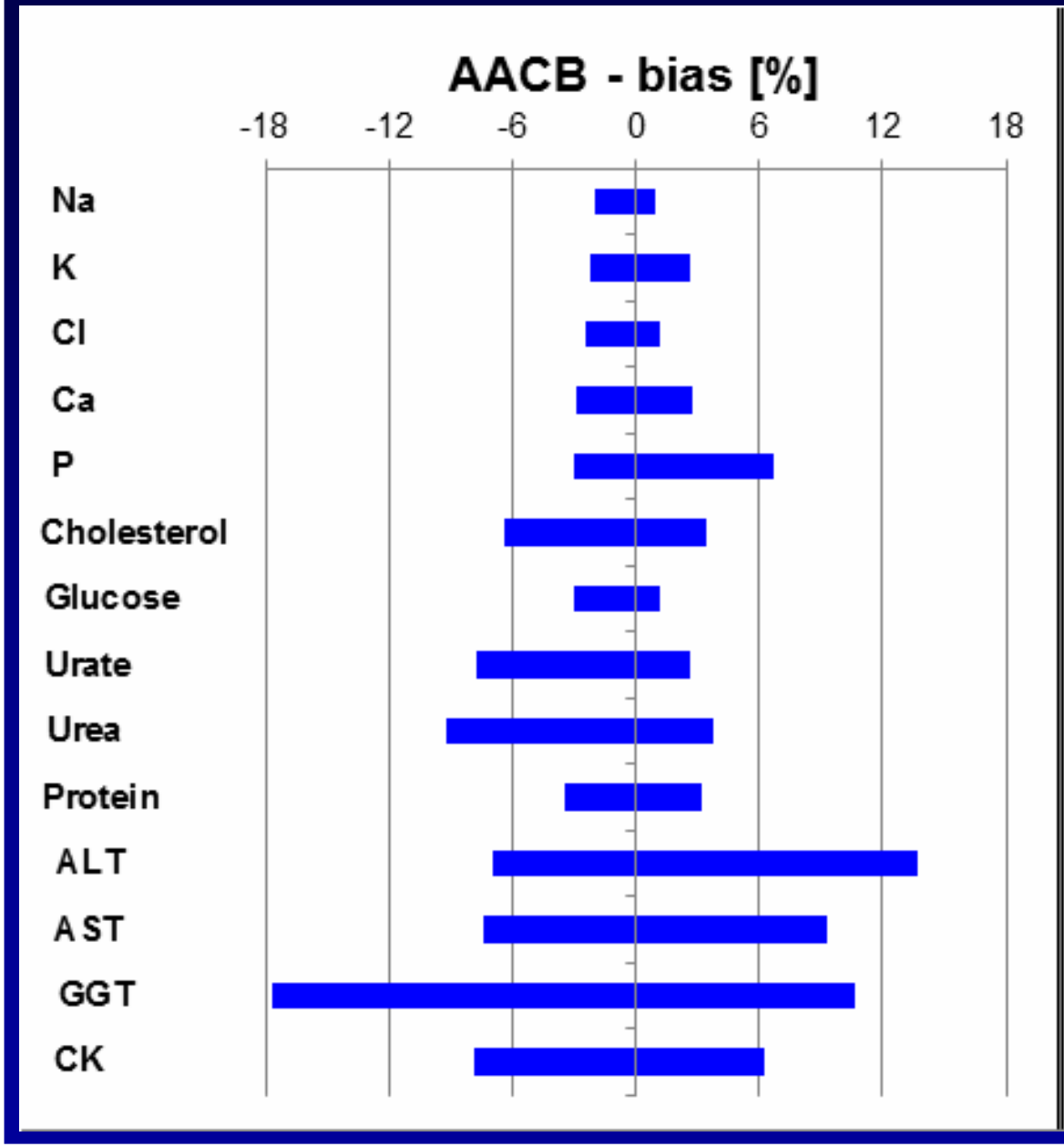
1.AACB - commutable native samples (Clin Biochem Rev 2014), certified values

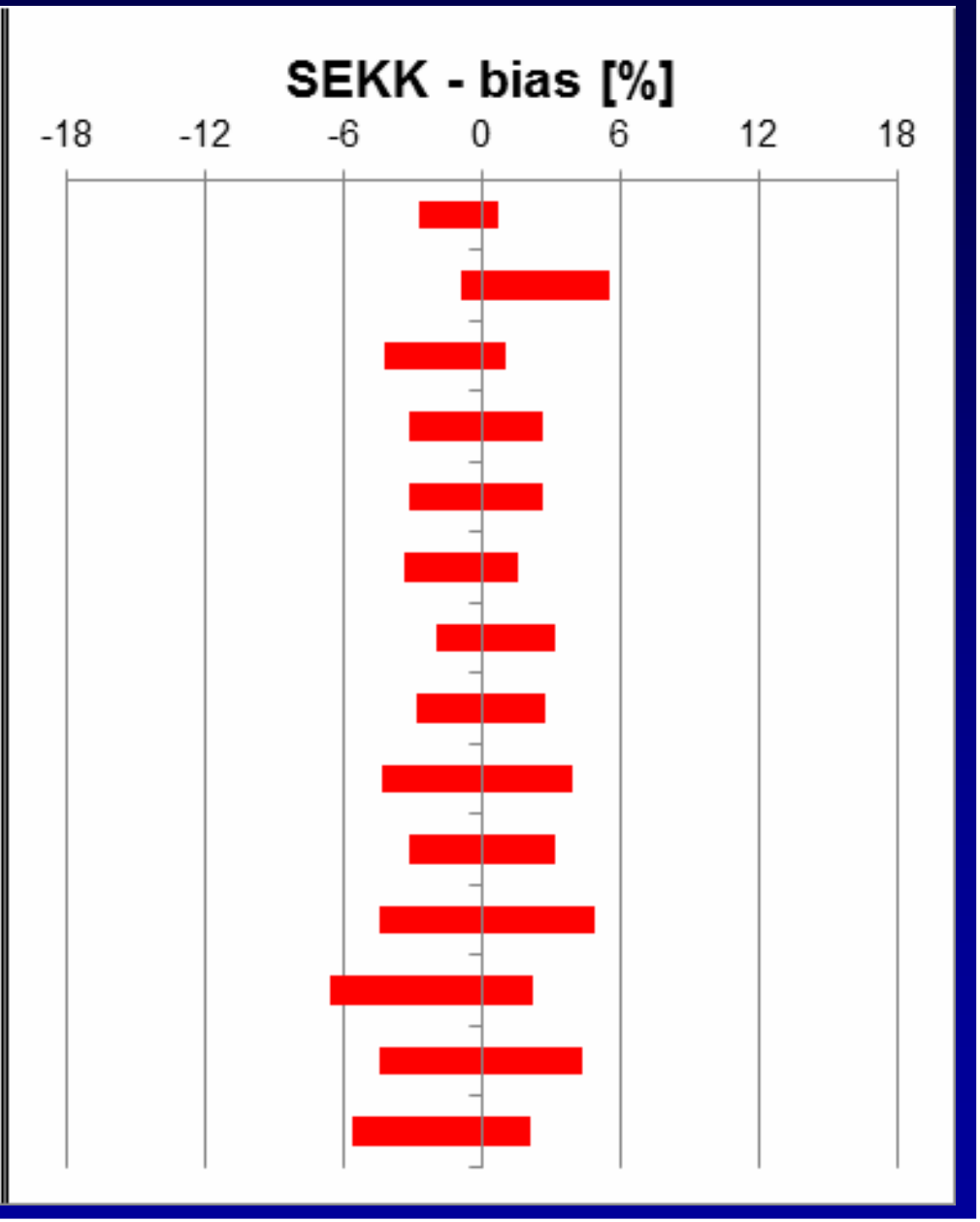
2.SEKK - tailor made lyophilized samples, certified values (RfB Bonn)

Control material well selected

(RMP – Mean) ≤ U_{ref} (ideall statement)

Ranges (min/max) biases in peer groups





Uncertainties of the results: basic concepts

- **Voluntary** part of our EQAS
- **No influence** to the participant‘s performance
- Participants report **relative combined expanded uncertainties (U_c)**
- **Calculation of U_c** according to: *Recommendations for calculating the uncertainty of quantitative measurement results in clinical laboratories* and by web calculator
- **Arrangement:** in selected routine programmes, not in POCT programmes

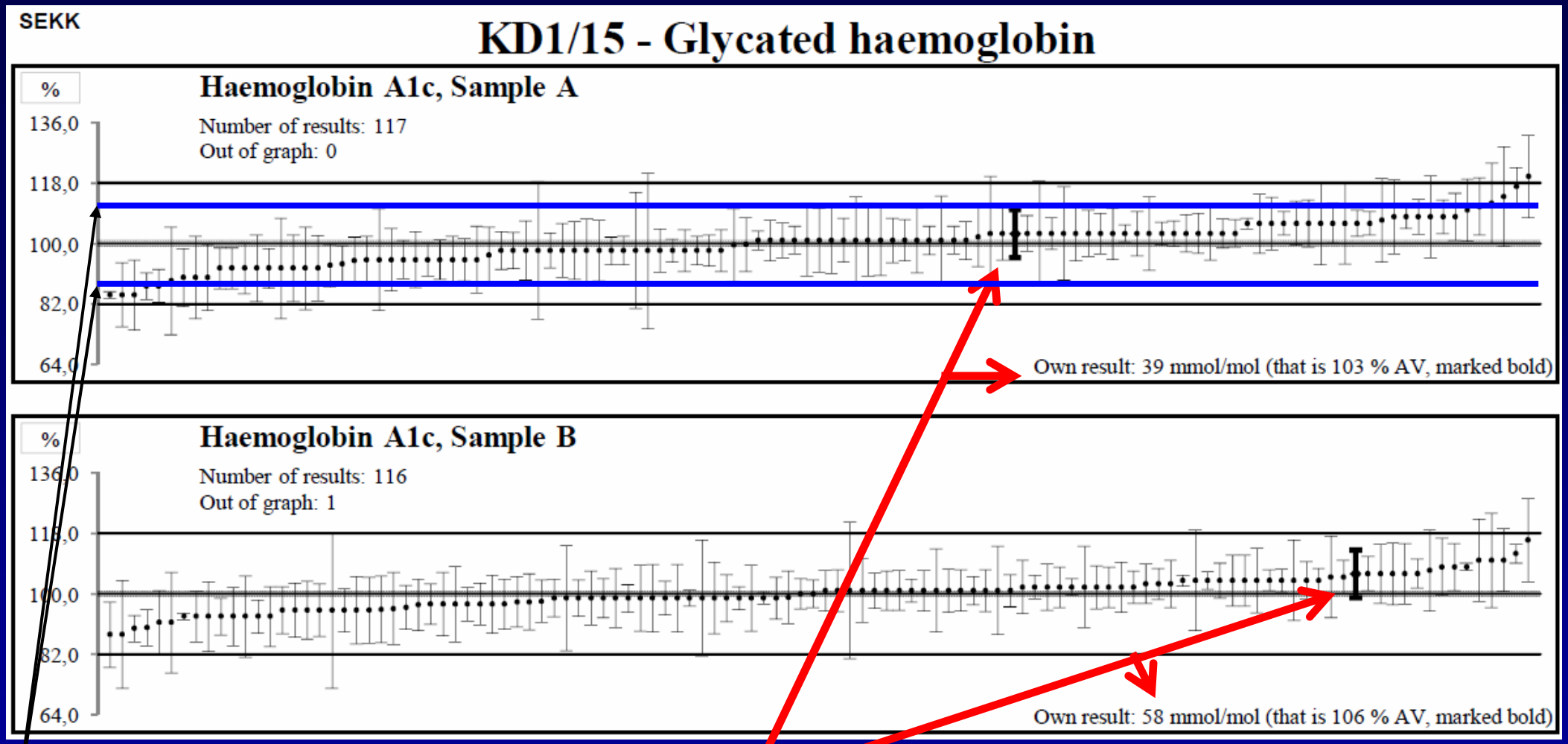
Calculation of uncertainties of the results

Top-bottom approaches

Partial uncertainties

- Repeatability
- Intermediate precision (IQC)
- Uncertainty of bias (EQA)
- Uncertainty of reference (asigned) values (certificate)

Uncertainties – output graph example



Results of the individual participant(46%)

10%

Unit: always %, means „% of AV“ (AV = 100 %)

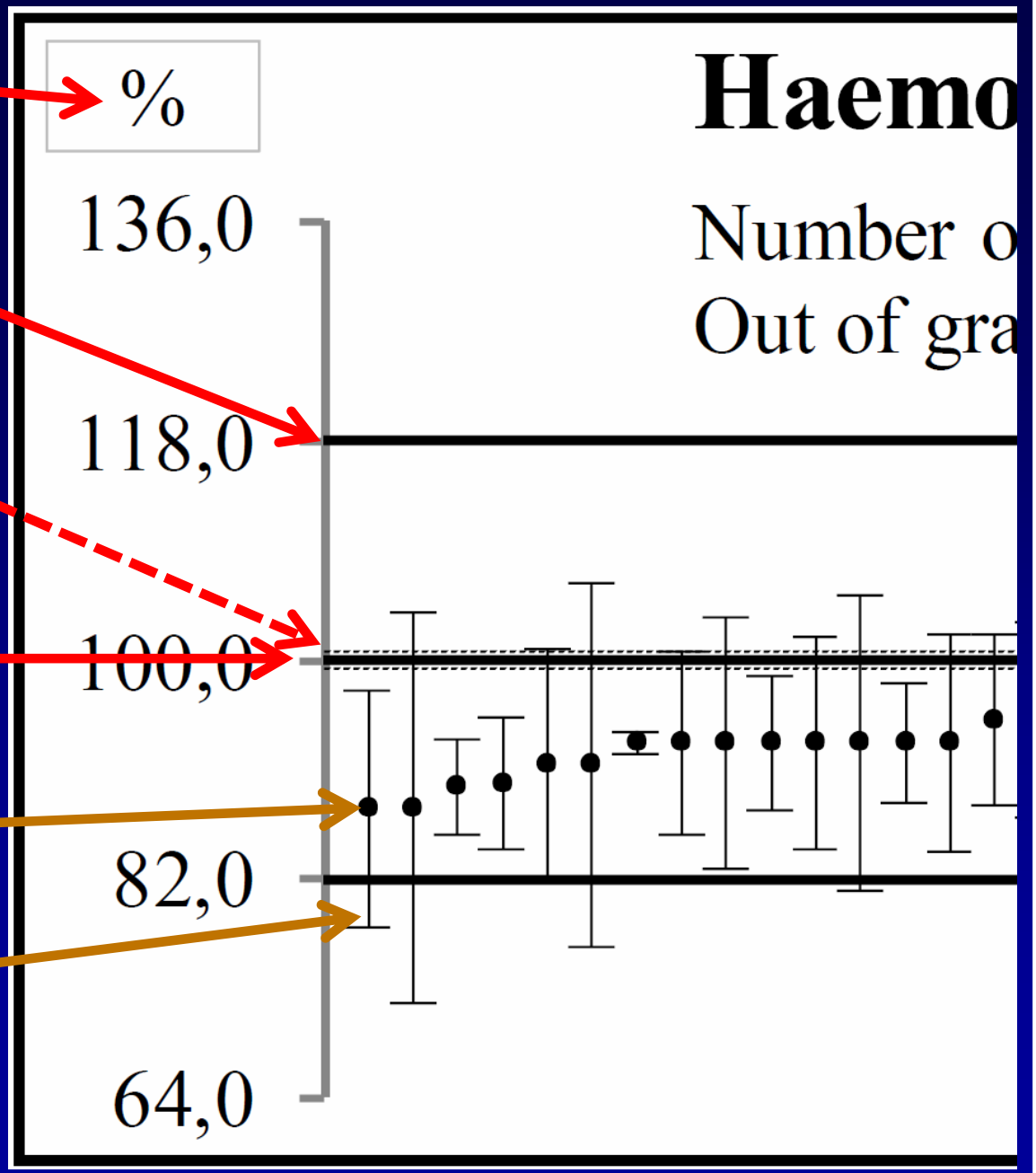
Straight line: criterion (D_{max} here ±18 %)

Dotted line: expanded uncertainty of AV ($U_{c,AV}$)

Straight line: AV (= 100 %)

Participant‘s result

Expanded uncertainty ($\pm U_c$) of participant‘s result



Thank you!