SKML performance goals

Reporting and scoring
With scope on improvement

Dr. Marc Thelen

About me

- Marc Thelen, Born 1967
- European Specialist in Laboratory Medicine, Clinical Chemist
- Medical Manager Laboratory for Clinical Chemistry
  Amphia ziekenhuis, Breda, the Netherlands
- Director of SKML, Dutch Eqas Organisation
- NVKC quality committee, since 2003
- Chaired transition from CCKL to ISO15189 in the Netherlands
- Chair of IVD committee NEN, Dutch standard organisation
- Participant member of ISO TC212 WG1
- Member of EFLM QC WG IVD
- Corr. Member of EFLM QC WG accreditation

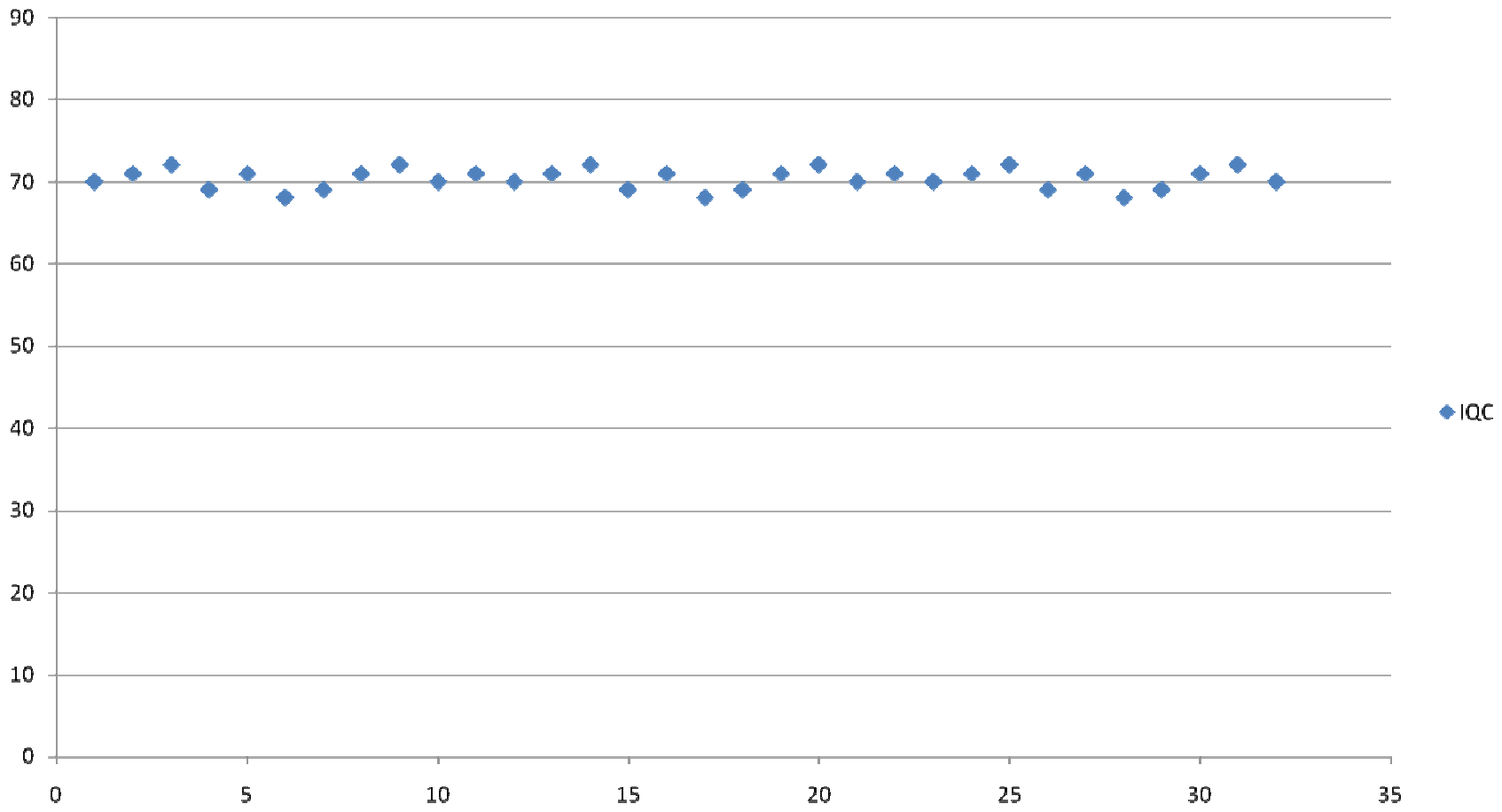
Meaning of Life of an EQAS organiser

- Client perspective
- What are EQAS organisers needed for?
- ISO 15189 accredited labs need:
  - 4.12 continuous improvement
  - 5.3.1.4 metrological traceability, ISO17511
  - 5.5.1. selection, validation and verification of methods
  - 5.5.1.4 measurement uncertainty
  - 5.6.3 interlaboratory comparison including corrective action

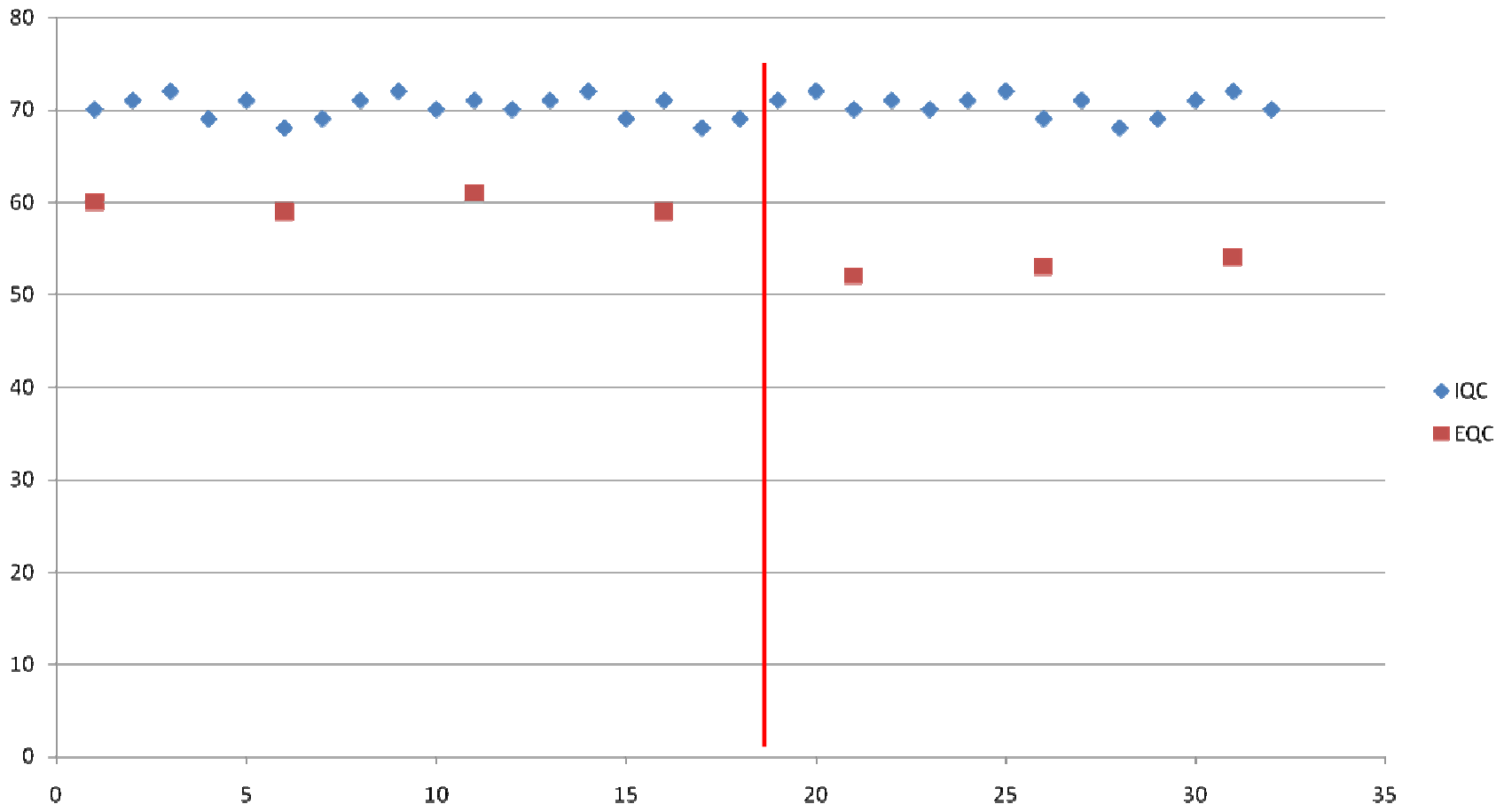
Risk management of accuracy

1. Method validation, verification
   - T=0
     trueness and imprecision are fit for intended use
2. Internal QC
   - Conditions as on T=0 are still true
3. External QC
   - What can be wrong?

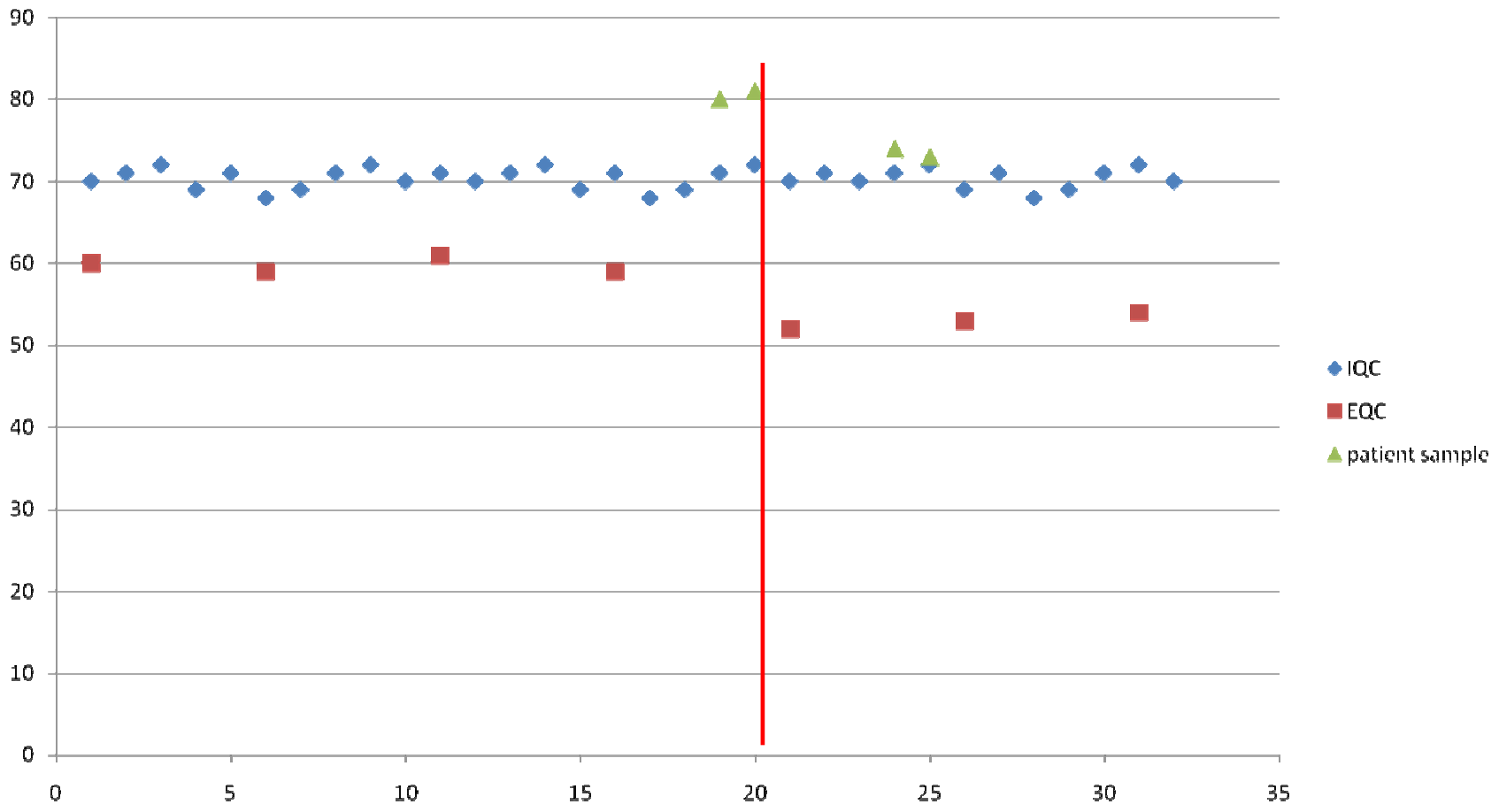
Risk of new bias, with stable IQC



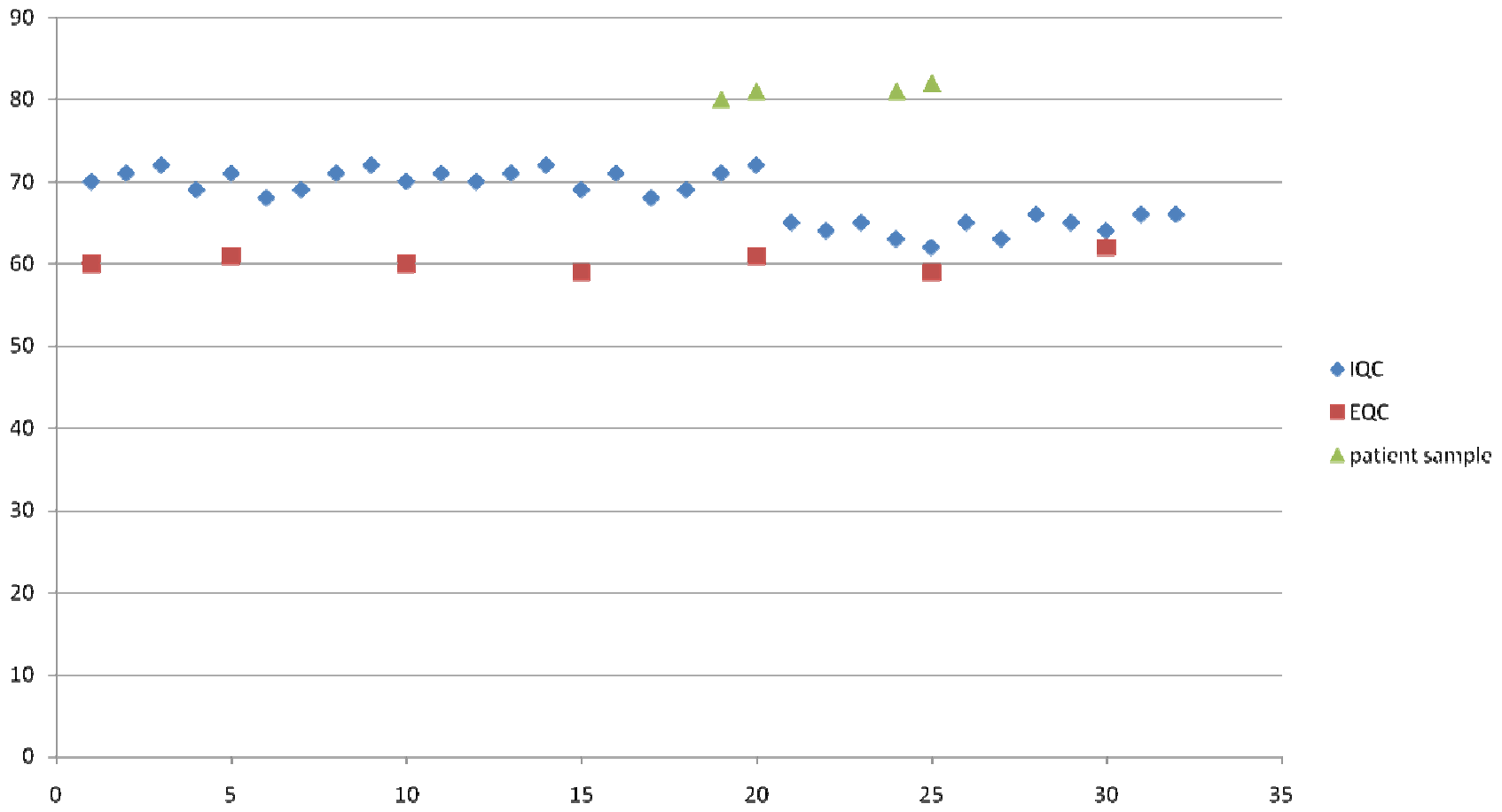
Risk of new bias, with stable IQC



Risk of new bias, with stable IQC



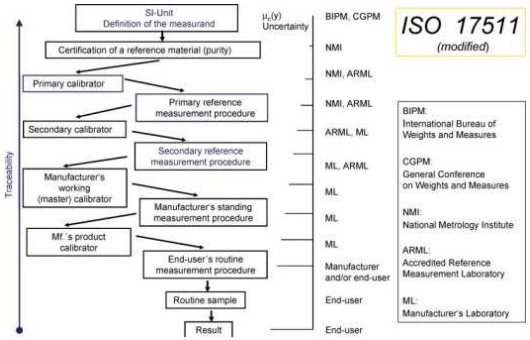
False alarm


90
80
70
60
50
40
30
20
10
0
0
5
10
15
20
25
30
35
IQC
EQC
patient sample

Goals for perfect EQAS

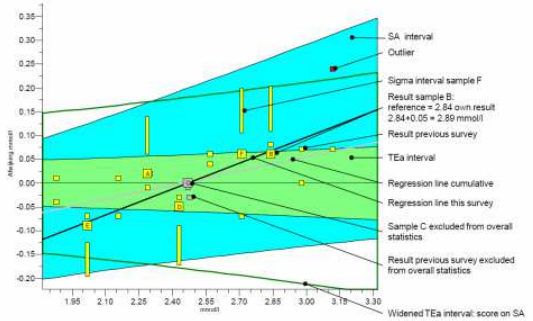
- Goals:
  - Verification of trueness and imprecision
  - Verification of harmonisation
- Materials as intended by ISO17043: Commutable, homogenous, stable
  - Material cannot be blamed
- Value assignment in reference labs using reference methods
  - Value assignment cannot be blamed
- Smart reporting
  - Participant knows what to do

SMART scoring of EQAS



- Specific:
  - Performance of lab, not of EQAS material
  - material and assigned values beyond discussion
  - Support root cause analysis: method grouping
- Measurable:
  - mathematical relation between statistical dispersion of results and score
- Achievable:
  - if SA precision profile>Tea, then score in SA precision profile
- Realistic:
  - Tea based on EFLM performance goal criteria
    - Biological variation. Medical useful: relation to useable quality in RCV
    - Clinical outcome, when possible; troponin-T
- Time dependent:
  - Multiple time point evaluation:
    - Short term
    - Long term

SKML MUSE: multiple sample evaluation

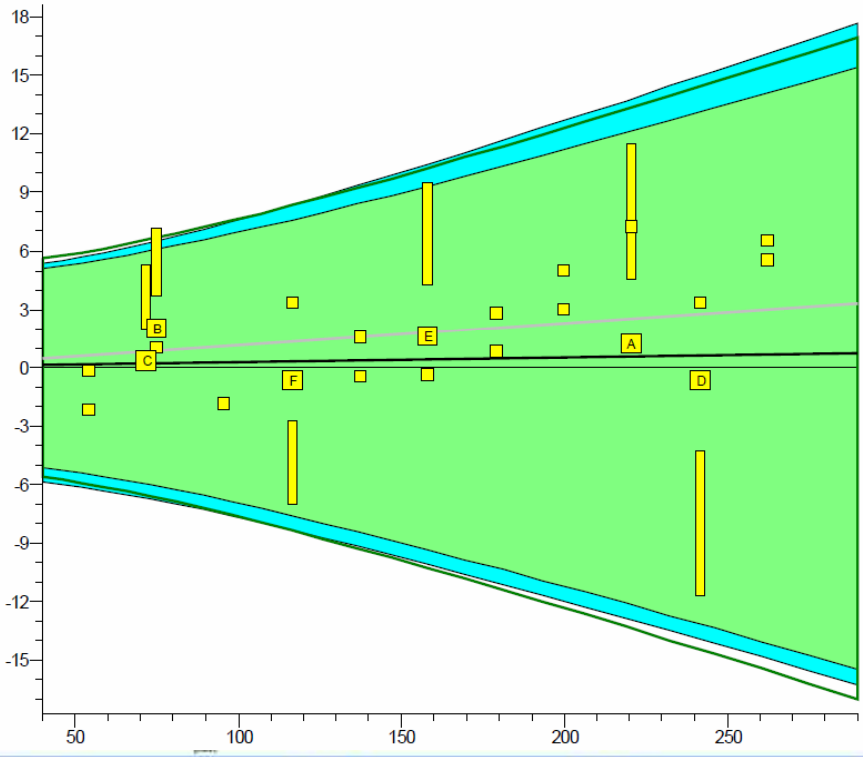


In the difference plot 2 regression lines are shown. These are time-weighted and calculated from the results achieved in this survey (black line) and cumulative (grey line). The regression lines are calculated after removal of outliers; the within-lab scatter is calculated as the residual scatter of the results around these regression lines.

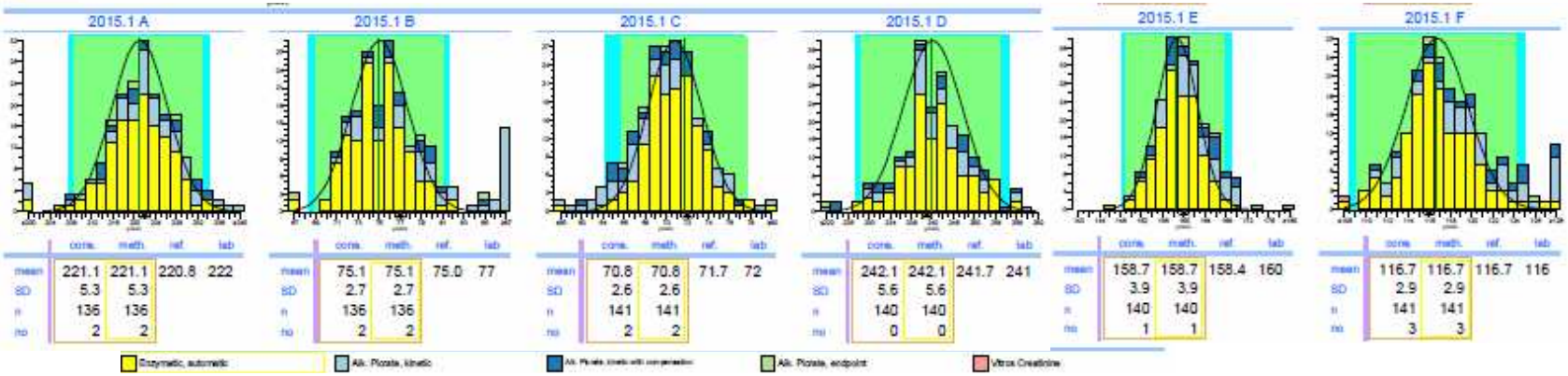
Example SKML MUSE report

Creatinine

units: µmol/L



	2015.1	cumulative
Trueness	+0.38%	+0.94%
Precision	0.90%	1.4%
Number	6	24
Outliers	0	0
Sigma-TE	4.6	4.2
Sigma-SA	5.0 2	4.6 2
Score pictogram		
Regression line	0.0 + 1.003.x	0.0 + 1.011.x
Consensus group	Enzymatische kreatinine	
Method	Enzymatic, automatic	
Analyser	Roche Cobas 6000	
Uw factor	0 + 1.000.x	
Methode factor	-1 + 1.001.x	

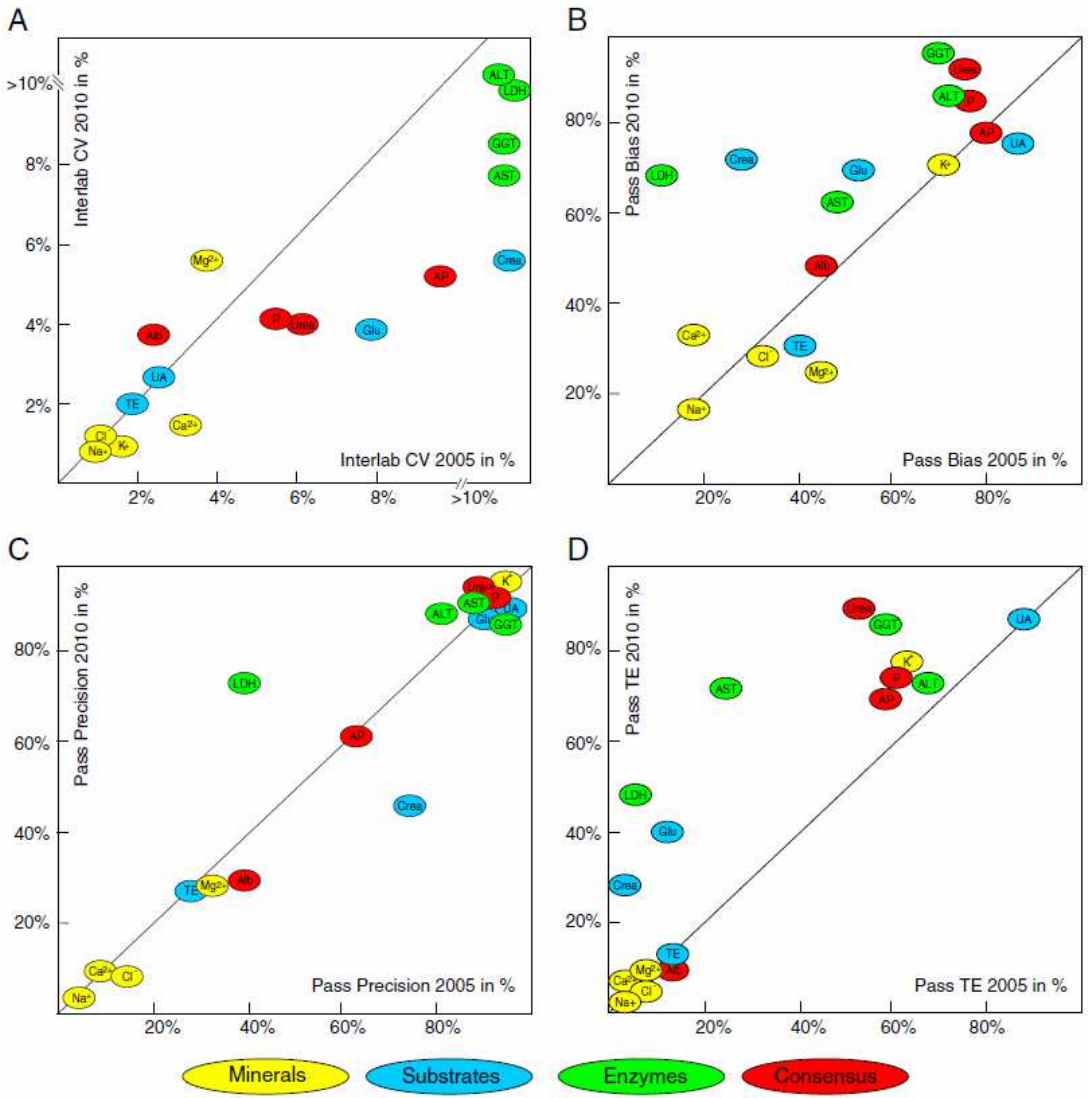


The three pillars of SKML

- Commutable materials
- Value assignment in reference labs
- PDCA facilitating reports

First successes: 2005-2010

C. Cobbaert et al. / Clinica Chimica Acta 414 (2012) 234–240



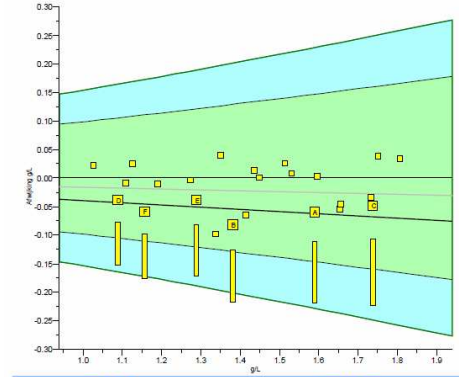
Example in protein chemistry

Trueness by consensus

Participant X

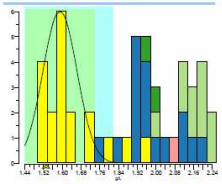
Combi Immunochemie 2014.1

α1-Antitrypsine — eenheid : g/L



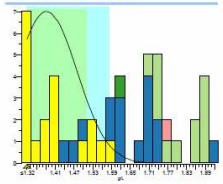
	2014.1	cumulatief
Juistheid	-4.0%	-1.6%
Precisie	1.2%	2.8%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	2.6	3.2
Sigma-SA	4.4	5.0
Score pictogram		
Regressielijn	0.00 + 0.961 x	0.00 + 0.984 x
Consensusgroep	Roche	
Methode	Roche (turb)	
Analyser	Roche Modular	

2014.1 A



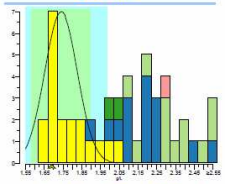
	cons.	meth.	ALTM	lab
gem.	1.59	1.59	1.89	1.53
SD	0.07	0.07	0.28	
n	19	19	48	
nu	2	2	0	

2014.1 B



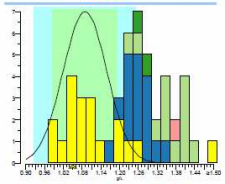
	cons.	meth.	ALTM	lab
gem.	1.38	1.38	1.60	1.30
SD	0.10	0.10	0.23	
n	19	19	49	
nu	0	0	0	

2014.1 C



	cons.	meth.	ALTM	lab
gem.	1.74	1.74	2.07	1.69
SD	0.09	0.09	0.31	
n	19	19	49	
nu	2	2	0	

2014.1 D

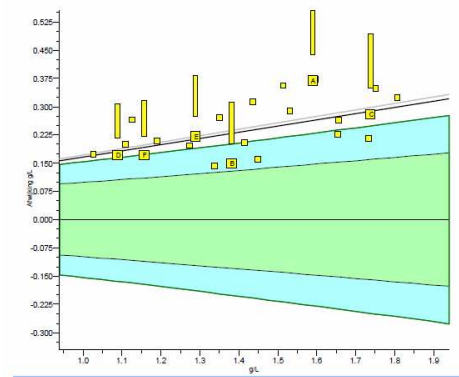


	cons.	meth.	ALTM	lab
gem.	1.09	1.09	1.24	1.05
SD	0.07	0.07	0.14	
n	19	19	50	
nu	1	1	0	

Participant Y

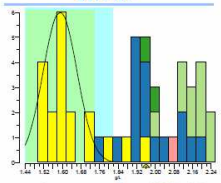
Combi Immunochemie 2014.1

α1-Antitrypsine — eenheid : g/L



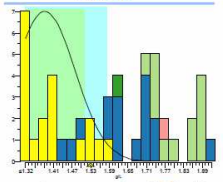
	2014.1	cumulatief
Juistheid	+16%	+17%
Precisie	4.2%	4.0%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	-1.4	-1.7
Sigma-SA	0.2	-0.1
Score pictogram		
Regressielijn	0.00 + 1.166 x	0.00 + 1.171 x
Consensusgroep	Roche	
Methode	Roche (turb)	
Analyser	Roche Cobas 6000	

2014.1 A



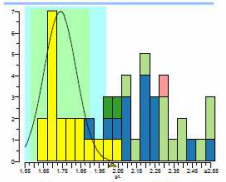
	cons.	meth.	ALTM	lab
gem.	1.59	1.59	1.89	1.96
SD	0.07	0.07	0.28	
n	19	19	48	
nu	2	2	0	

2014.1 B



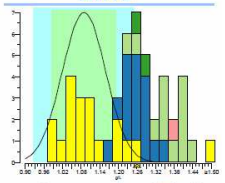
	cons.	meth.	ALTM	lab
gem.	1.38	1.38	1.60	1.53
SD	0.10	0.10	0.23	
n	19	19	49	
nu	0	0	0	

2014.1 C



	cons.	meth.	ALTM	lab
gem.	1.74	1.74	2.07	2.02
SD	0.09	0.09	0.31	
n	19	19	49	
nu	2	2	0	

2014.1 D



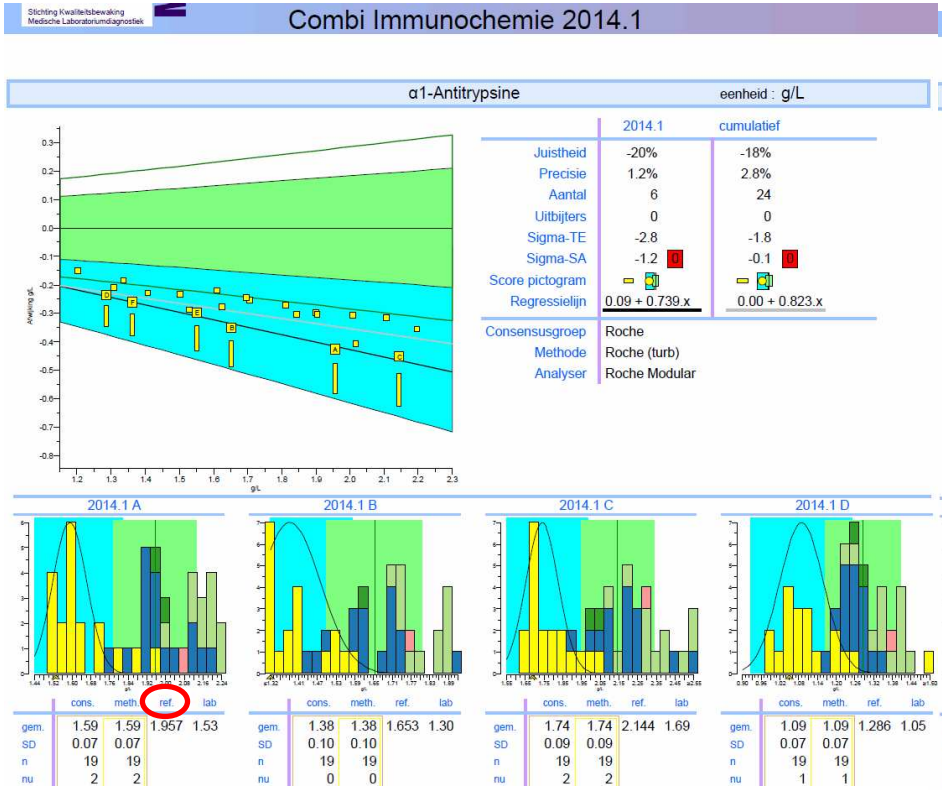
	cons.	meth.	ALTM	lab
gem.	1.09	1.09	1.24	1.26
SD	0.07	0.07	0.14	
n	19	19	50	
nu	1	1	0	

Difference between labs and methods reflects difference in patients

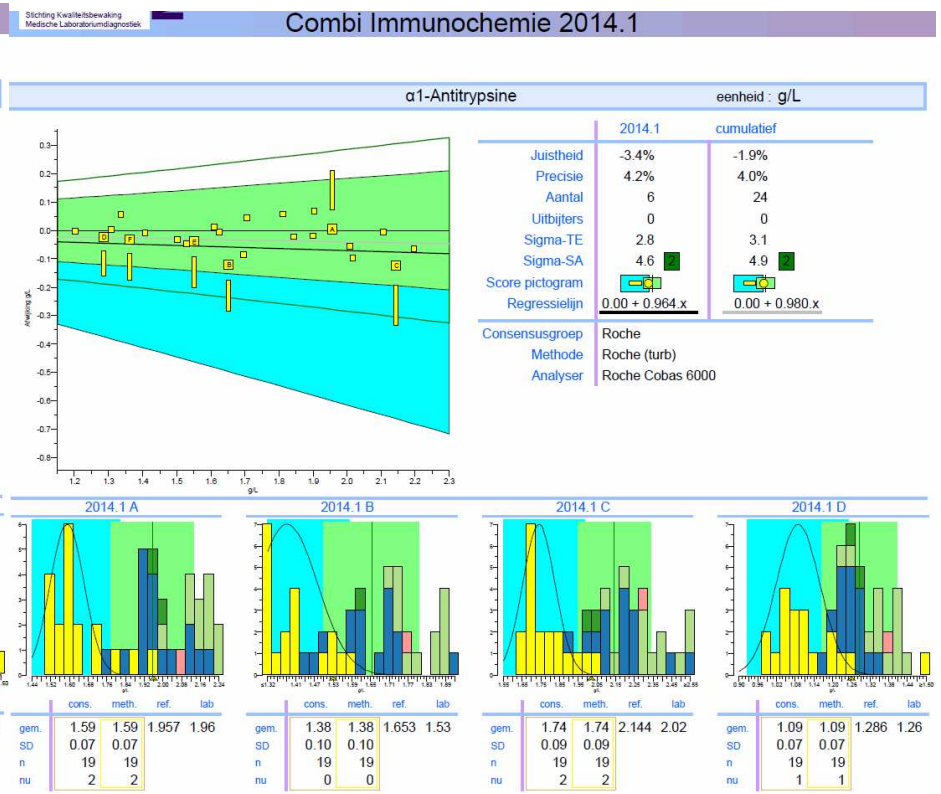
Value assignment in reference method

Trueness by reference method

Participant X



Participant Y



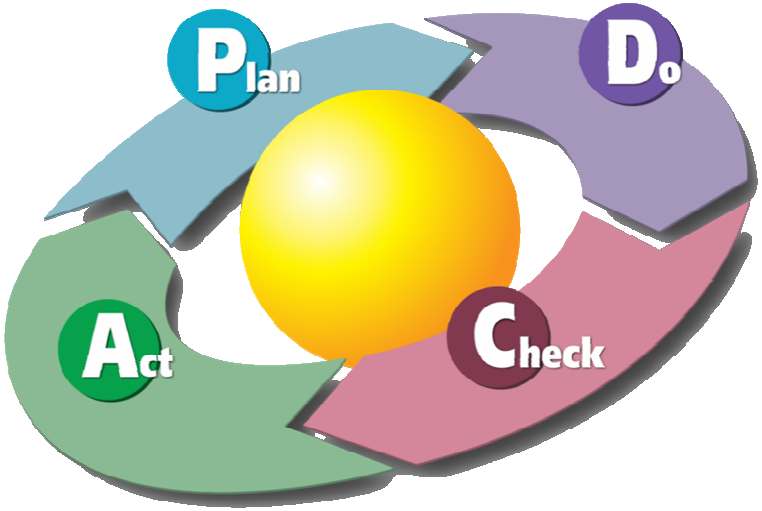
Who is right?

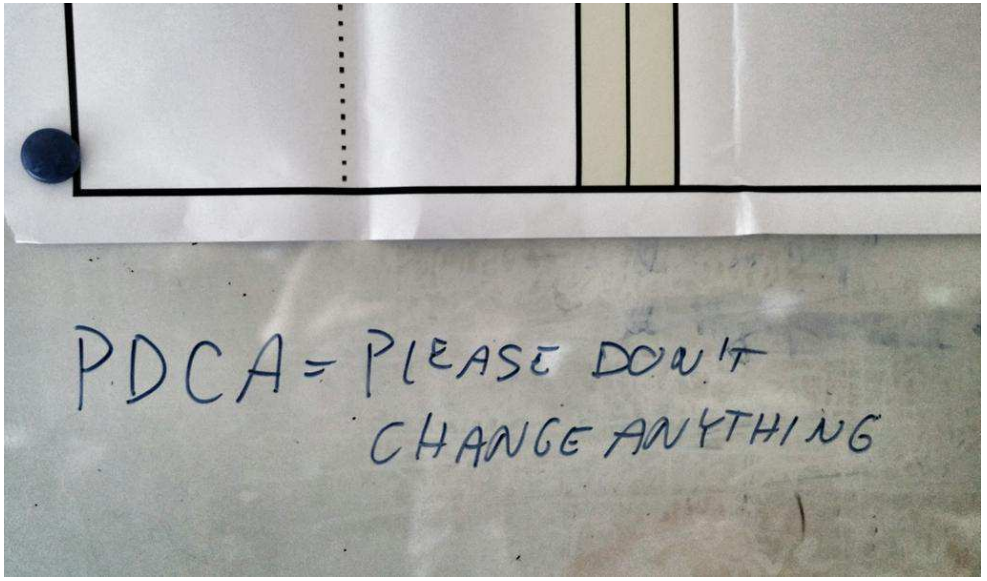
SKML successes so far

- 5-10 years experience in general chemistry with
  - Commutable materials
  - Value assignment in reference labs

  Has resulted in:
  - Improved between lab cv: harmonisation
  - Improved trueness: standardisation
- 2014 introduction of multi-sample score MUSE
- 2015 introduction of value assignment in protein chemistry

Room for improvement?





Amphia Ziekenhuis