Use of Target Values in EQA

Dr. Anja Kessler
Bonn, Germany

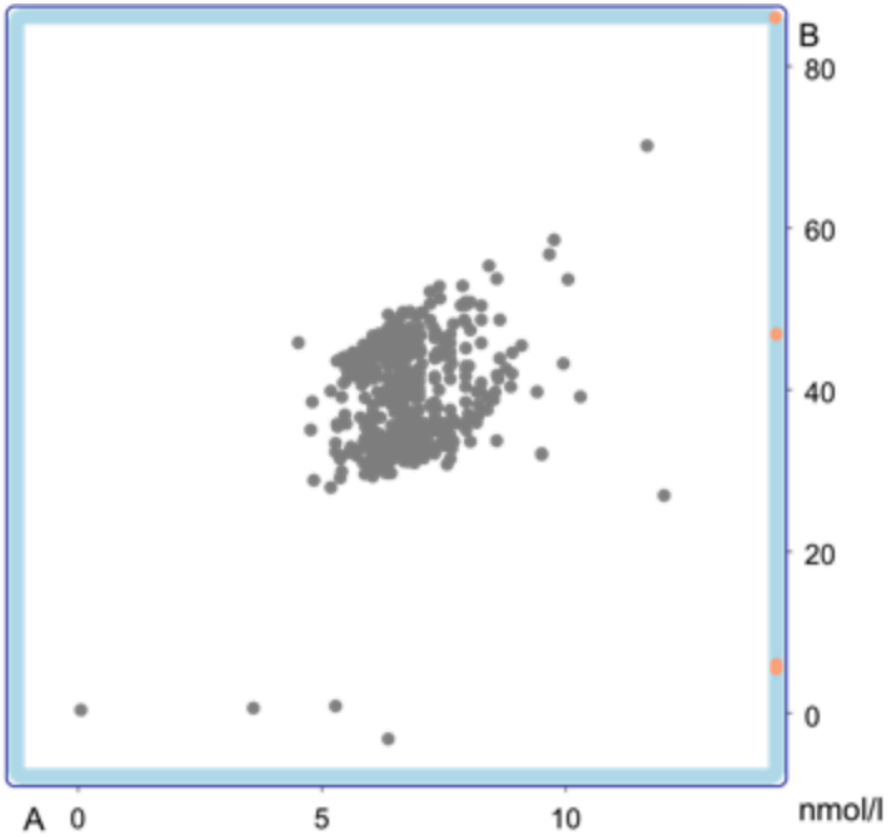
External Quality Assessment

Example: Progesterone

580 participants

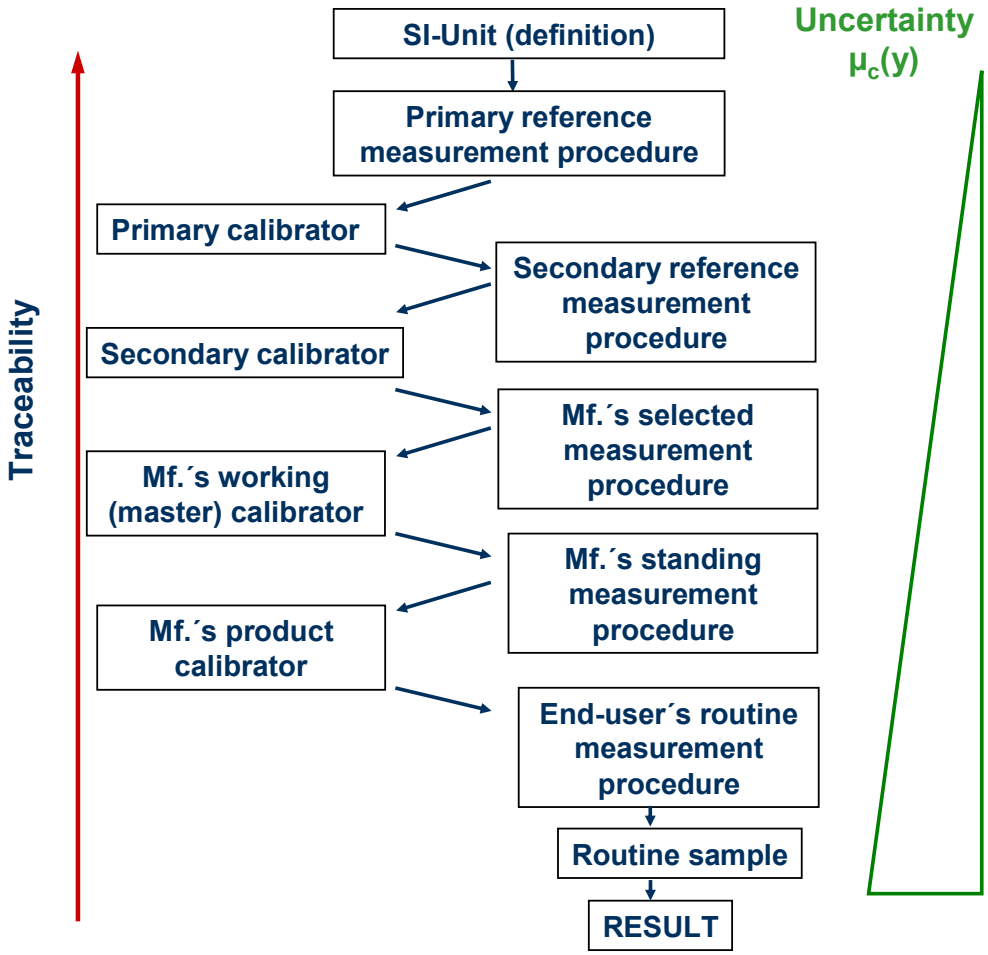
Measurement principles:

- Luminescence detection
- Radioactivity detection
- Fluorescence detection
- Mass spectrometry
- ...



Which result is accurate?
Are the results comparable within certain limits?

Traceability in Laboratory Medicine



BIPM:
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NMI:
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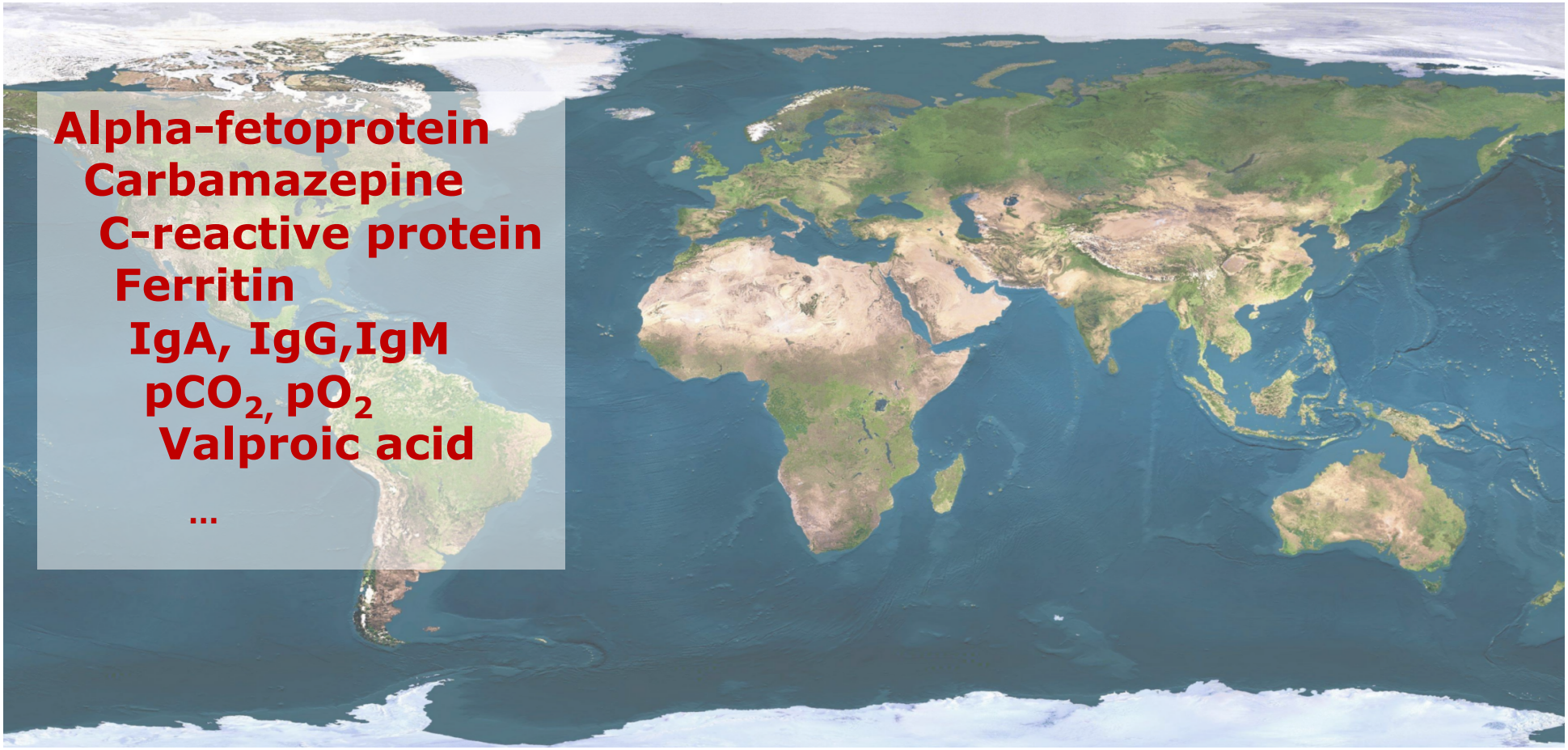
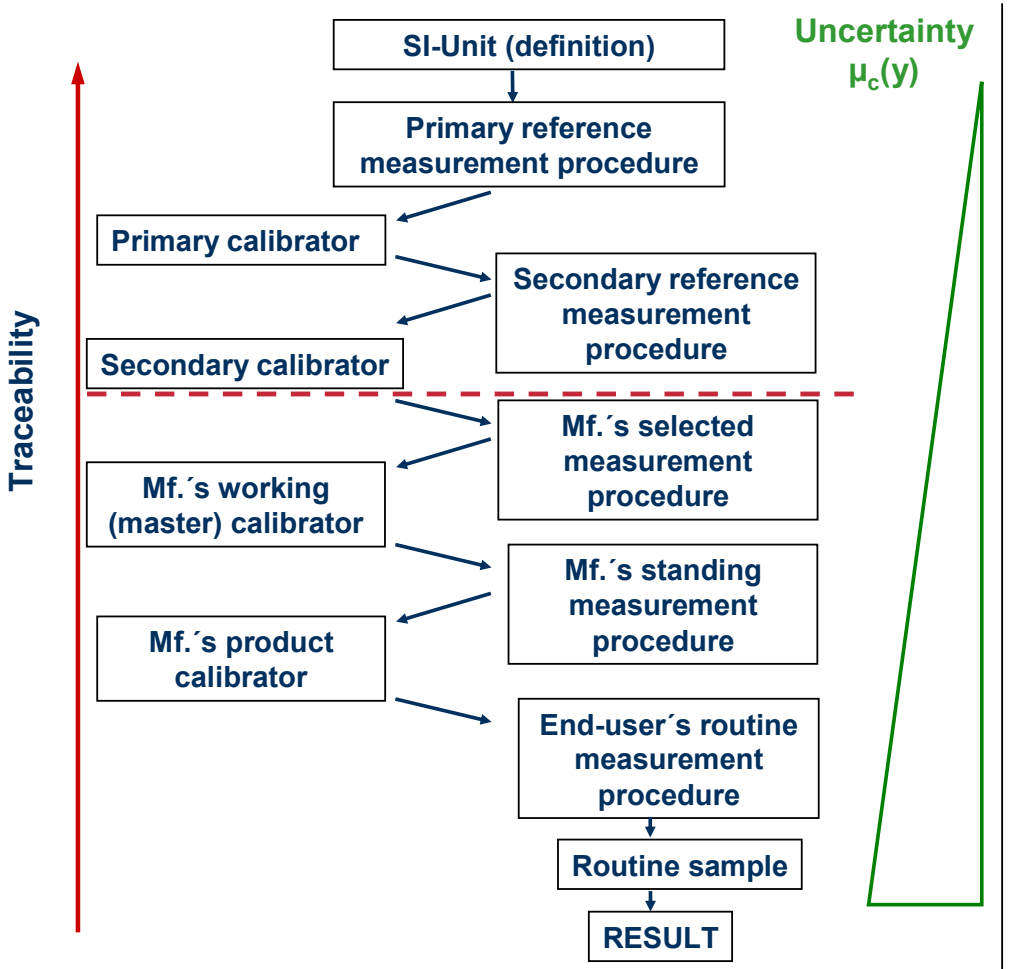
Adapted from **ISO 17511**

Traceability for Measurands in EQA
- present state-



Traceability in Laboratory Medicine



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RiliBÄK – Table B1a

1 No.	2 Measurand	3 Permissible relative deviation of a single result or the relative root mean square, respectively	4 Rili-BAEK applicable concentration intervals of columns 3 and 5			5 Permissible relative deviation in EQA	6 Type of target value in EQA
			From	To	Unit		
⋮							
11	Carbamacepine	12.0%	2	20	mg/L	20.0%	NV
12	Carcinoembryonic antigen (CEA)	14.0%	1	200	µg/L	24.0%	NV
13	Chloride	4.5%	70	150	mmol/L	8.0%	RMV
14	Cholesterol (total)	7.0%	50	350	mg/dL	13.0%	RMV
			1.3	9.1	mmol/L		
15	Cortisol	16.0%	>60	500	µg/L	30.0%	RMV
			>166	1380	nmol/L		
		18.5%	20	≤60	µg/L		
			55	≤166	nmol/L		
16	Creatine kinase (CK) EC 2.7.3.2	11.0%	50	1000	U/L	20.0%	RMV
			0.83	16.7	µkat/L		
17	C-reactive protein (CRP)	13.5%	1	120	mg/L	20.0%	NV
18	Digitoxin	15.5%	5	80	µg/L	30.0%	RMV
19	Digoxin	14.0%	>1	5	µg/L	30.0%	RMV
		17.5%	0.5	≤1	µg/L		
20	Erythrocytes	4.0%	1.5	7	10^{12}/L	8.0%	RMV
21	Oestradiol 17-beta	22.0%	10	500	ng/L	35.0%	RMV
			37	1835	pmol/L		
⋮							

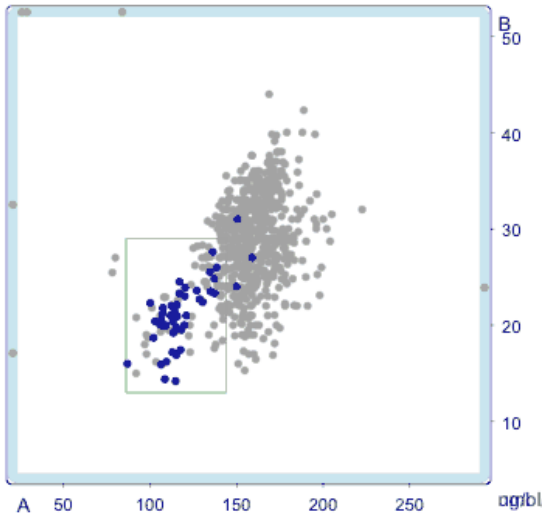
Kit Dependent Target Values

HM1/13

Ferritin

Lumineszenzmessung - Kit 13

Split 1



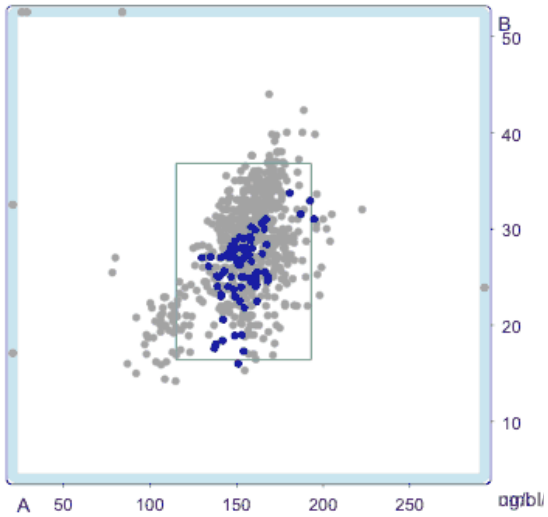
Anzahl Teilnehmer	47	
Zielwert	115	21
Grenzen	86,2 - 144	13 - 29
Mittelwert	117,527	21,085

HM1/13

Ferritin

Lumineszenzmessung - Kit 40

Split 1



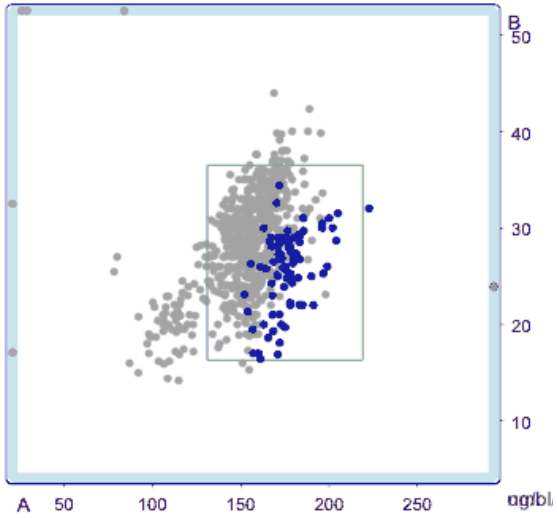
Anzahl Teilnehmer	81	
Zielwert	154	26,6
Grenzen	115 - 193	16,4 - 36,8
Mittelwert	154,195	26,015

HM1/13

Ferritin

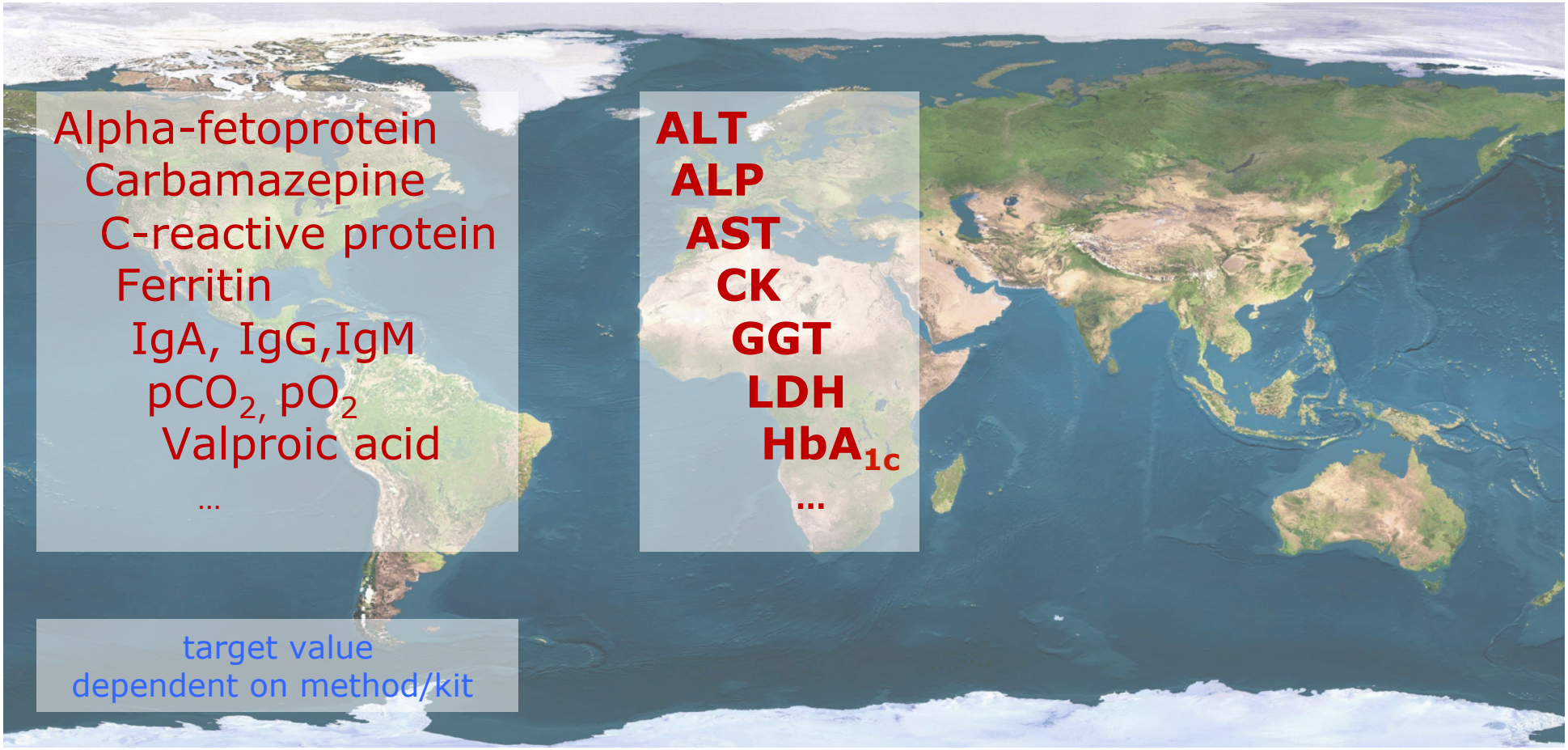
Lumineszenzmessung - Kit 4

Split 1

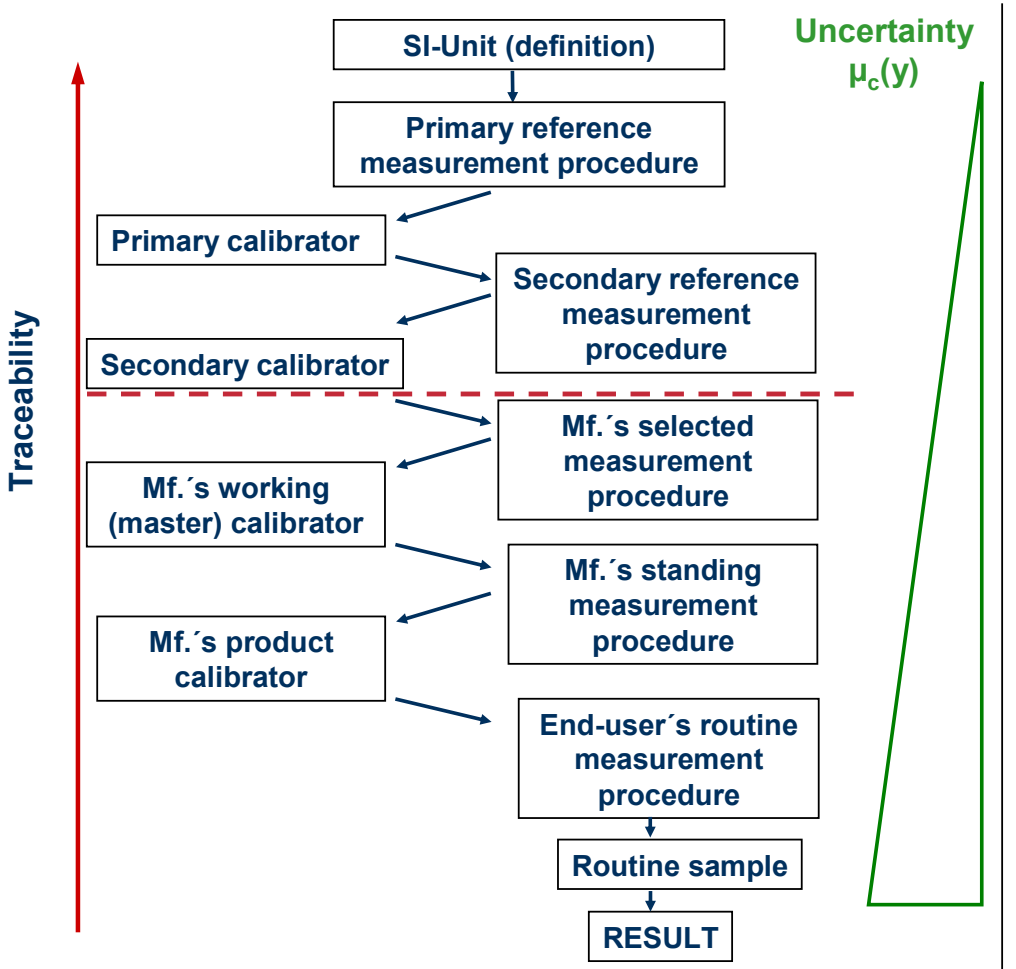


Anzahl Teilnehmer	82	
Zielwert	175	26,4
Grenzen	131 - 219	16,3 - 36,5
Mittelwert	193,774	25,779

Traceability for Measurands in EQA
- present state-



Traceability in Laboratory Medicine



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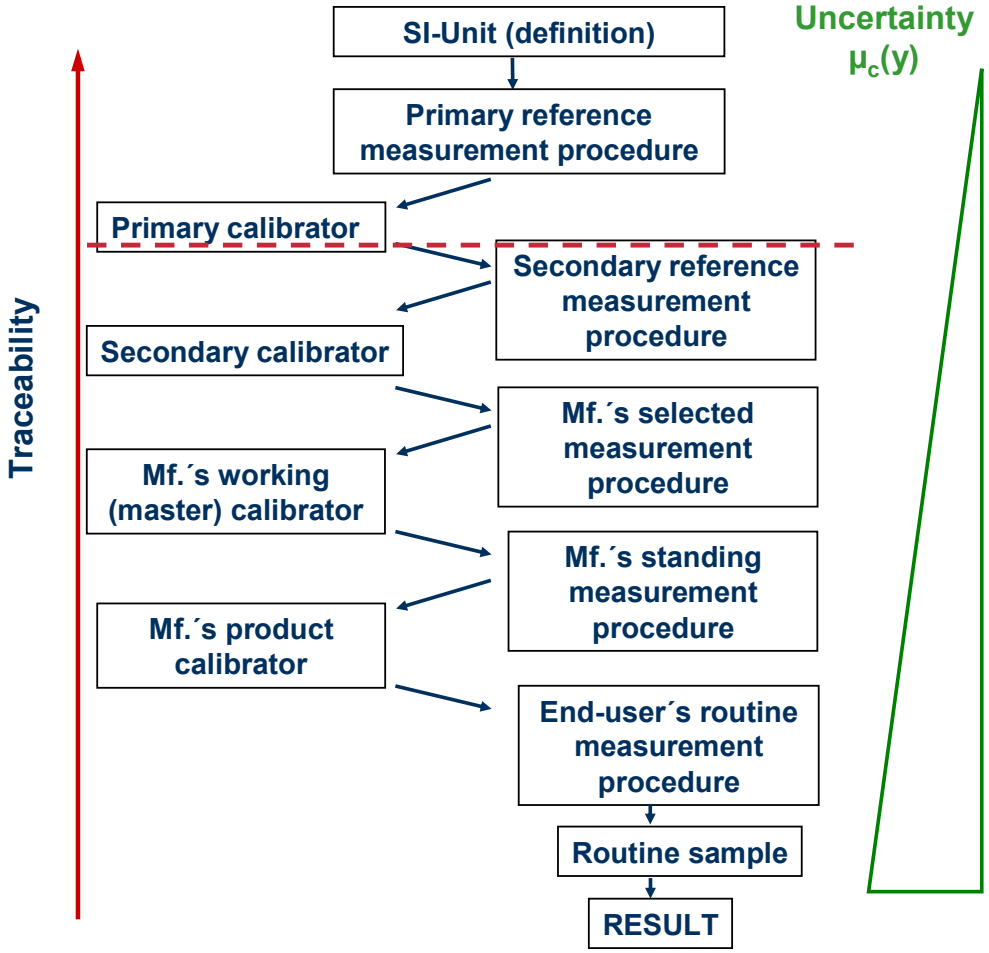
Traceability in Laboratory Medicine



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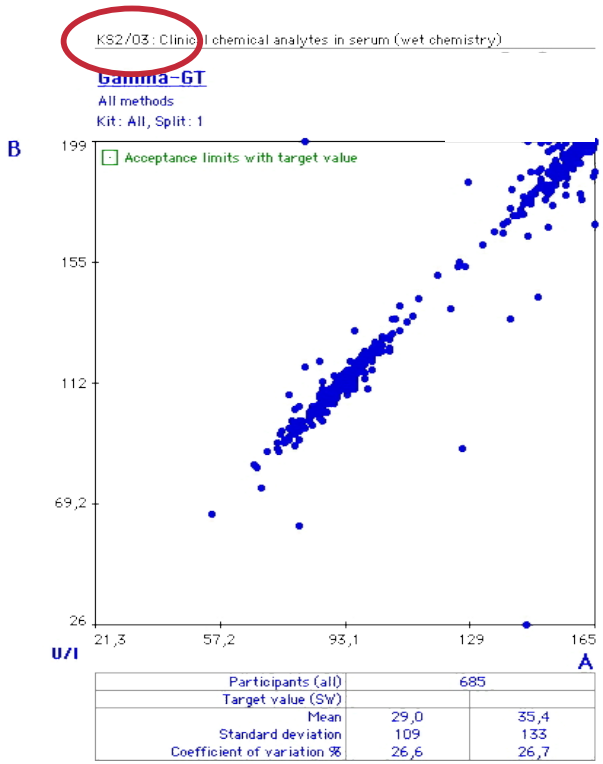
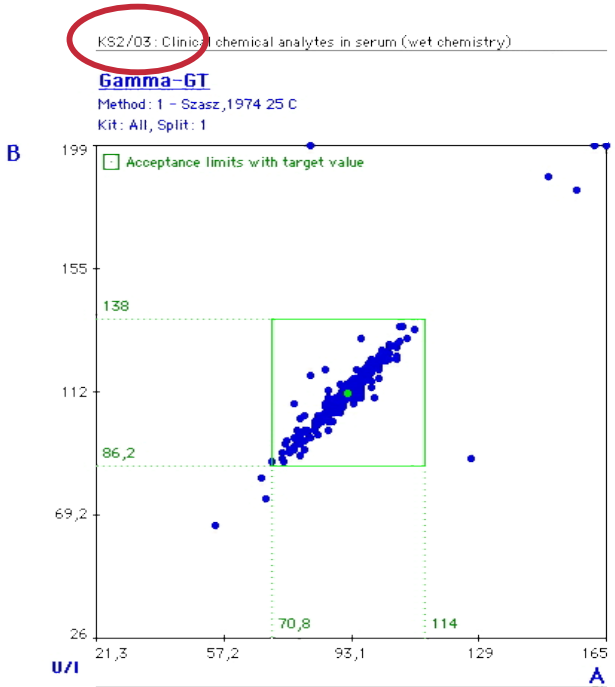
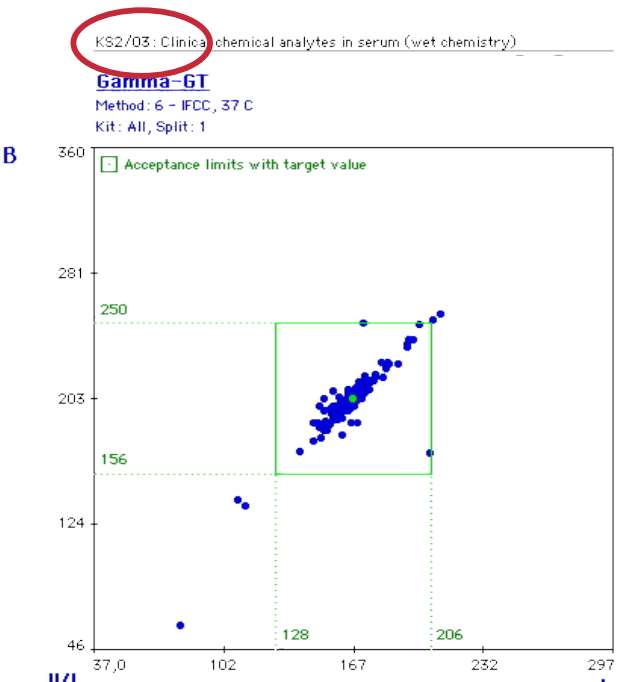
Enzymes – Situation before Standardization



Participants (all)	685	
Target value (SW)		
Mean	29,0	35,4
Standard deviation	109	133
Coefficient of variation %	26,6	26,7

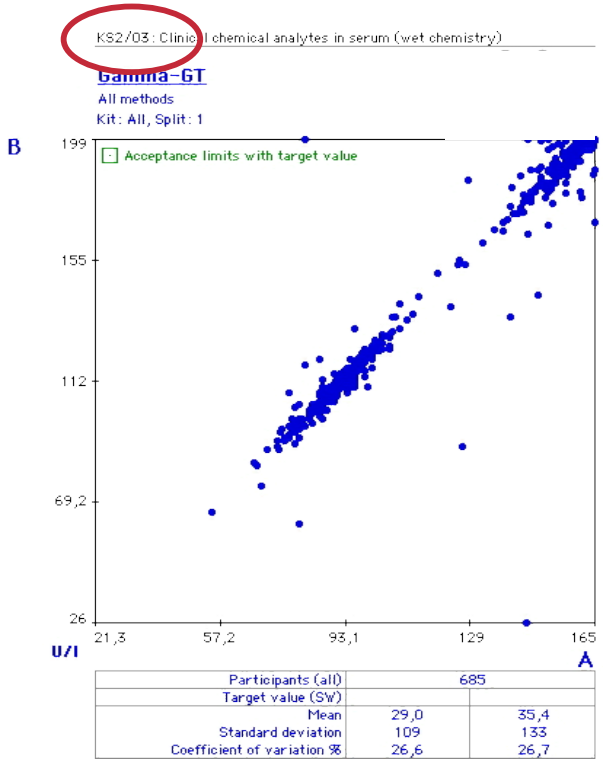


Participants (all)	359	
Target value (SW)	A = 92,0	B = 112
Mean	8,90	10,8
Standard deviation	92,0	112
Coefficient of variation %	9,68	9,70



Participants (all)	152	
Target value (SW)	A = 167	B = 203
Mean	14,9	19,7
Standard deviation	166	203
Coefficient of variation %	8,94	9,75

Enzymes – Situation after Standardization



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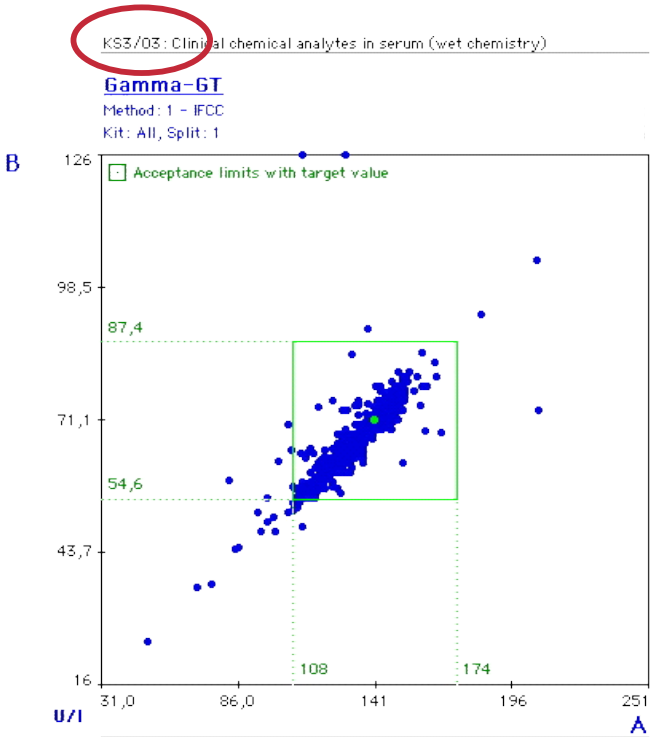
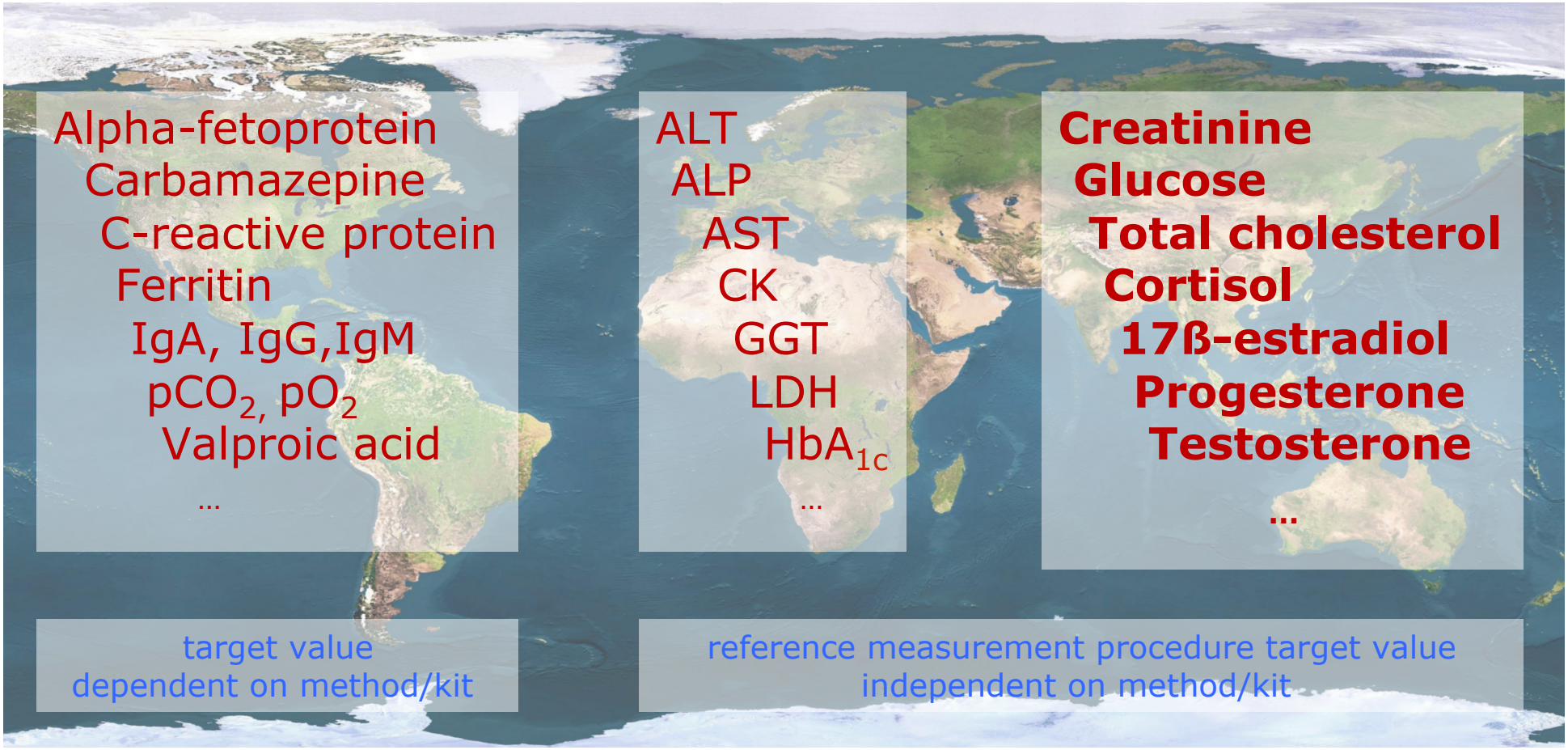
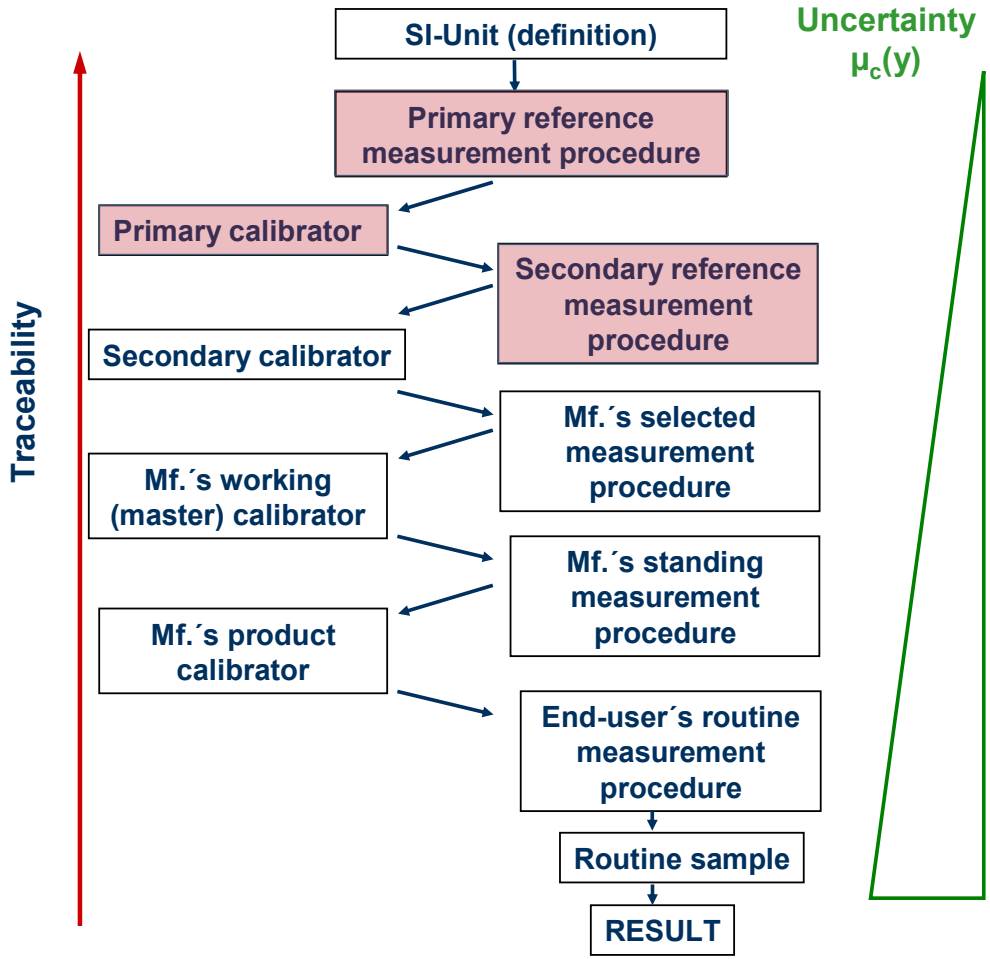


Participants (all)	733	
Target value (RMW)	A = 141	B = 71,0
Mean	12,5	6,40
Standard deviation	133	66,2
Coefficient of variation %	9,45	9,66

Traceability for Measurands in EQA
- present state-



Traceability in Laboratory Medicine



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⋮							

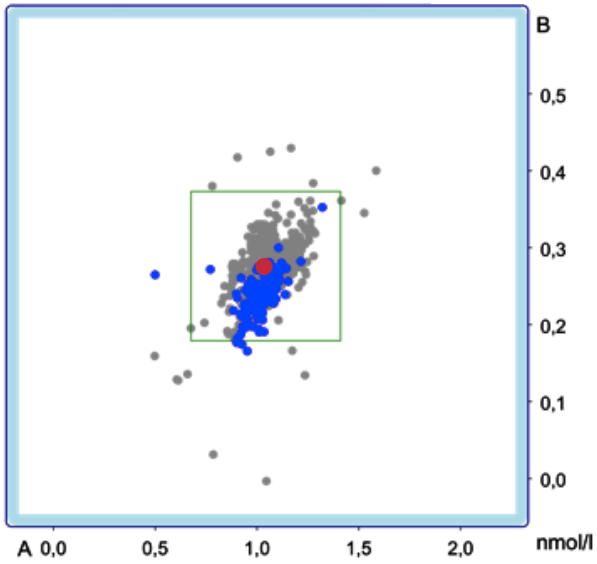
Survey ‚Hormones'

HM1/16

Estradiol-17beta

Lumineszenzmessung - Kit 44

Split 1



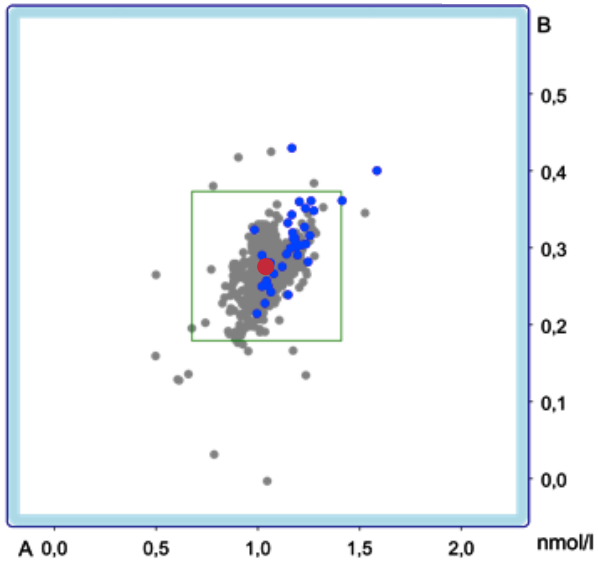
number of results	153	
target value	1,04	0,276
limits	0,676 - 1,41	0,179 - 0,373
mean	1,015	0,24
standarddeviation	0,08	0,026
coefficient of variation	7,852	10,974

HM1/16

Estradiol-17beta

Lumineszenzmessung - Kit 13

Split 1



number of results	35	
target value	1,04	0,276
limits	0,676 - 1,41	0,179 - 0,373
mean	1,163	0,304
standarddeviation	0,12	0,048
coefficient of variation	10,361	15,636

Joint Committee for Traceability in Laboratory Medicine

RfB Referenzinstitut für Bioanalytik

BIPM

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

ilac

http://www.bipm.org : JCTLM database

REFERENCE MEASUREMENT SYSTEMS

- Reference materials
- Reference measurement procedures
- Services of reference measurement laboratories

Reference Measurement Systems

The laboratory has to make use of a reference measurement procedure approved according to ISO 15193 and reference materials approved according to ISO 15194.

The laboratory has to be accreditated according to ISO/IEC 17025 and ISO 15195.

The laboratory has to participate regularly in collaborative surveys for calibration laboratories.

EQA for Calibration Laboratories

www.dgkl-rfb.de:81

EQA for Calibration Laboratories

RfB Referenzinstitut für Bioanalytik

ifcc International Federation of Clinical Chemistry and Laboratory Medicine | JCTLM

RELA - Homepage
External quality control for Reference Laboratories

RfB Referenzinstitut für Bioanalytik

RELA Home

Welcome
login
Registration/ Accou

RELA in progress
order RELA 2016
enter RELA 2016 results

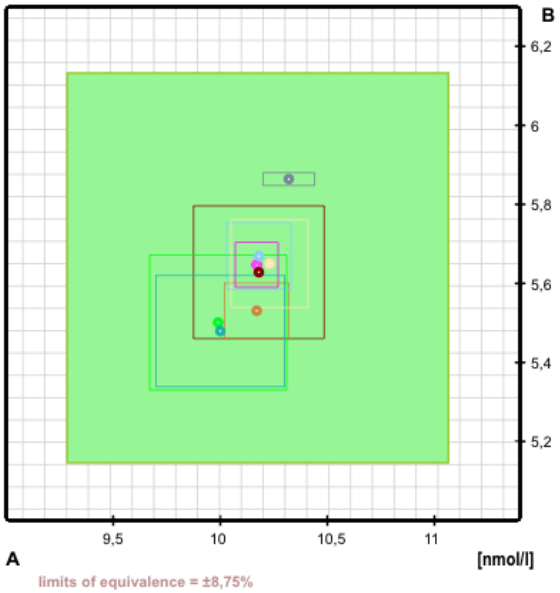
former RELA results
Choose year...

RELA 2015

All or choose Lab ...
select lab analytes | full address

Testosteron | show result plot
with limits of equivalence

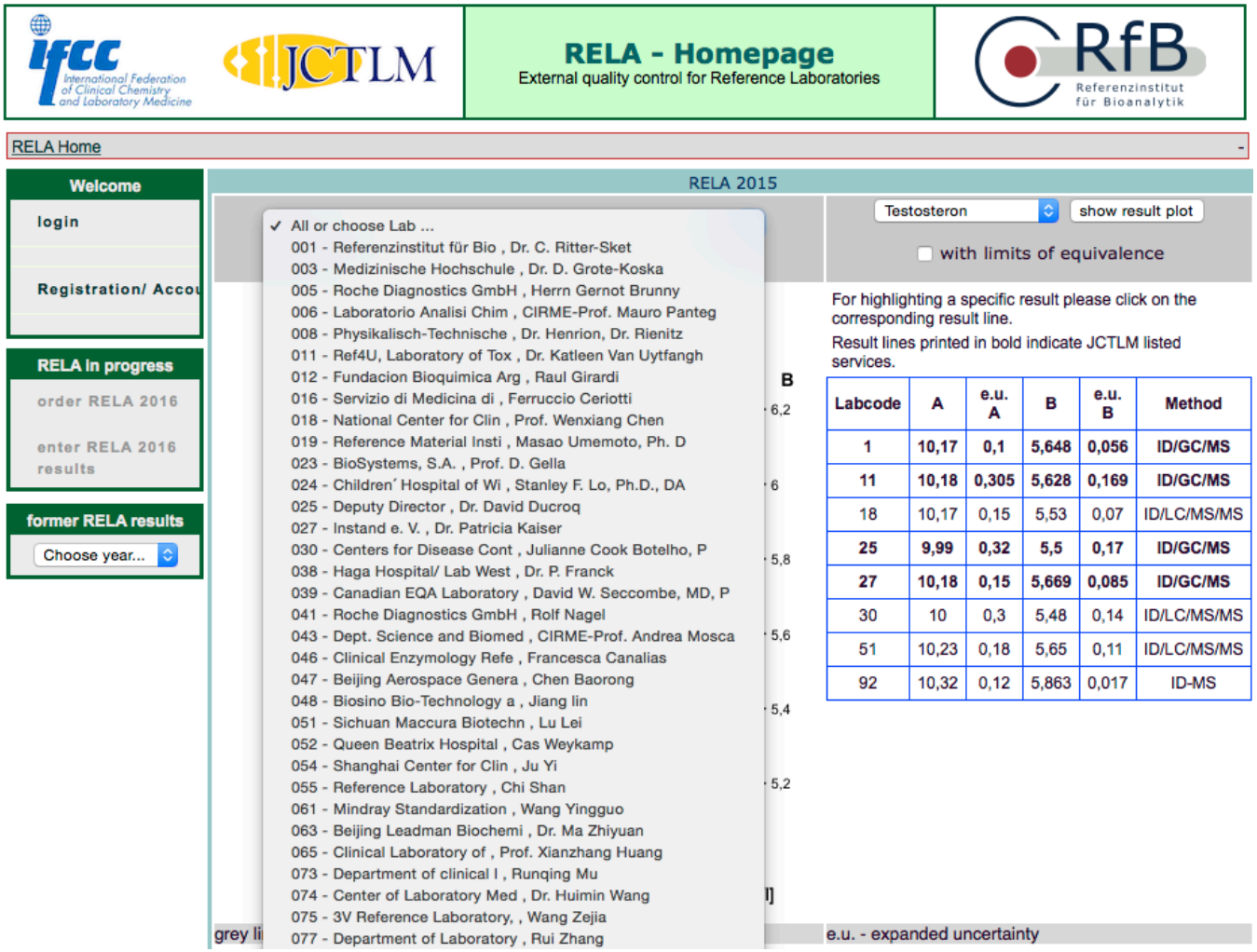
For highlighting a specific result please click on the corresponding result line.
Result lines printed in bold indicate JCTLM listed services.



Labcode	A	e.u. A	B	e.u. B	Method
1	**10,17**	**0,1**	**5,648**	**0,056**	**ID/GC/MS**
11	**10,18**	**0,305**	**5,628**	**0,169**	**ID/GC/MS**
18	10,17	0,15	5,53	0,07	ID/LC/MS/MS
25	**9,99**	**0,32**	**5,5**	**0,17**	**ID/GC/MS**
27	**10,18**	**0,15**	**5,669**	**0,085**	**ID/GC/MS**
30	10	0,3	5,48	0,14	ID/LC/MS/MS
51	10,23	0,18	5,65	0,11	ID/LC/MS/MS
92	10,32	0,12	5,863	0,017	ID-MS

grey lines indicate a one-percent grid | e.u. - expanded uncertainty

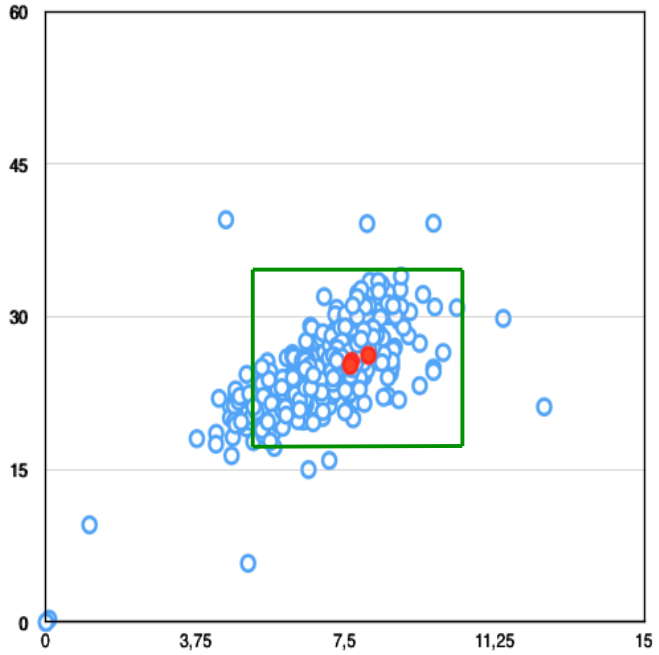
EQA for Calibration Laboratories



Linking Routine and Calibration Laboratories

Testosterone

HM 1/16 vs. RELA2014



680 routine labs

3 calibration labs

Limits of Acceptance: 35%

Implementation of Traceability

The implementation of quality assurance for clinical measurands requires the support of

- National Metrology Institutes
- Scientific Societies of Clinical Chemistry and Laboratory Medicine
- Accreditation Bodies
- Suppliers of Certified Reference Materials
- Calibration Laboratories

(also known as: Reference Measurement Laboratories)

- IVD Industry
- External Quality Assessment Organizers
- Legal Authorities
- Medical Laboratories themselves

Summary and Outlook

About 40 reference measurement systems are available to assign independent target values for interlaboratory comparisons. (most frequently analysed measurands)

However, many measurands still have to be evaluated by method/kit dependent target values.

Scientific work is necessary to develop reference measurement systems for further measurands in laboratory medicine.

The implementation of traceability in laboratory medicine and the improvement of comparability of EQA results depend on the contribution of many parties.