

The role of EQA in the monitoring of metrological traceability in laboratory medicine



Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

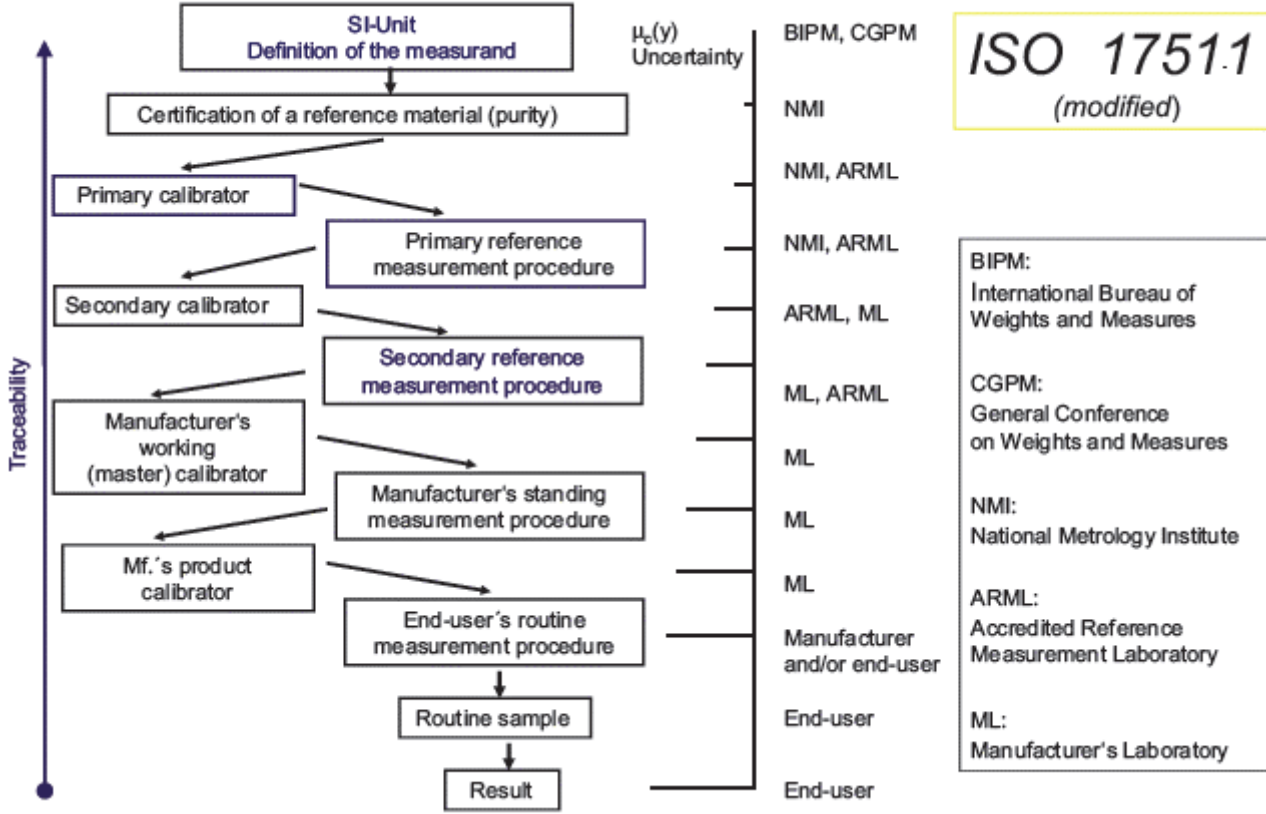
Prof Marc Thelen, PhD

About Marc Thelen



- Born in 1967
- European Specialist in Laboratory Medicine, Clinical Chemist Amphia hospital, Breda, the Netherlands
- Director of SKML, Dutch EQA Organisation for Lab. Medicine
- Professor by special appointment quality in medical laboratory care, Radboud University, Nijmegen, the Netherlands
- Chair of IVD committee NEN, Dutch standard organisation
- Member of ISO TC212 WG1 and WG2
- Member of drafting team of ISO15189 revision 2019-2022
- Member of EFLM QC WGs Accreditation and IVD
- Member of EFLM TFG “Performance specifications for EQAS”

ISO 17511 on metrological traceability



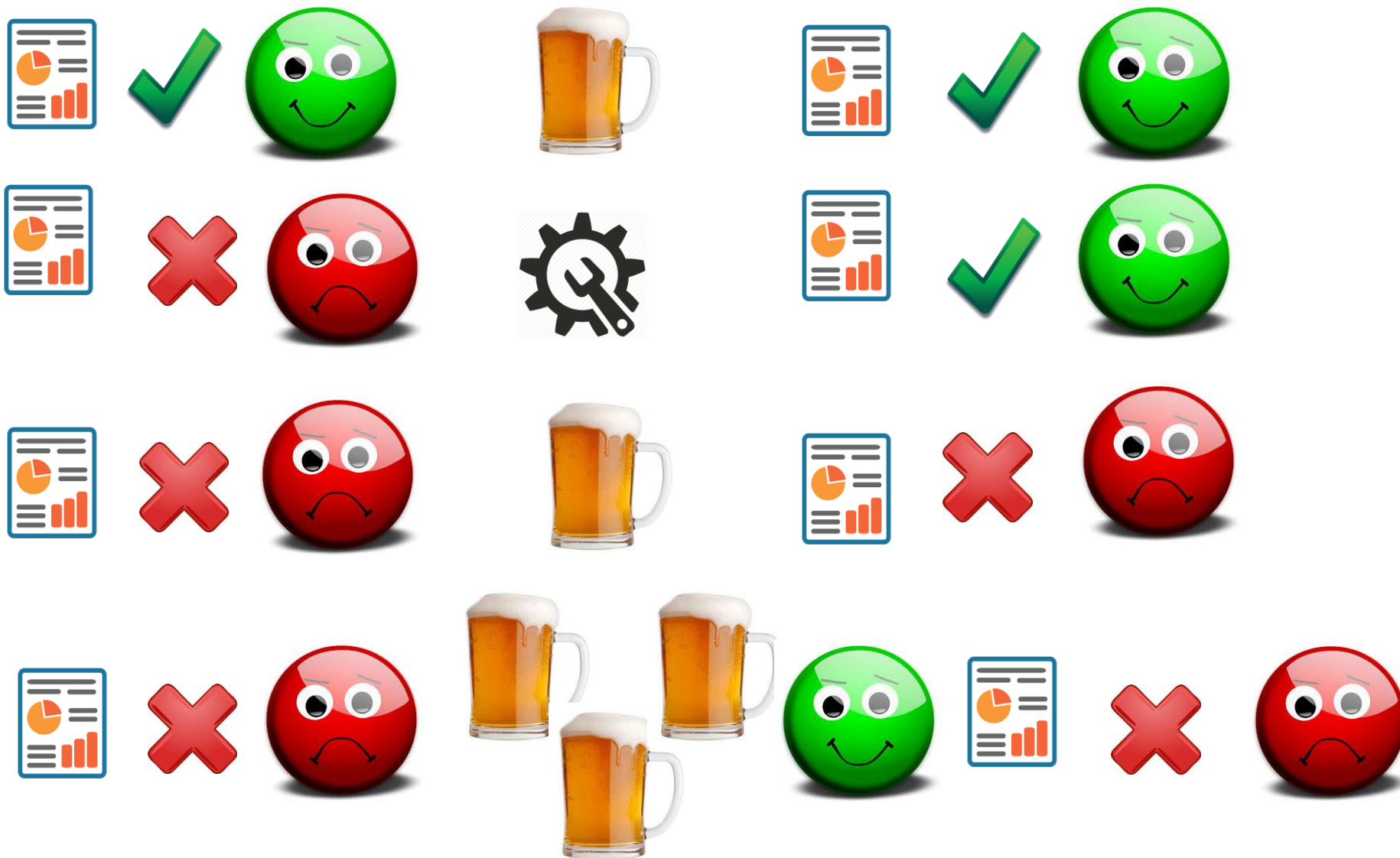
ISO 15189 elements on trueness

- 5.3.1.2 Acceptance of equipment
- 5.3.1.4 Calibration and metrological traceability
- 5.5.1 Validation/verification
- 5.5.1.4 Measurement uncertainty
- 5.6.2. Quality Control
- 5.6.3 EQA
- 5.6.3.2 Alternative approach for EQA

The concept of residual risk

1. ISO 15189:2012, 5.5.1.3
Method validation, verification
 - $T=0$; bias and imprecision are suitable for intended use
2. ISO 15189:2012, 5.6.2
Internal QC
 - Conditions as on $T=0$ are still true
 - Or if not, still meet criteria of acceptance on $t=0$
3. ISO 15189:2012, 5.6.3
External QC
 - What can be wrong?

The role for EQA in the PDCA of trueness



Consequences for the characteristics of EQA

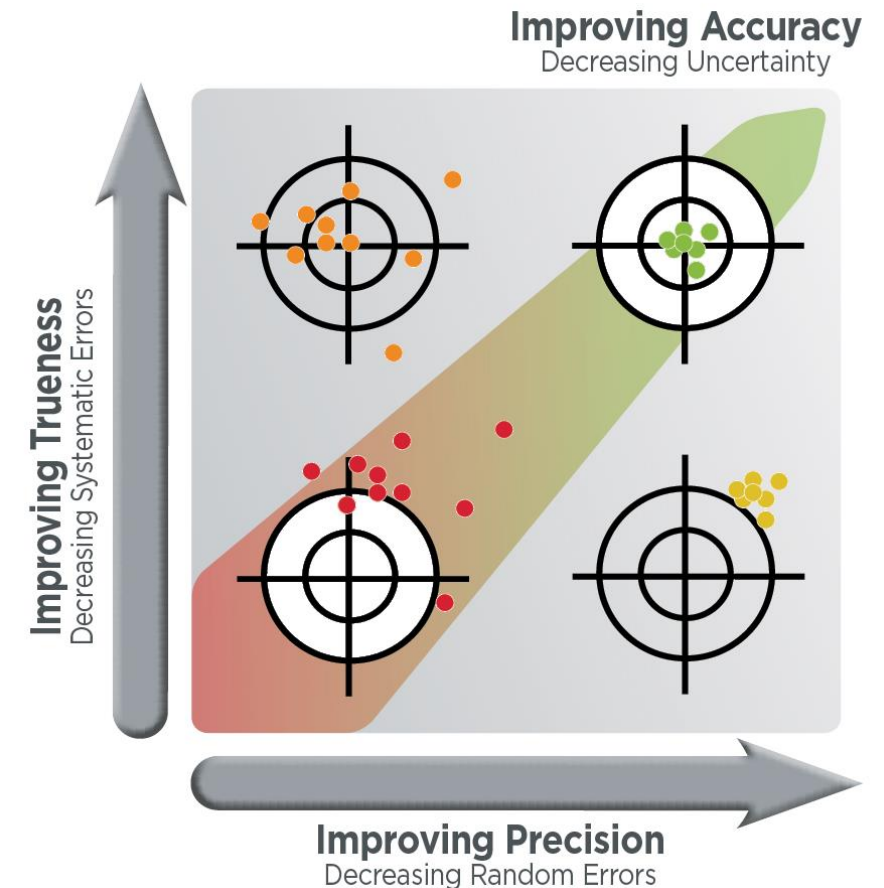
- Target value: **indisputable**:
 - Set by reference laboratory (Cobbaert)
- Material: **indisputable**
 - Commutable (Miller)
- Report: **actionable**
 - Smart reporting of performance related to analytical performance specifications
 - You know **when to be satisfied**
 - And **what to do** if not

SKML report ambitions

- Actionable: direct corrective action if needed
- SMART
 - Specific
 - Measurable
 - Achievable
 - Realistic
 - Time dependent

SMART reports

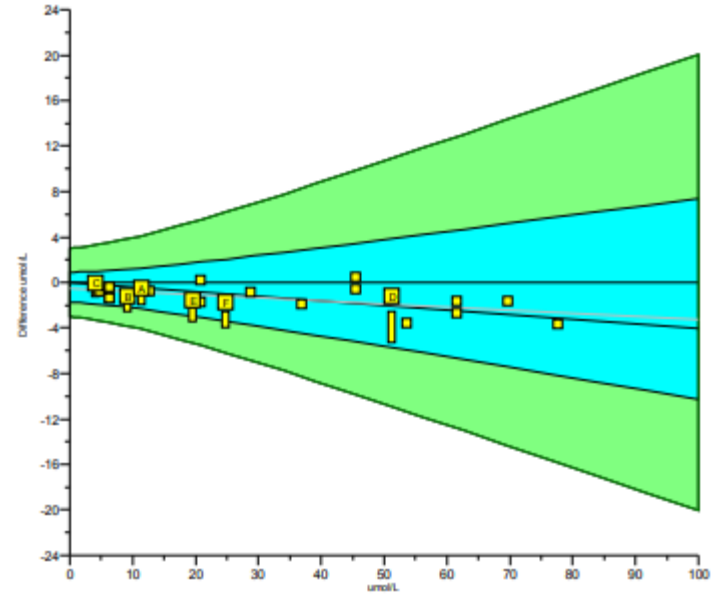
- **Specific:**
 - Performance of lab, not of EQAS material
 - material and assigned values beyond discussion
 - Support root cause analysis: multi sample approach and method grouping
- **Measurable:**
 - Separate measures for bias and imprecision: requires **multi sample approach**
 - Score reflects bias and imprecision
- **Achievable**
 - Don't punish participants for malperformance of IVD industry
 - if SA precision profile > TE_a, then score in SA precision profile
- **Realistic:**
 - TE_a based on EFLM Milan 2014 performance goals
 - Clinical outcome, when data are available; troponin-T
 - Biological variation. Medical useful: relation to useable quality in RCV
 - State of the art, when BV not available or unachievable
- **Time dependent:**
 - Short term
 - Long term







SMART reports

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Bilirubin units: umol/L

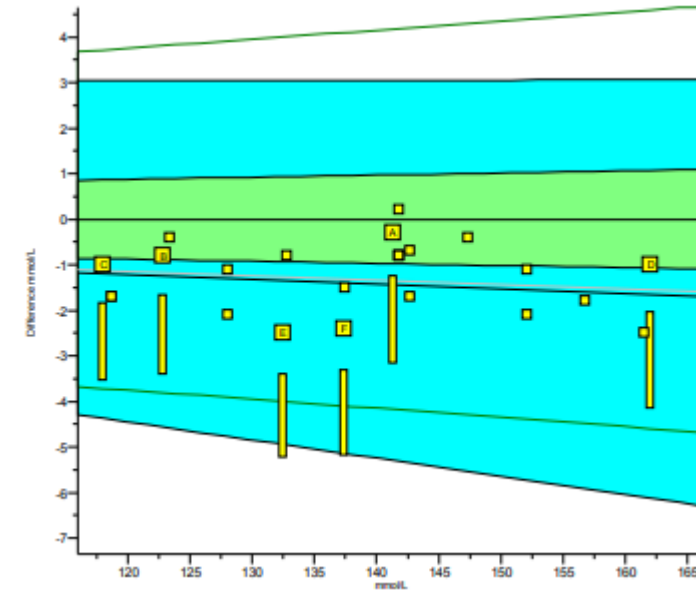






	2021.1	cumulative
Trueness	-5.4%	-4.7%
Precision	3.1%	2.9%
Number	6	24
Outliers	0	0
Sigma-TE	6.0 	6.0 
Sigma-SA	3.1	3.1
Score pictogram		
Regression line	$0.0 + 0.959.x$	$-0.6 + 0.973.x$
Consensus group	Colorimetrie alle reagentia	
Method	Roche	
Analyser	Roche cobas c501, c502	
Your factor	$0 + 1.000.x$	
Method factor	$0 + 1.002.x$	

SMART reports

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Sodium units: mmol/L



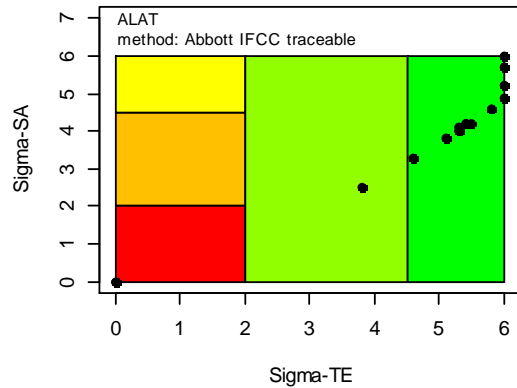
	2021.1	cumulative
Trueness	-1.0%	-1.0%
Precision	0.68%	0.56%
Number	6	24
Outliers	0	0
Sigma-TE	0.3	0.4
Sigma-SA	4.3 	4.5 
Score pictogram		
Regression line	$0.0 + 0.990.x$	$0.0 + 0.990.x$
Consensus group	ISE	
Method	Roche	
Analyser	Roche ISE cobas 8000	
Your factor	$0 + 1.000.x$	
Method factor	$0 + 1.000.x$	

What's next?

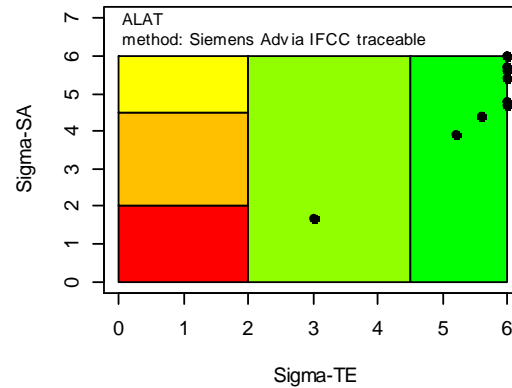
- Tolerance limits corrected for uncertainty of target value
- Within laboratory between instrument comparison statistics
- Management reports
 - For dialogue with IVD industry:
 - Performance of all participants in one view per test
 - For labs:
 - Performance of all tests in one view per participant

SaTe graph, all participants, one test, per IVD provider

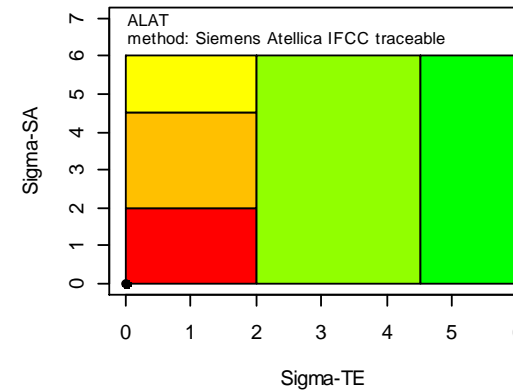
Clinical Chemistry, blood survey 2020.4



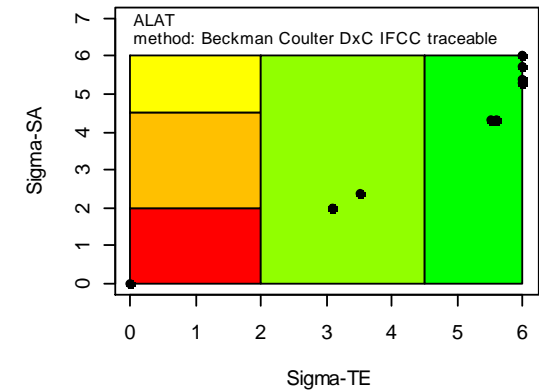
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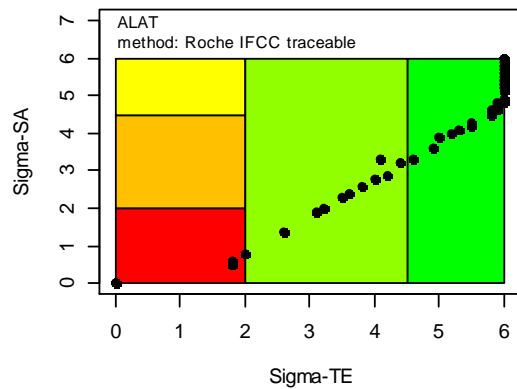
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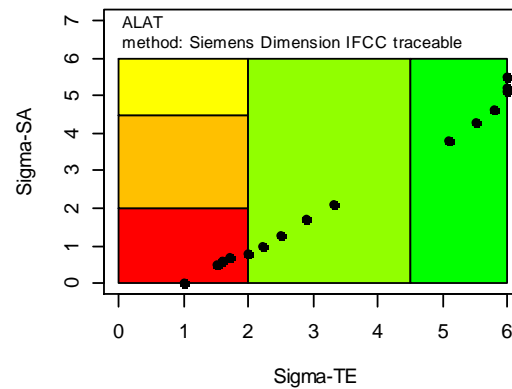
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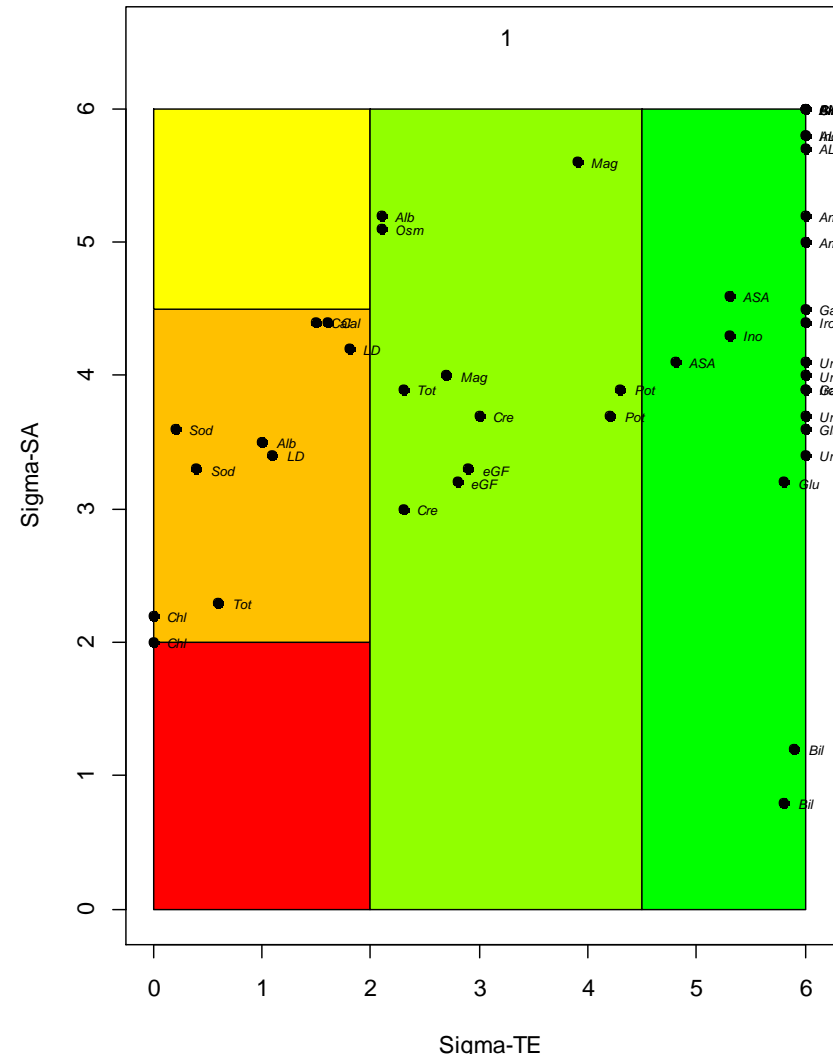


Clinical Chemistry, blood survey 2020.4



SaTe graph, all tests, one participant

Clinical Chemistry, blood survey 2020.4



What have you learned about EQA reports?

Actionable EQA reports

- A. Are digitally animated reports
- B. contain recommended actions for participants
- C. Contain information that give direction for corrective action

What have you learned about me?

Marc Thelen

- Likes Beer
- Likes Whine
- Likes the way Cas has inspired him to make difficult stuff to look easy

Bonus slide, for all, but especially Cas

SKML prize: quality standard

- 2007: Baadenhuijsen: graphical SKZL reports
- 2009: Ross: harmonization of Growth hormone
- 2011: Willems: merger of SKZL with all other Dutch eqa to
- 2013: Jansen: harmonization of all SKML scheme reports
- 2015: Steigstra: SKML software for process and reports
- 2019: Franck: reference lab for enzymes
- 2021: Weykamp: making the assessment of harmonization easy

