

Use of Target Values in EQA

Dr. Anja Kessler
Bonn, Germany

External Quality Assessment

Example: Progesterone

580 participants

Measurement principles:

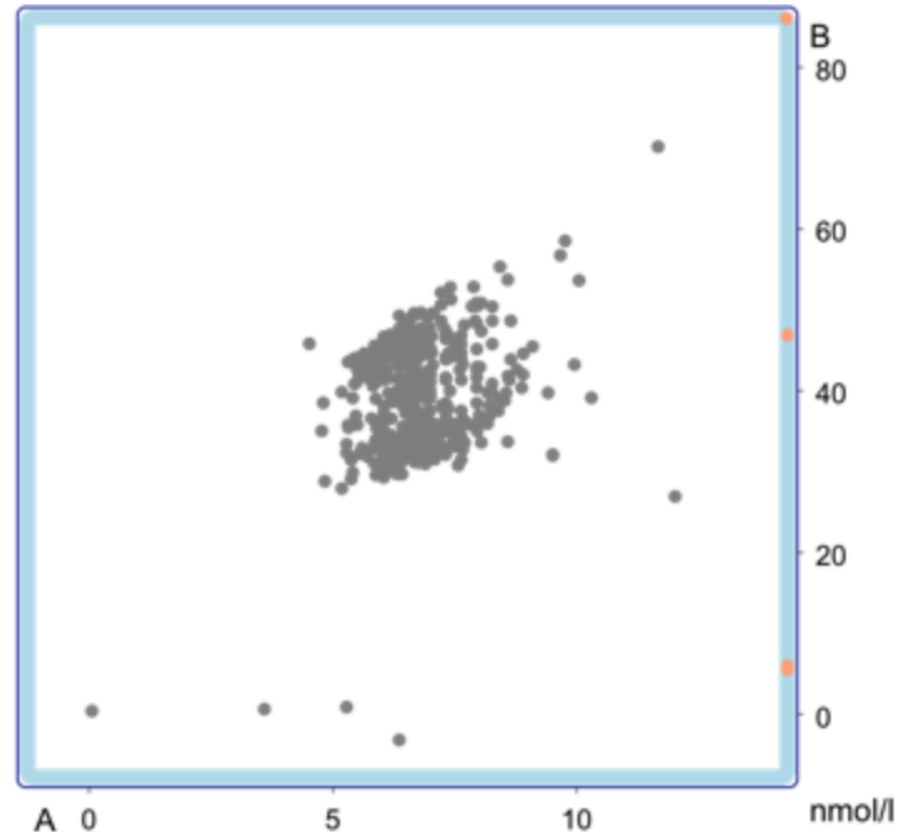
Luminescence detection

Radioactivity detection

Fluorescence detection

Mass spectrometry

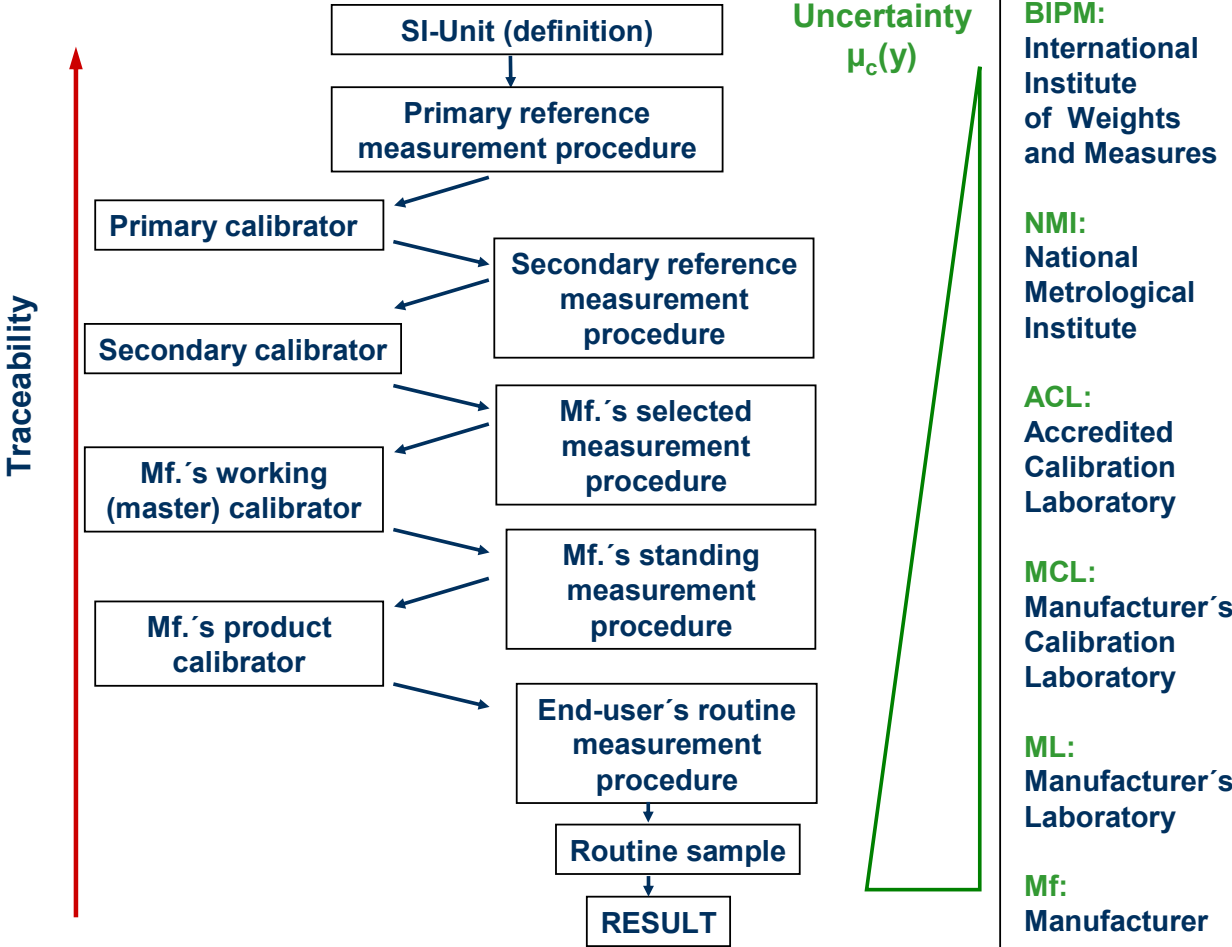
...



Which result is accurate?

Are the results comparable within certain limits?

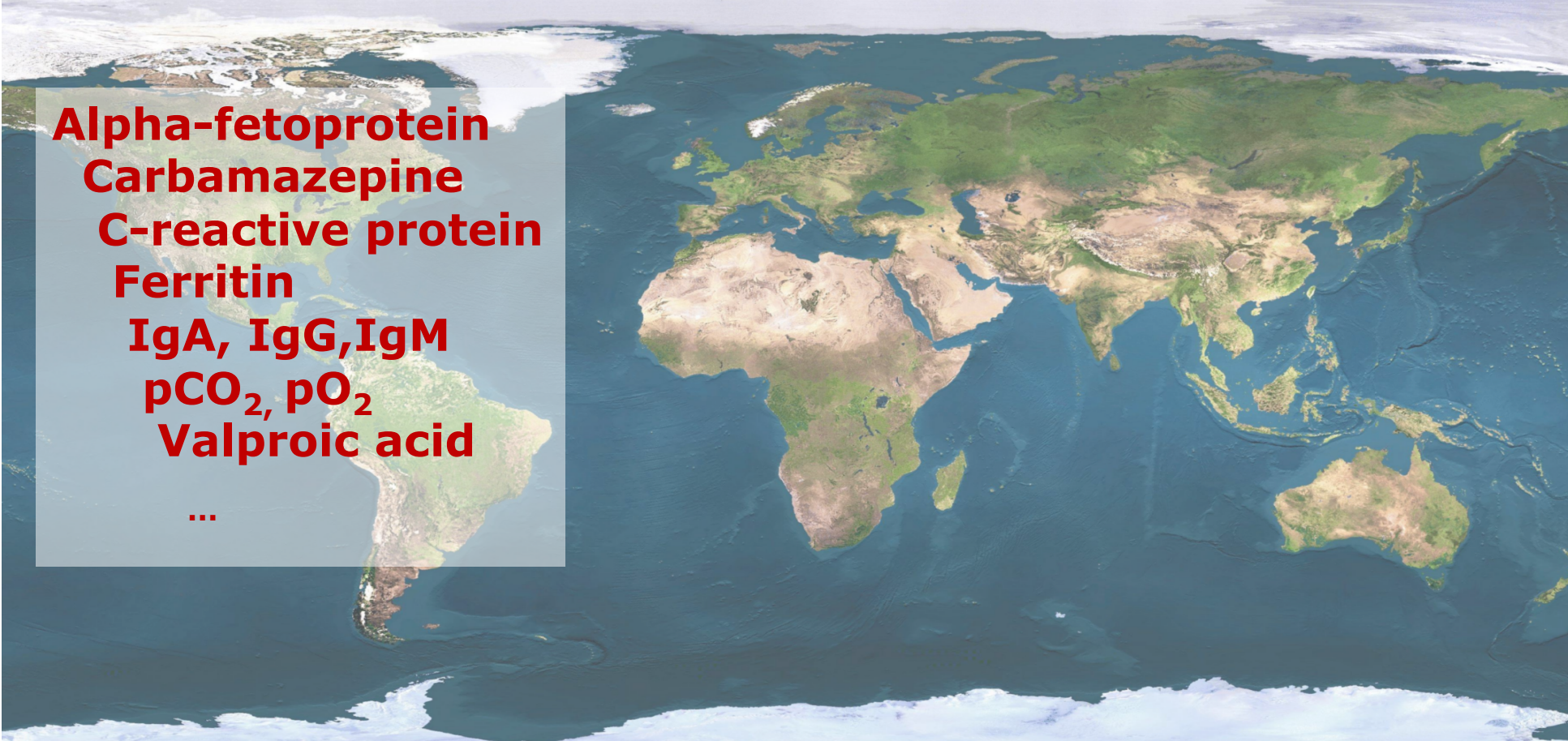
Traceability in Laboratory Medicine



Adapted from **ISO 17511**

Traceability for Measurands in EQA

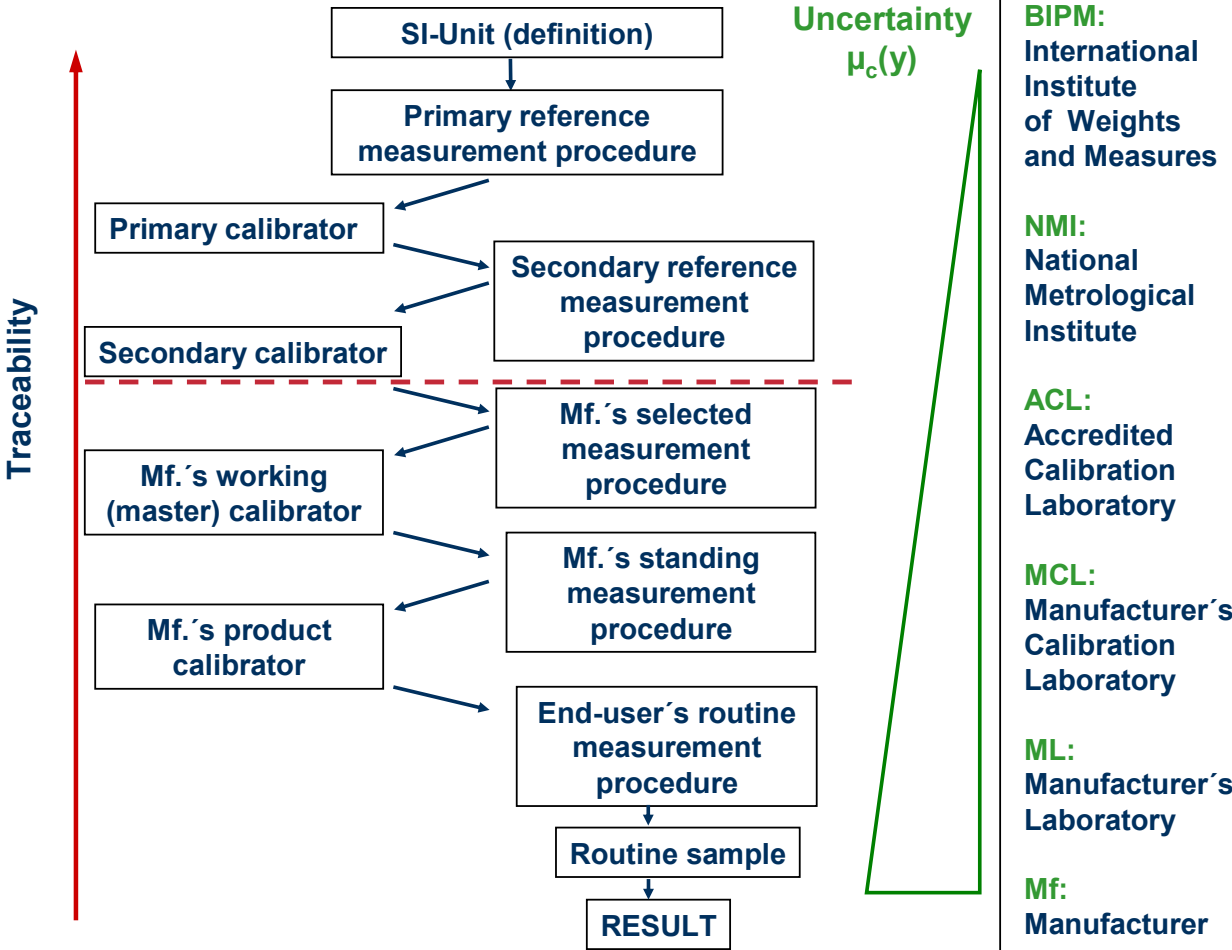
- present state-



Alpha-fetoprotein
Carbamazepine
C-reactive protein
Ferritin
IgA, IgG, IgM
pCO₂, pO₂
Valproic acid

...

Traceability in Laboratory Medicine

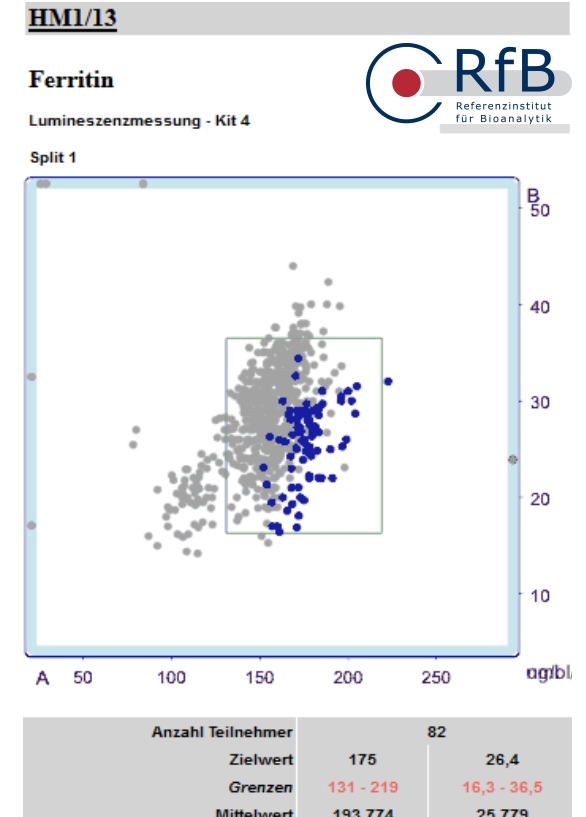
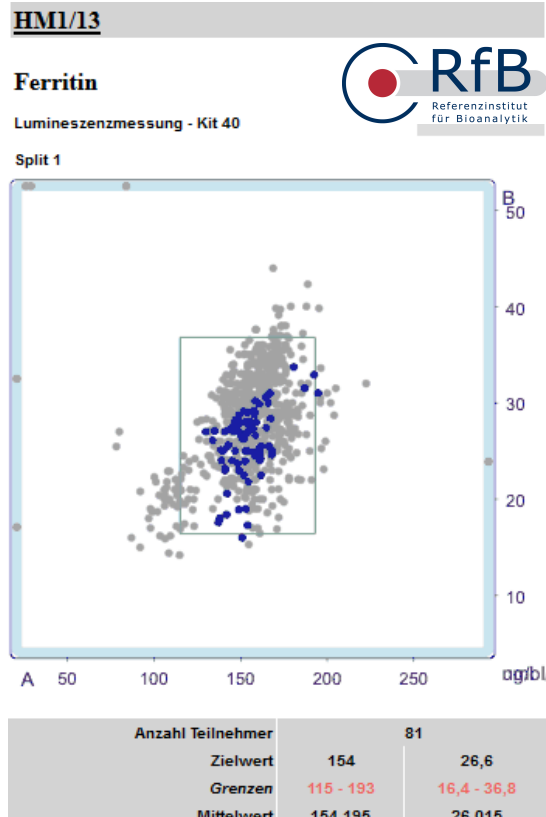
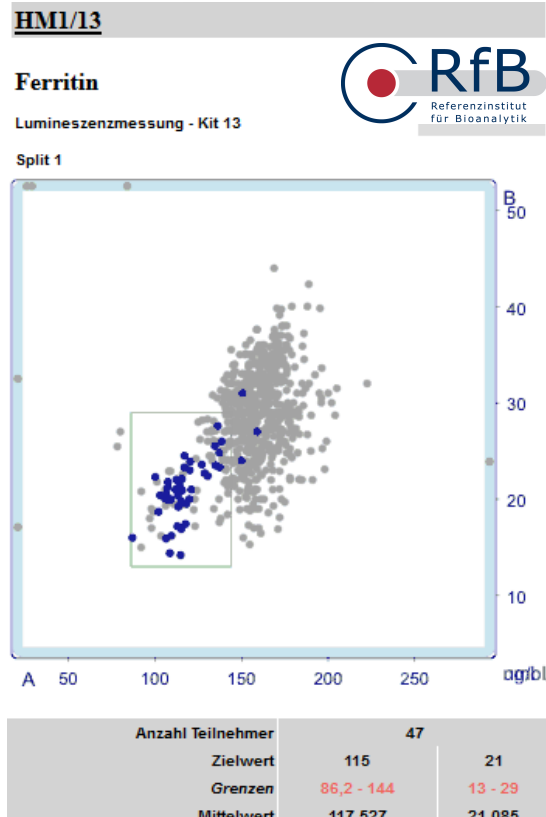


Adapted from **ISO 17511**

RiliBÄK – Table B1a

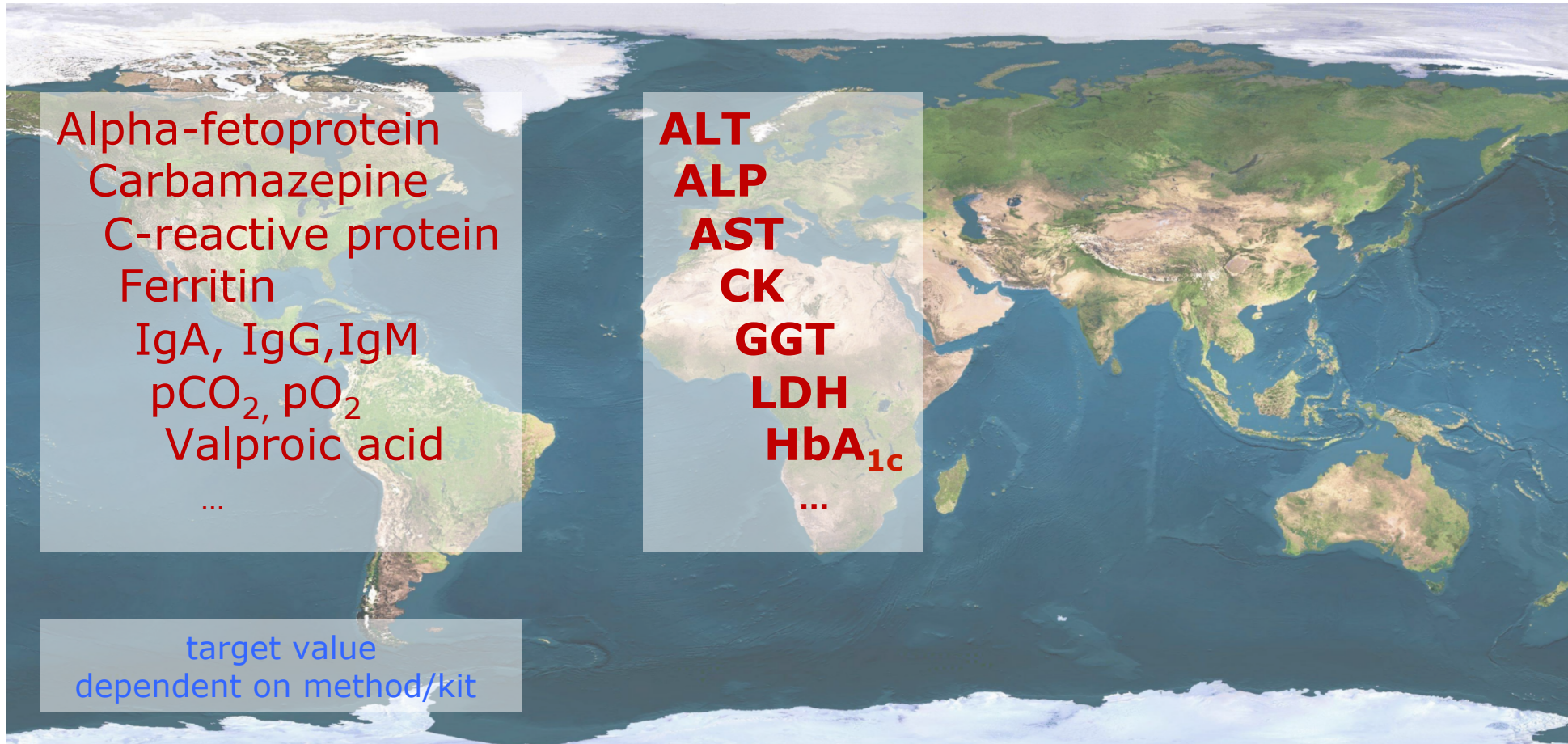
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			From	To	Unit		
⋮							
11	Carbamacepine	12.0%	2	20	mg/L	20.0%	NV
12	Carcinoembryonic antigen (CEA)	14.0%	1	200	µg/L	24.0%	NV
13	Chloride	4.5%	70	150	mmol/L	8.0%	RMV
14	Cholesterol (total)	7.0%	50	350	mg/dL	13.0%	RMV
15	Cortisol	16.0%	1.3	9.1	mmol/L	30.0%	RMV
			>60	500	µg/L		
			>166	1380	nmol/L		
			18.5%	20	≤60		
16	Creatine kinase (CK) EC 2.7.3.2	11.0%	55	≤166	nmol/L	20.0%	RMV
			50	1000	U/L		
			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		
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

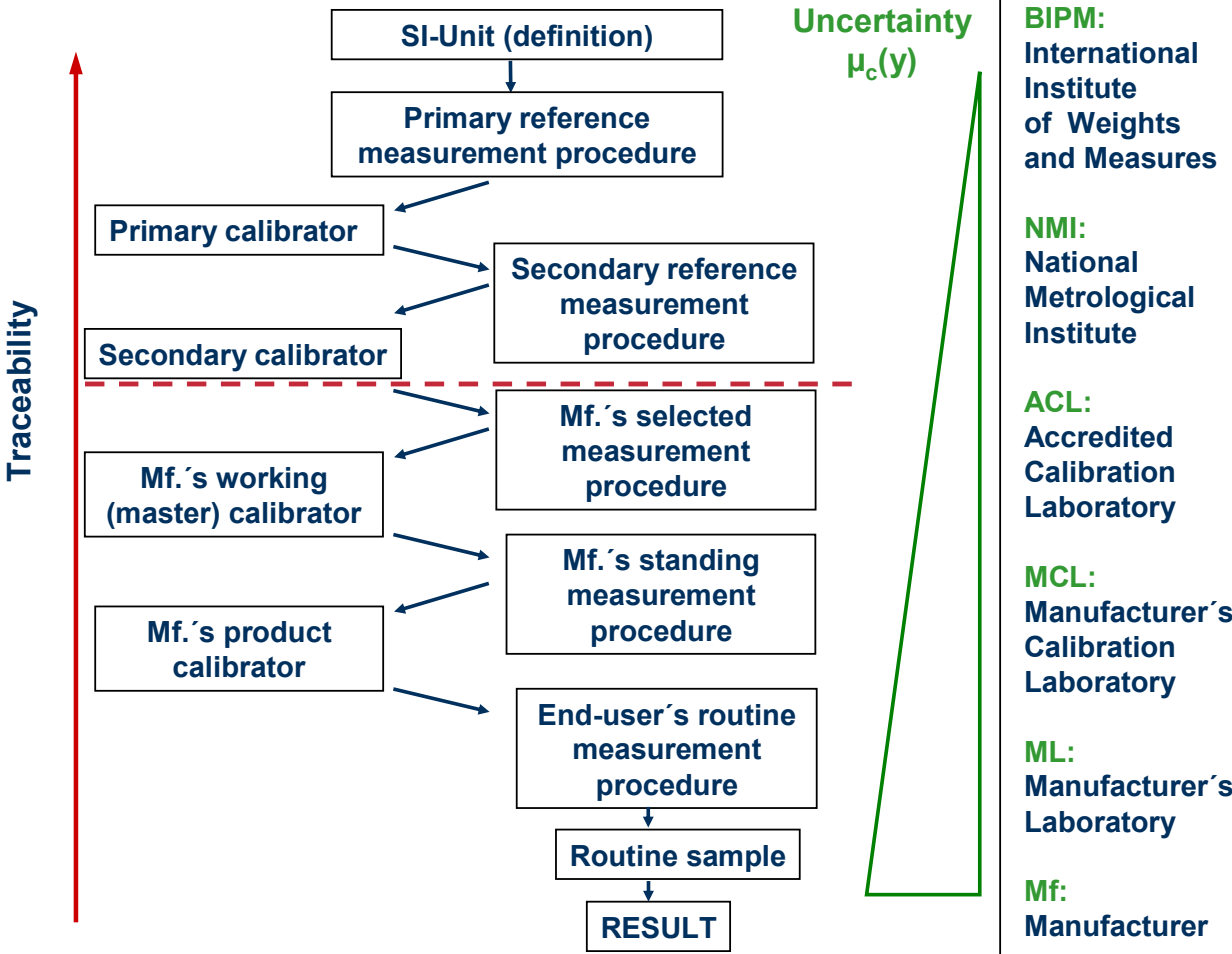


Traceability for Measurands in EQA

- present state-

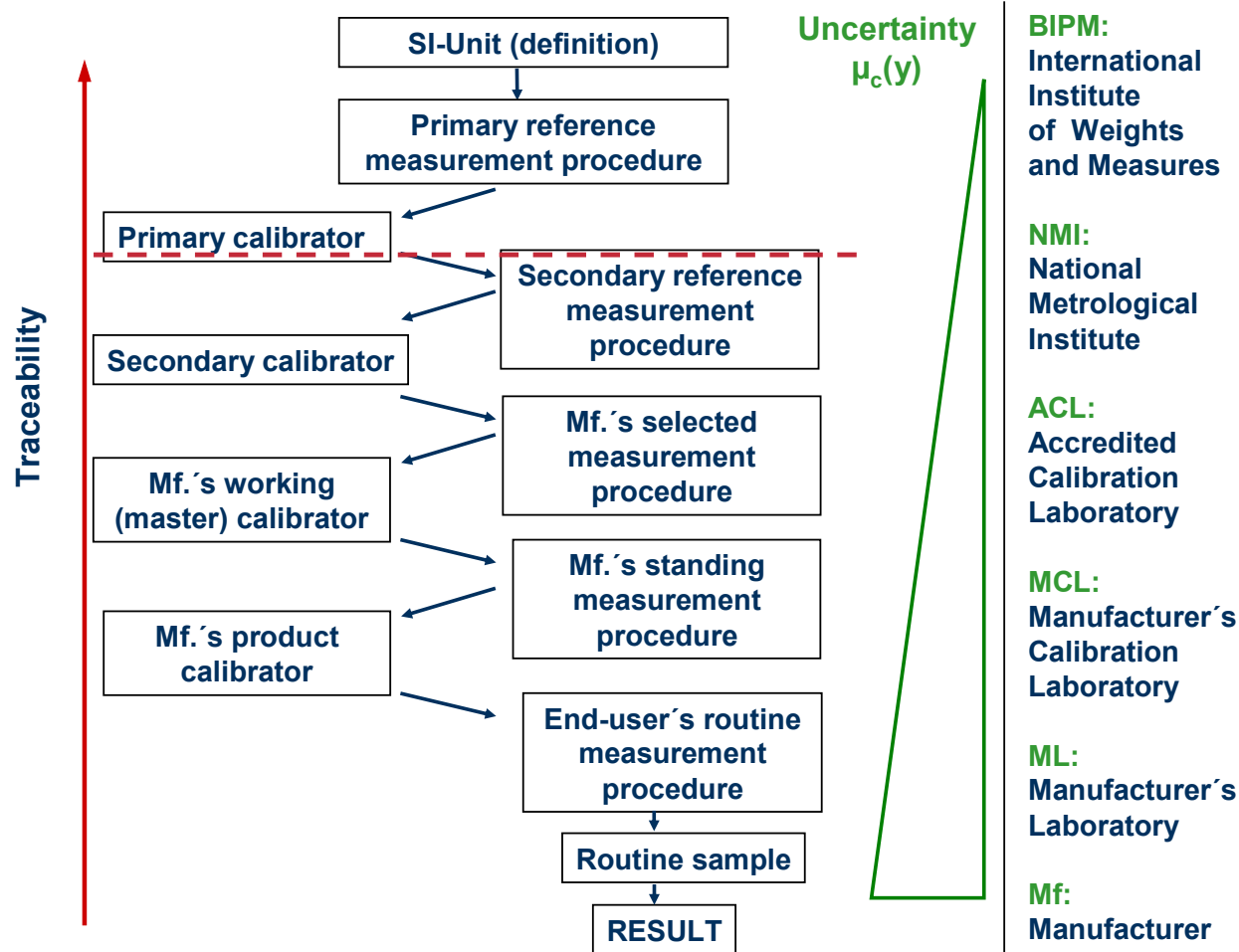


Traceability in Laboratory Medicine



Adapted from **ISO 17511**

Traceability in Laboratory Medicine



Adapted from **ISO 17511**

RiliBÄK – Table B1a

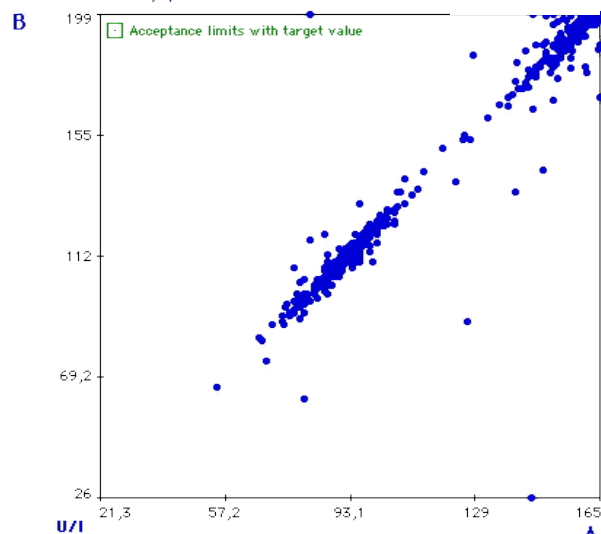
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:							

Enzymes – Situation before Standardization

KS2/03: Clinical chemical analytes in serum (wet chemistry)

Gamma-GT

All methods
Kit: All, Split: 1

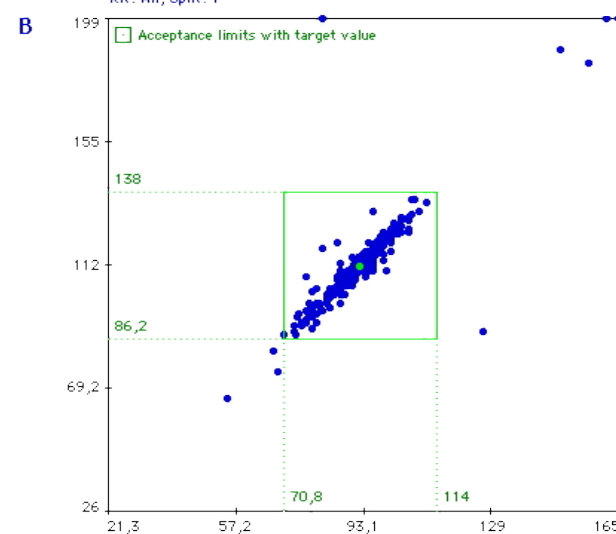


Participants (all)		685	
Target value (Sw)			
Mean	29,0	35,4	
Standard deviation	109	133	
Coefficient of variation %	26,6	26,7	

KS2/03: Clinical chemical analytes in serum (wet chemistry)

Gamma-GT

Method: 1 - Szasz, 1974 25 C
Kit: All, Split: 1

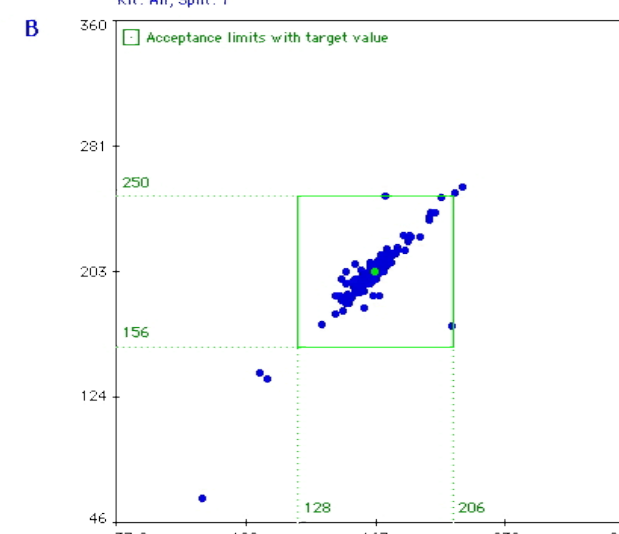


Participants (all)		359	
Target value (Sw)			
Mean	A = 92,0	B = 112	
Standard deviation	8,90	10,8	
Coefficient of variation %	9,68	9,70	

KS2/03: Clinical chemical analytes in serum (wet chemistry)

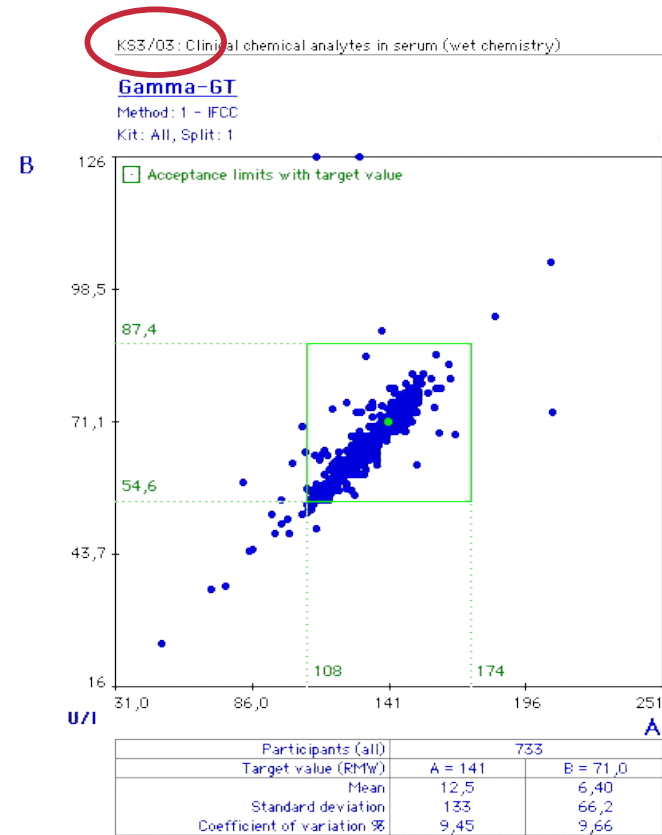
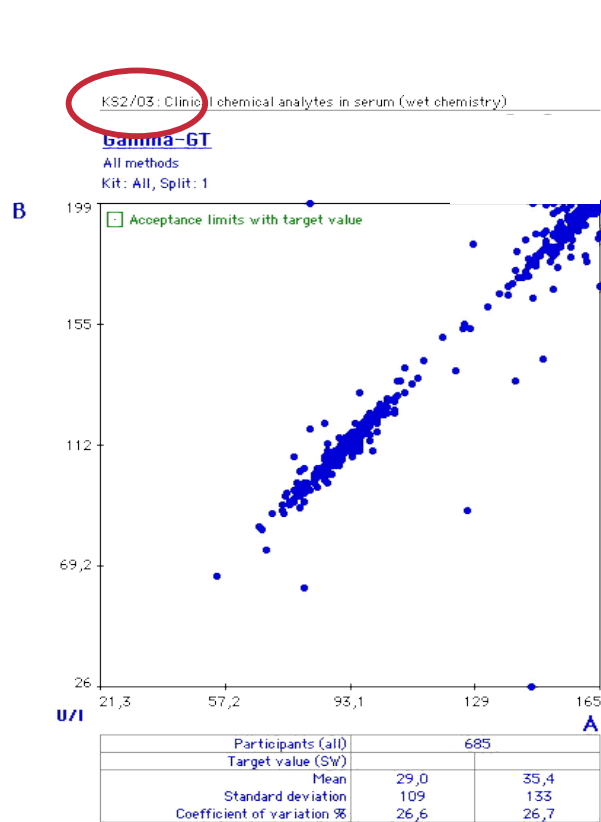
Gamma-GT

Method: 6 - IFCC, 37 C
Kit: All, Split: 1



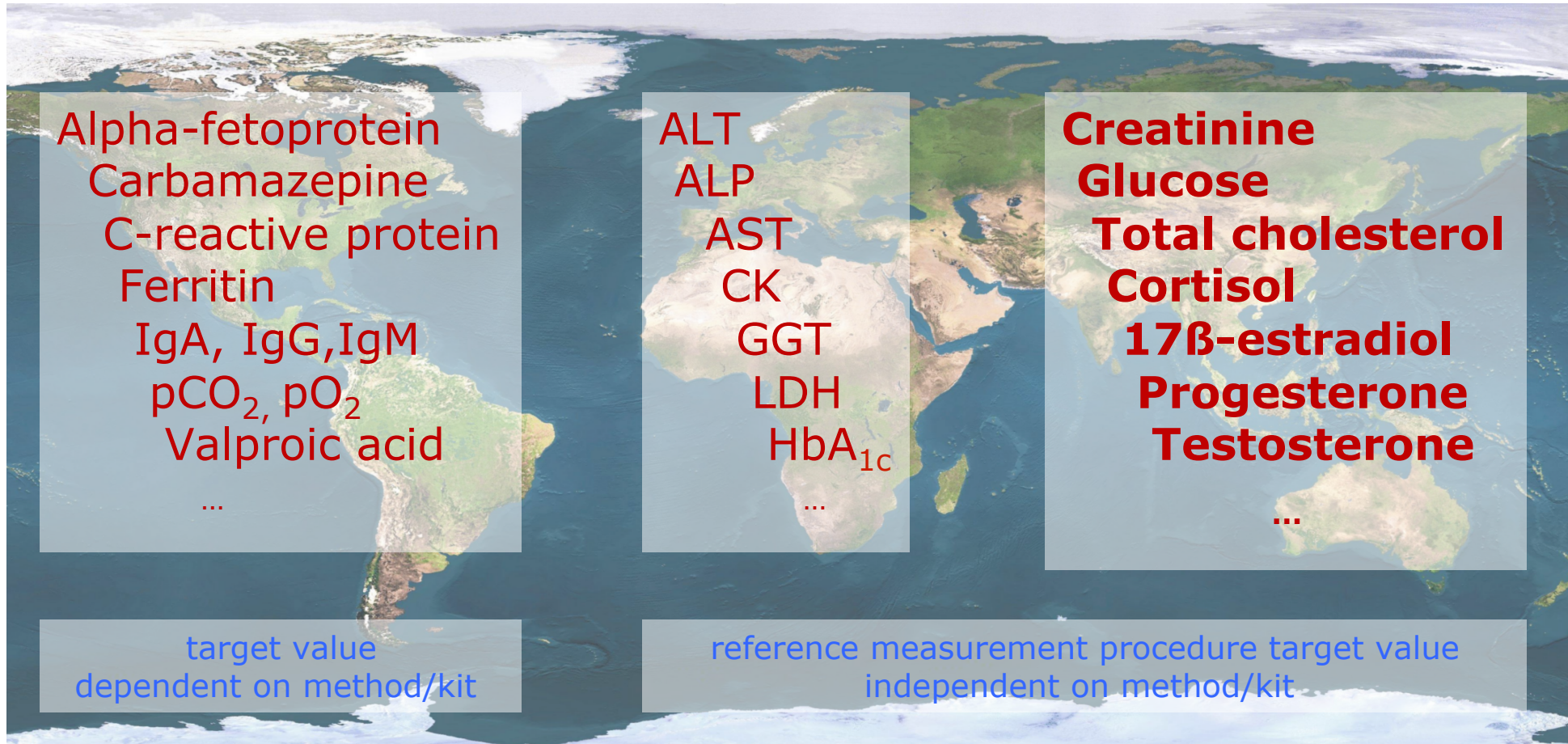
Participants (all)		152	
Target value (Sw)			
Mean	A = 167	B = 203	
Standard deviation	14,9	19,7	
Coefficient of variation %	8,94	9,75	

Enzymes – Situation after Standardization

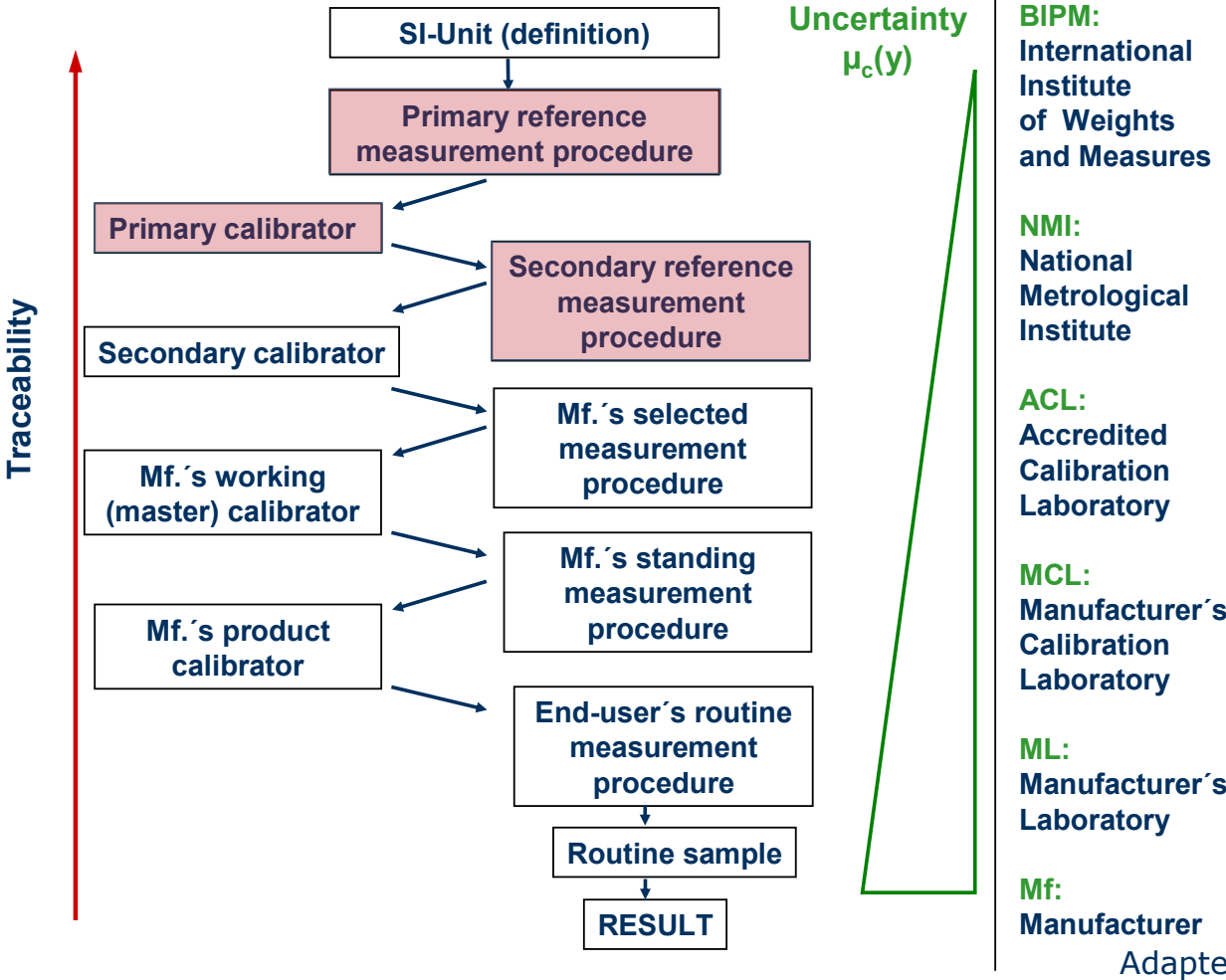


Traceability for Measurands in EQA

- present state-



Traceability in Laboratory Medicine



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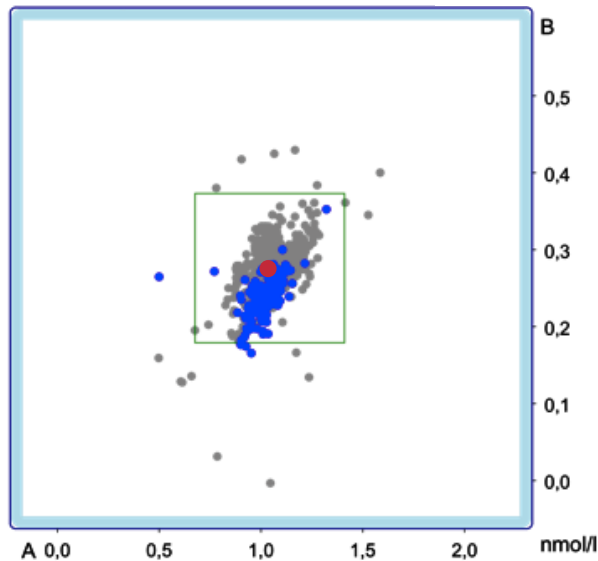
Survey ,Hormones'

HM1/16

Estradiol-17beta

Lumineszenzmessung - Kit 44

Split 1



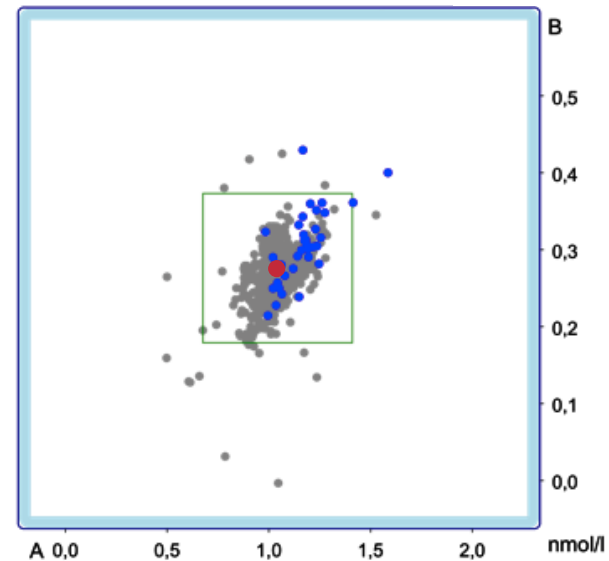
number of results		153
target value	1,04	0,276
limits	0,676 - 1,41	0,179 - 0,373
mean	1,015	0,24
standarddeviation	0,08	0,026
coefficient of variation	7,852	10,974

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



<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 accredited according to **ISO/IEC 17025** and **ISO 15195**.

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

EQA for Calibration Laboratories



		RELA - Homepage External quality control for Reference Laboratories	
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Home

Welcome

login

Registration/ Account

RELA - IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine

This site gives you all the information you will need for participating in the RELA scheme.

Time schedule for the annual surveys (may vary slightly)

Announcement: September 1

Deadline for ordering: September 30

Shipment of samples: October 15

Deadline for transmission of results: April 15 (following year)

Reporting results to participants: May 15

Publishing results on this website: June 15

RELA in progress

order RELA 2016

enter RELA 2016 results

former RELA results

✓ Choose year...

- RELA 2003
- RELA 2004
- RELA 2005
- RELA 2006
- RELA 2007
- RELA 2008
- RELA 2009
- RELA 2010
- RELA 2011
- RELA 2012
- RELA 2013
- RELA 2014
- RELA 2015

Please refer to the navigation area on the left to (for instructions see our new [RELA web manual](#))

- register or log in

- order the survey

- entering your results

- get the evaluation of past surveys

The whole RELA process is described in detail in the [IFCC-RELA-EQAS procedure manual](#).

Offered measurands:

Metabolites and substrates (META): total cholesterol, total glycerol, creatinine, uric acid, urea, glucose, total bilirubin

Electrolytes (ELEC): sodium, potassium, chloride, calcium, lithium, magnesium

Enzymes (ENZY): ALT, AP, AST, CK, LDH, GGT, amylase

Glycated hemoglobins (GLYC): HbA1c

Proteins (PROT): total protein

Hormones (HORM): aldosterone, cortisol, progesterone, testosterone, estradiol-17 β , estriol, 17-OH-progesterone

Thyroid hormones (THYR): total thyroxine (TT4), total tri-iodothyronine (TT3), free thyroxine (ft4)

Therapeutic drugs (THER): digoxin, digitoxin, theophylline

Vitamins (VITA): 25-OH-vitamin D3

www.dgkl-rfb.de:81

www.rfb.bio

EQA for Calibration Laboratories



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/ Account

RELA in progress

order RELA 2016

enter RELA 2016 results

former RELA results

Choose year... ▾

RELA 2015

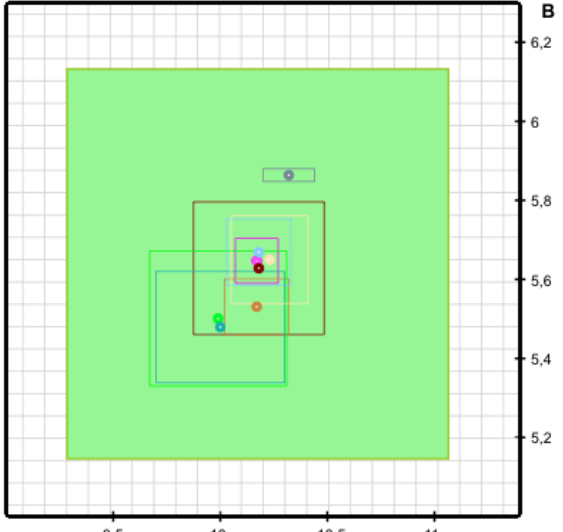
All or choose Lab ... ▾

select lab analytes full address

Testosteron ▾ show result plot

with limits of equivalence

Testosteron



limits of equivalence = $\pm 8,75\%$

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

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

EQA for Calibration Laboratories





International Federation
of Clinical Chemistry
and Laboratory Medicine



JCTLM

RELA - Homepage
External quality control for Reference Laboratories



Referenzinstitut
für Bioanalytik

RELA Home

Welcome

login

Registration/ Account

RELA In progress

order RELA 2016

enter RELA 2016 results

former RELA results

Choose year... ▼

RELA 2015

✓ All or choose Lab ...

- 001 - Referenzinstitut für Bio , Dr. C. Ritter-Sket
- 003 - Medizinische Hochschule , Dr. D. Grote-Koska
- 005 - Roche Diagnostics GmbH , Herrn Gernot Brunny
- 006 - Laboratorio Analisi Chim , CIRME-Prof. Mauro Panteg
- 008 - Physikalisch-Technische , Dr. Henrion, Dr. Rienitz
- 011 - Ref4U, Laboratory of Tox , Dr. Katleen Van Uytfangh
- 012 - Fundacion Bioquimica Arg , Raul Girardi
- 016 - Servizio di Medicina di , Ferruccio Ceriotti
- 018 - National Center for Clin , Prof. Wenxiang Chen
- 019 - Reference Material Insti , Masao Umemoto, Ph. D
- 023 - BioSystems, S.A. , Prof. D. Gella
- 024 - Children' Hospital of Wi , Stanley F. Lo, Ph.D., DA
- 025 - Deputy Director , Dr. David Ducroq
- 027 - Instand e. V. , Dr. Patricia Kaiser
- 030 - Centers for Disease Cont , Julianne Cook Botelho, P
- 038 - Haga Hospital/ Lab West , Dr. P. Franck
- 039 - Canadian EQA Laboratory , David W. Seccombe, MD, P
- 041 - Roche Diagnostics GmbH , Rolf Nagel
- 043 - Dept. Science and Biomed , CIRME-Prof. Andrea Mosca
- 046 - Clinical Enzymology Refe , Francesca Canalias
- 047 - Beijing Aerospace Genera , Chen Baorong
- 048 - Biosino Bio-Technology a , Jiang lin
- 051 - Sichuan Maccura Biotechn , Lu Lei
- 052 - Queen Beatrix Hospital , Cas Weykamp
- 054 - Shanghai Center for Clin , Ju Yi
- 055 - Reference Laboratory , Chi Shan
- 061 - Mindray Standardization , Wang Yingguo
- 063 - Beijing Leadman Biochemi , Dr. Ma Zhiyuan
- 065 - Clinical Laboratory of , Prof. Xianzhang Huang
- 073 - Department of clinical I , Runqing Mu
- 074 - Center of Laboratory Med , Dr. Huimin Wang
- 075 - 3V Reference Laboratory , Wang Zejia
- 077 - Department of Laboratory , Rui Zhang

Testosteron ▼ show result plot

with limits of equivalence

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B

6.2

6

5.8

5.6

5.4

5.2

e.u. - expanded uncertainty

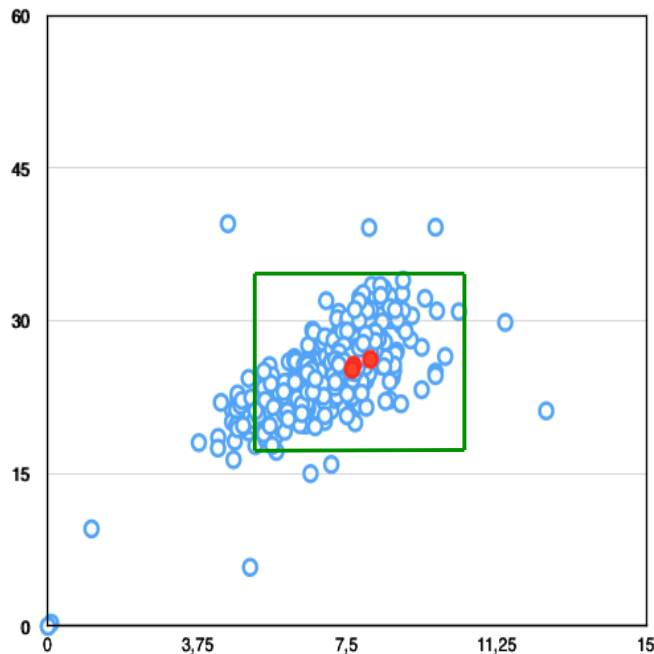
www.rfb.bio




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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.