



Implementing Traceability in EQAS

Jonathan Middle, PhD

UK NEQAS Organiser 1987 – 2009

Member IFCC C-TLM

www.jgmaq.co.uk drjgmiddle@gmail.com



Editorial **Mauro Panteghini**

Application of traceability concepts to analytical quality control may reconcile total error with uncertainty of measurement

Table 1 Mandatory requirements for the applicability of External Quality Assessment (EQA) results to evaluation of the performance of individual laboratories.

Feature	Aim
EQA material values assigned with reference procedures by an accredited reference (calibration) laboratory	To check the measurement uncertainty of participating laboratories against the reference measurement systems
Proved commutability of EQA material(s)	To allow transferability of participating laboratory performance to patient samples
Definition of the clinically allowable uncertainty of measurement	To verify the suitability of laboratory measurements in clinical setting

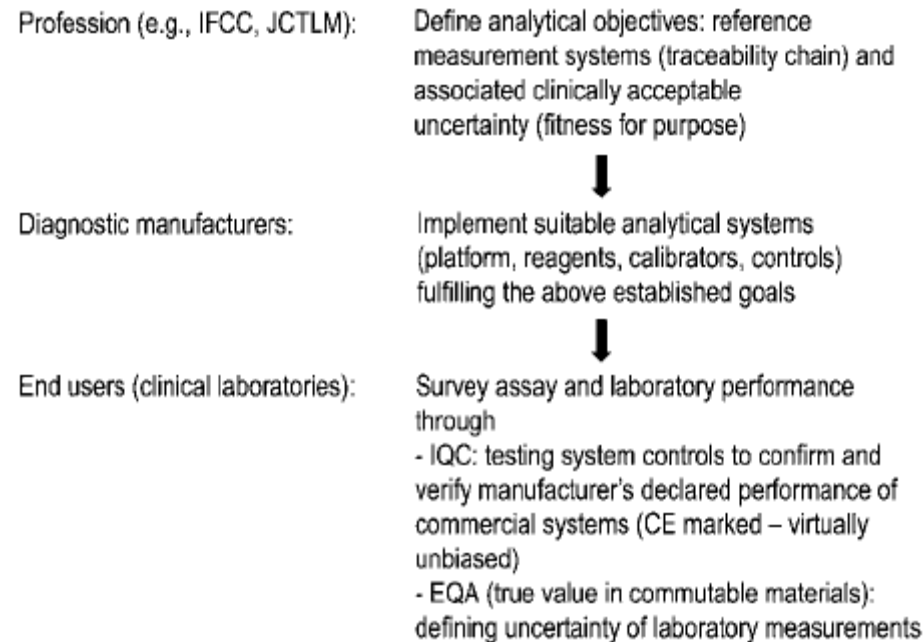
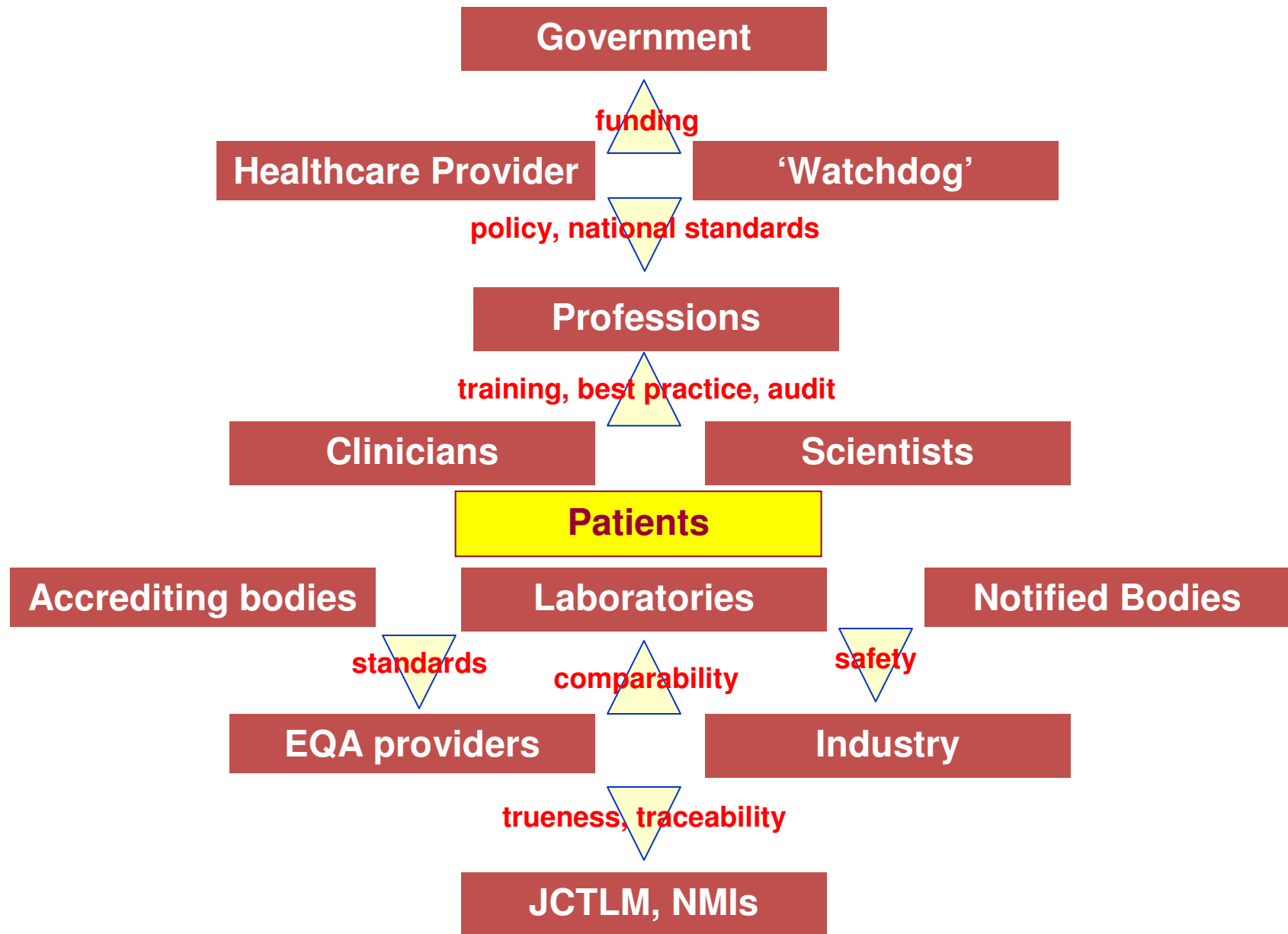


Figure 2 Steps of the process and different responsibilities for implementing traceability of patient results and defining their uncertainty.

We operate in a complex and multi-faceted environment where there are many important 'triangular relationships'.

But we must always remember that it is the patient who is central!



Fundamentals - 1

- What do patients think?

“Surely, every instrument in every laboratory should get the same result for any given analyte in my sample, as they are measuring the same thing?”

How can they possibly be different?

It is inconceivable that you highly paid professionals with all your fancy analysers and computers, could possibly allow this to happen!

How can doctors manage to diagnose and treat us with this chaotic and scandalous situation?

Why aren't you doing something about it?

Fundamentals - 2

- What do doctors and nurses think?

“Our lab is great – they get the results back to us really quickly and they tell us if they are normal or not.

If we need help with choosing which tests to do or understanding what the results mean, they are always there for us.

It is a big headache though, when the normal ranges have to change if they buy a new instrument, or the manufacturer changes the assay.

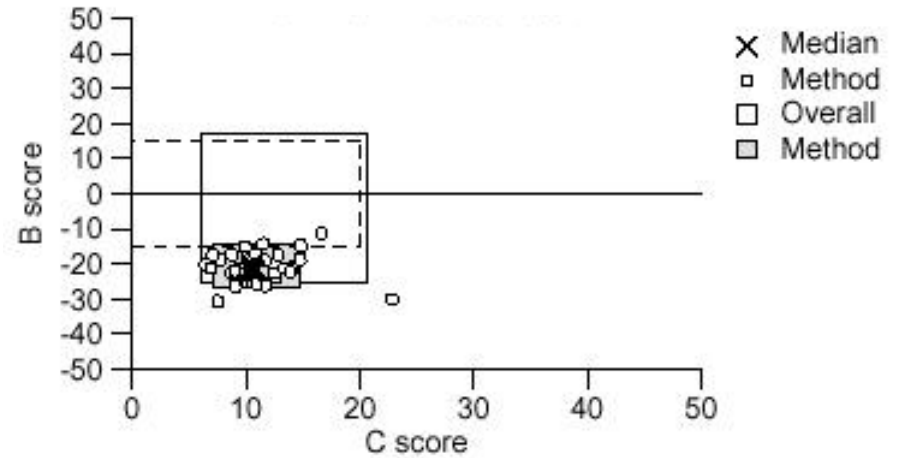
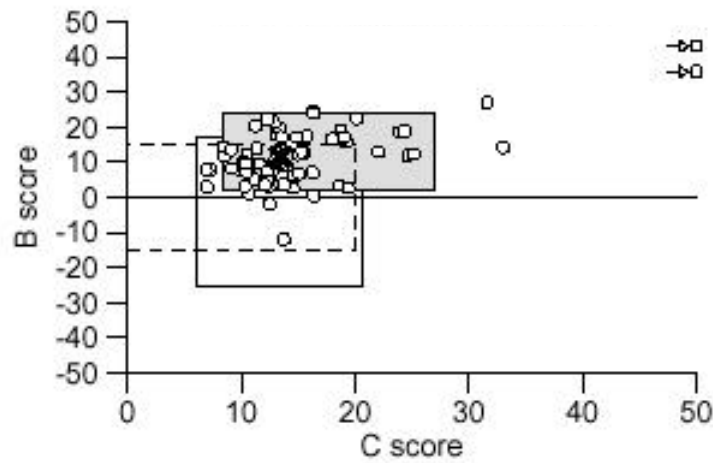
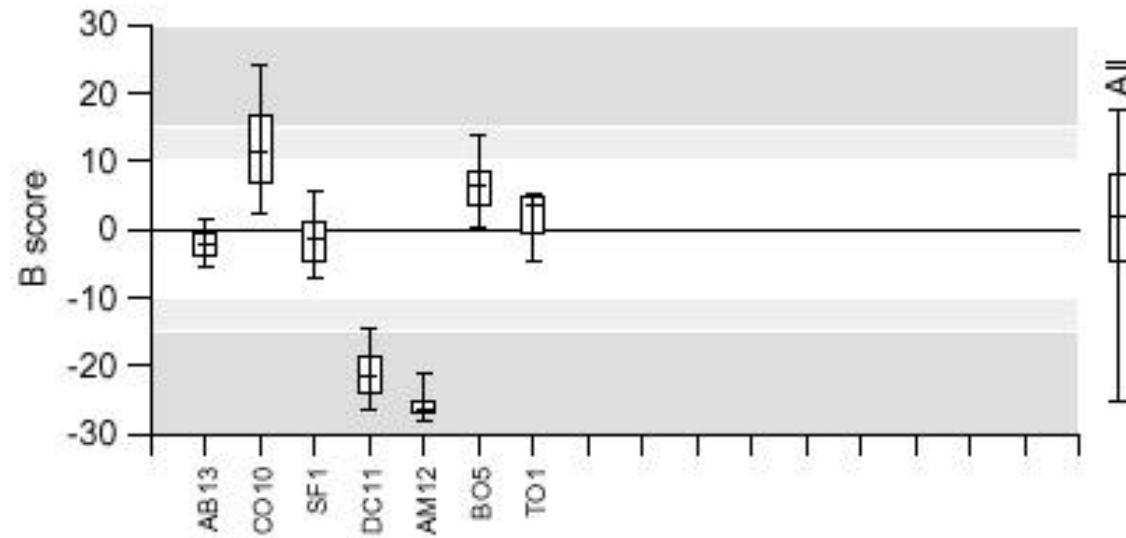
And it always causes us grief when a patient has come from another hospital and their previous results are really different.”

Why are methods different? - 1

- Because we allow them to be!
- It is a free market and there is no over-arching organisation that can enforce global quality standards of accuracy and comparability
- It doesn't really matter anyway, as labs have their own reference ranges and doctors soon get used to them
- Lab results are only a small part of the overall clinical process, and doctors will ignore any results that don't fit the clinical picture

Is this an acceptable view?

UK NEQAS for Oestradiol – 2009 Annual Review



Why are methods different? - 2

- 'Master' Calibration?
- Analytical Specificity?
- 'Adjustments' to 'compensate' for poor analytical quality?
- Meeting customer expectations?
- Patent issues?
- 'Marketing' issues?

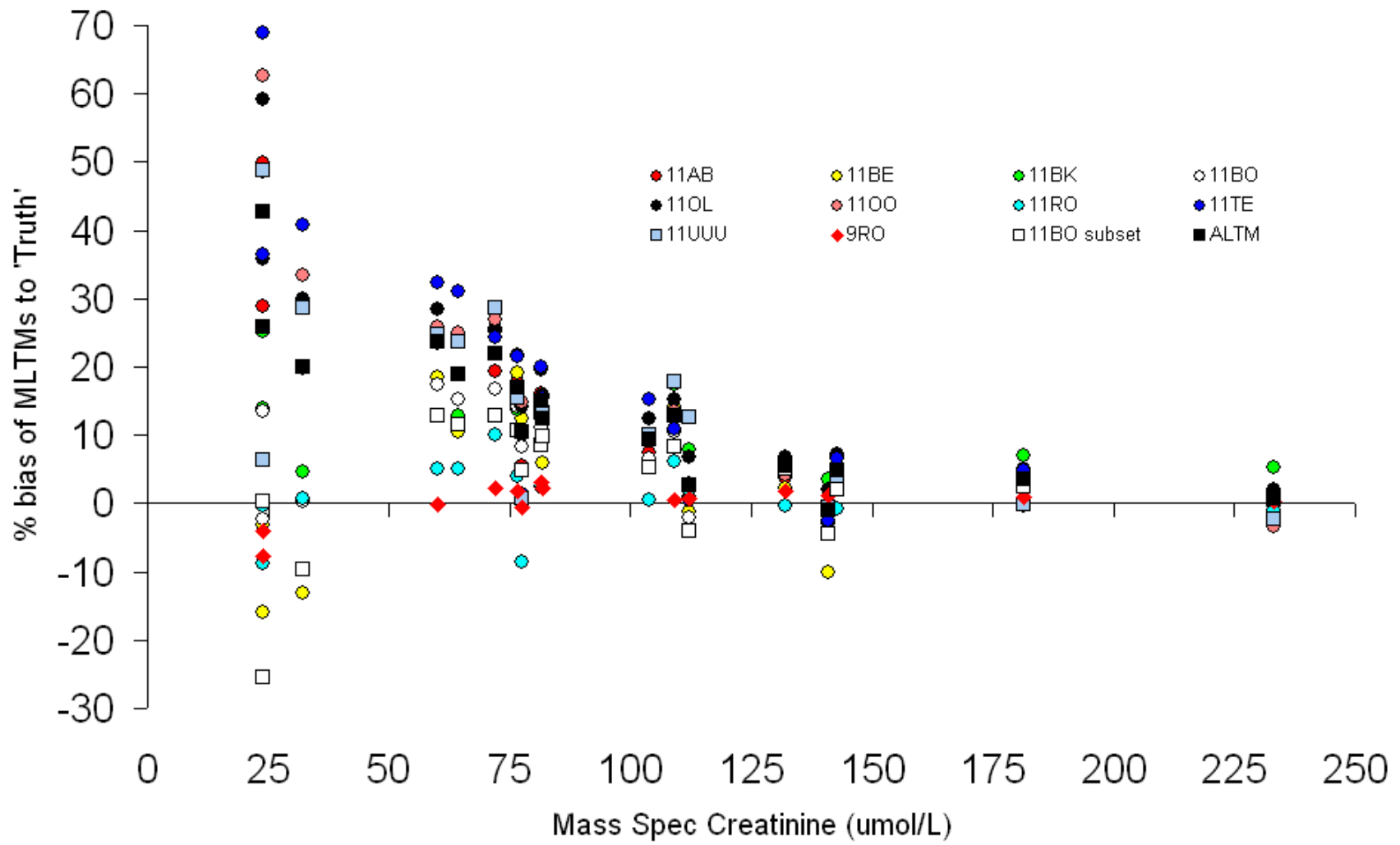
These issues beg the question:

“Why can't the diagnostic industry collaborate in terms of standardisation and metrological traceability but compete on design, speed and cost?”

So, if you had kidney disease, which method would you want your creatinine to be assayed by?

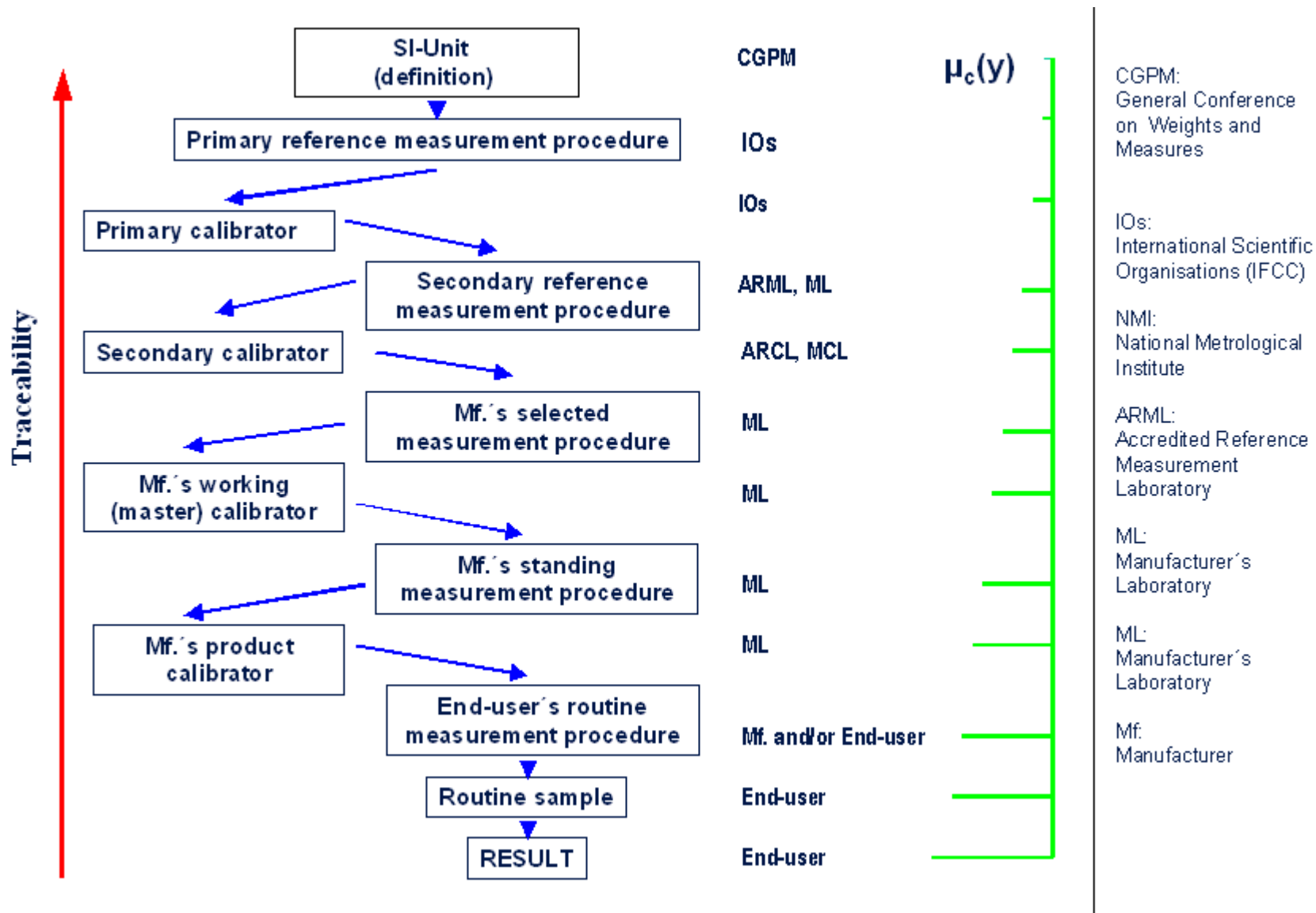
UK NEQAS for Clinical Chemistry Creatinine Bias to IDMS exercise

(with thanks to Finlay MacKenzie)



You know this diagram by now!

The Traceability Chain



**But it is very important to
remember this :-**

Traceability and Specificity

<http://www.ifcc.org/ejifcc/vol13no3/130301002n.htm>

An inevitable precondition for the establishing of traceable results to calibrators and control materials is the specificity of the measurement procedures applied. **Results of measurement cannot be traceable when the procedure applied partially detects components which are not consistent with the definition of the measurand.**

The complete traceability chain is valid only for those measurable quantities that can have a value expressed in SI units. When primary or secondary calibrators are not available, the traceability chain for many measurands in laboratory medicine ends at a lower level, e.g. at the manufacturer's standing measurement procedure.

Professor Lothar Siekmann, Bonn

DHEAS interference in Testosterone assays

Sample identifiers	319A	319B	319C				
DHEAS added ($\mu\text{mol/L}$)	0.00	10.07	20.14				
Assayed DHEAS ($\mu\text{mol/L}$)	4.5	13.8	24.8				
n	Median testosterone (nmol/L) (inter-quartile range) [2-way paired t-test p value]			slope	intcpt	r^2	
All laboratories	230	1.60 (1.40-1.80)	2.00 (1.67-2.50)	2.20 (1.70-3.60)	0.0298	1.63	0.9643
Major methods							
Roche E170 Modular	46	1.50 (1.40-1.70)	2.60 (2.46-2.80) [p<0.0001]	3.80 (3.60-4.10) [p<0.0001]	0.1142	1.48	0.9994
Abbott Architect	18	1.85 (1.77-1.90)	2.96 (2.78-3.12) [p<0.0001]	3.99 (3.80-4.11) [p<0.0001]	0.1063	1.86	0.9994
Roche Elecsys	22	1.40 (1.30-1.50)	2.45 (2.24-2.59) [p<0.0001]	3.50 (3.30-3.69) [p<0.0001]	0.1043	1.40	1.0000
Beckman Access / Dxl	18	1.65 (1.49-1.70)	2.35 (2.15-2.50) [p<0.0001]	2.99 (2.77-3.10) [p<0.0001]	0.0665	1.66	0.9991
DPC Immulite 2000 / 2500	18	1.65 (1.45-1.89)	1.66 (1.50-1.99) [NS]	1.80 (1.50-1.98) [NS]	0.0077	1.62	0.8218
Bayer Advia Centaur	80	1.71 (1.60-1.91)	1.79 (1.53-1.95) [NS]	1.80 (1.60-2.03) [p=0.013]	0.0047	1.72	0.8620

Traceability and Specificity - 2

It follows that a method that is not specific for the measurand cannot be properly calibrated.

A nonspecific assay has to have its calculation algorithm 'adjusted' so as to give 'expected values'.

Such adjustments are revealed by recovery exercises (see later)

Traceability and EQA

Assertion - #1

Only properly designed independent, objective and educational EQA has the ability continuously to monitor the state of the art of clinical laboratory analysis in a way that enables improvements to be made in trueness and comparability

Assertion - #2

The diagnostic industry will not address problems of lack of trueness and comparability identified by EQA, unless companies have complete confidence in the materials used and the reliability of target values.

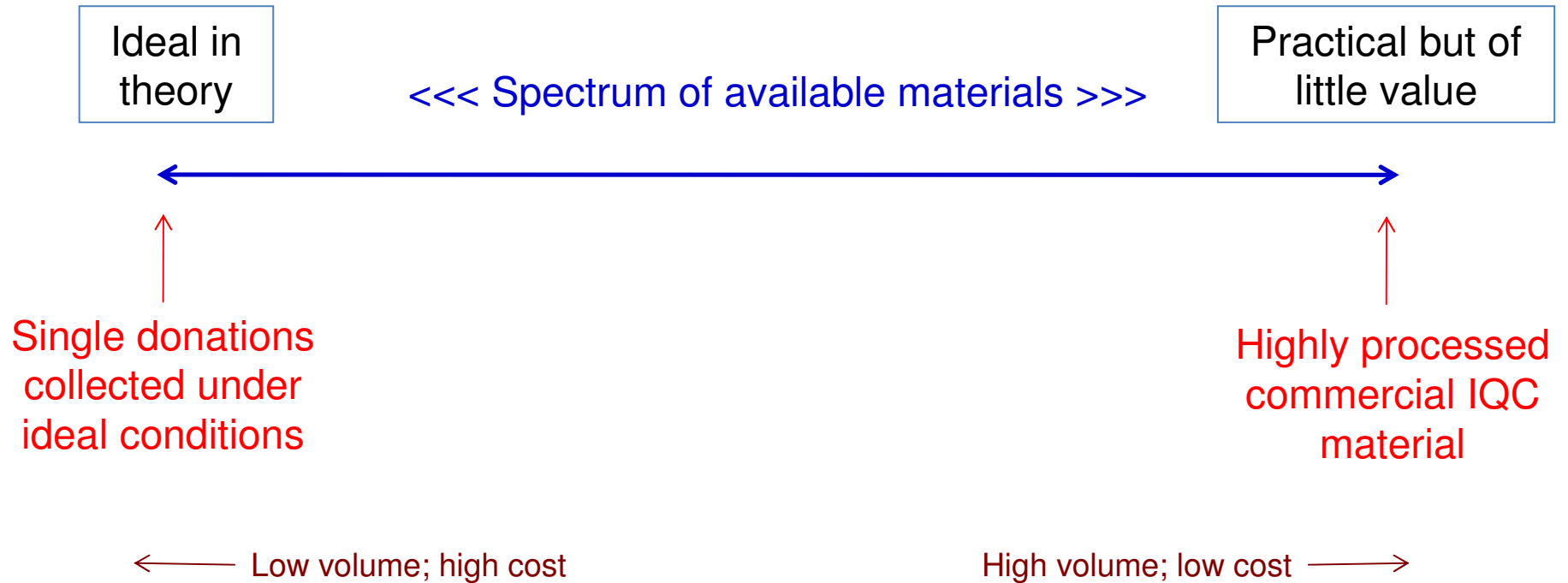
Assertion - #3

But ... The professional bodies associated with laboratory medicine **must** provide strong leadership in generating analytical and clinical quality specifications with which industry are required to comply.

Good EQA Design

- Clinically important analyte concentrations
- Materials as close as possible to the patient matrix
- Minimal processing (freeze-thaw, spiking)
- Like-with-like pooling (gender, age, analyte concentration)
- Sufficient number of samples per distribution
- Sufficient number of distributions per annum / cycle
- Easy to understand statistical analysis and reporting
- Strong lines of communication (participants & industry)
- Accreditation to ISO 17043 or equivalent

EQA Materials



EQA Materials – the best compromise?

- Single donations collected by the National Blood Service
- Each donation analysed for key analytes
- Donations pooled like-with-like (gender, age, analyte concentration etc)
- Minimal freeze-thawing
- ‘Spiking’ with pure analyte when necessary (under conditions of minimal matrix disturbance by the carrier solvent)
- Sufficient volume to ensure repeat distribution over time
- Careful long term storage in properly maintained freezers

EQA Target Values

- **Consensus means derived from participants' data**
 - **All-laboratory Trimmed Mean (ALTM)** - results from all all participants
 - **Grouped Laboratory Trimmed Mean (GLTM)** - results from a rational grouping of methods based, for example, on a single measurement principle
 - **Method Laboratory Trimmed Mean (MLTM)** - results from a single method
- **Externally derived**
 - **Weighed in value (eg for drugs)**
 - **Value from a method or group of methods known to be unbiased to the Reference Method**
 - **Assigned Reference Method value from a member of a reference laboratory network**

EQA Target Values

- **ALTM / GLTMs**
 - Reflect the state of the art
 - Provide an overall means of assessing variability amongst methods
 - Reveal changes in individual methods
 - Encourage improvements in comparability
- **MLTMs**
 - Do not encourage improvements in comparability
 - Allow method-specific changes to go un-noticed
- **Externally derived target values**
 - Must be validated by other means to be accepted
 - Must be traceable to a reference measurement system if they are used to determine trueness

The Ideal EQA Target Value

Assigned value obtained for each material distributed, from an established reference method laboratory – registered with JCTLM, member of a network and participant in RELA

Pros

- Independent of routine methodological problems and participants' data
- No argument with validity

Cons

- Cost
- Availability
- Manufacturers may elect to standardise on the EQA target

Regularly reporting Reference Method values alongside consensus values



Birmingham Quality

UKNEQAS for Glycated Haemoglobins

Laboratory :

Distribution : 342

Date : 07-Nov-2010

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Analyte : HbA1c [IFCC] (mmol/mol)

Spec. Pool Pool description / Treatments / Additions

342A 501 Diabetic donor volunteer
 342B 502 Diabetic donor volunteer
 342C 503 Diabetic donor volunteer

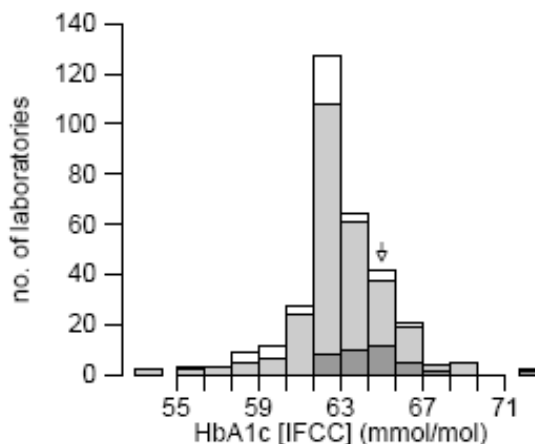
- All methods
- Derived
- Tosoh G8 [5TO8]

Your A score is 0 ● ↔
 Your B score is +3.8 ● ↔
 Your C score is 1.4 ● ↔

The A limit is 200
 The B limit is +/- 5.0
 The C limit is 5.0

Specimen : 342A

	n	Mean	SD	CV(%)
Analytical	42	62.4	2.2	3.5
Menarini HA 8160 [4BN3]	14	61.6	2.3	3.7
Siemens DCA Vantage [4TE8]	12	62.6	2.6	4.1
Tosoh G7 [4TO5]	10	63.0	1.7	2.6
Derived	278	63.3	1.8	2.8
Bayer DCA 2000 [5TE3]	49	63.2	2.1	3.3
BioRad D-10 [5BX7]	6	65.0	2.5	3.8
BioRad Variant (II) [5BX4]	24	63.8	2.1	3.3
Menarini HA 8160 [5BN3]	94	62.7	1.4	2.2
Primus [5GM1]	9	63.3	1.7	2.6
Siemens DCA Vantage [5TE8]	24	62.7	2.1	3.4
Tosoh G7 [5TO5]	17	64.0	1.5	2.4
Tosoh G8 [5TO8]	36	64.5	1.2	1.9



Your result 65
 Target value (GLTM) 63.3
 Your specimen:
 %bias +2.7 ◆
 transformed bias 0
 Accuracy Index 0
 2ndary IFCC value 62.2
 DCCT comp. value 7.85
 ALTM (for information only) 63.19

Group mean

Method mean

Reference values

ALTM



Birmingham Quality

UKNEQAS for Glycated Haemoglobins

Distribution : 342

Date : 07-Nov-2010

Laboratory :

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Analyte : HbA1c [DCCT] (%)

Spec. Pool Pool description / Treatments / Additions

342A	501	Diabetic donor volunteer
342B	502	Diabetic donor volunteer
342C	503	Diabetic donor volunteer

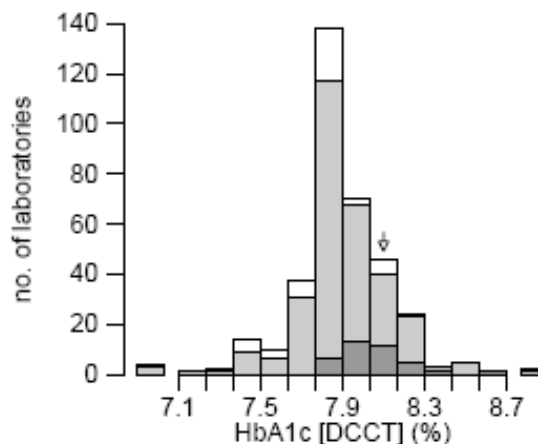
- All methods
- Analytical
- Tosoh G8 [4TO8]

Your A score is 83 ● ↗
 Your B score is +2.7 ● ↔
 Your C score is 1.1 ● ↔

The A limit is 200
 The B limit is +/- 5.0
 The C limit is 5.0

Specimen : 342A

	n	Mean	SD	CV(%)
Analytical	309	7.93	0.18	2.2
Bayer DCA 2000 [4TE3]	53	7.91	0.20	2.6
BioRad D-10 [4BX7]	12	7.94	0.33	4.1
BioRad Variant (II) [4BX4]	27	7.98	0.19	2.4
Menarini HA 8160 [4BN3]	101	7.88	0.14	1.7
Primus [4GM1]	9	7.93	0.17	2.1
Siemens DCA Vantage [4TE8]	27	7.85	0.20	2.5
Tosoh G7 [4TO5]	18	7.99	0.15	1.9
Tosoh G8 [4TO8]	37	8.05	0.12	1.5
Derived	40	7.85	0.21	2.7
Menarini HA 8160 [5BN3]	14	7.77	0.25	3.2
Siemens DCA Vantage [5TE8]	12	7.86	0.26	3.3



Your result 8.1
 Target value (GLTM) 7.93
 Your specimen: %bias +2.2 ◆
 transformed bias +73
 Accuracy Index 73
 2ndary IFCC value 62.2
 DCCT comp. value 7.85
 ALTM (for information only) 7.91

Group mean

Method mean

Reference values

ALTM

**Using the reference method to
assign values to a small number of
EQA materials, distributed in
special exercises**



Birmingham Quality

UKNEQAS for Steroid Hormones

Laboratory : **10167**

Distribution : **339**

Date : 15-Apr-2008

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Analyte : Cortisol (nmol/L)

Spec. Pool Pool description / Treatments / Additions

339A C353 Normal serum [F]
 339B C354 Normal serum [F]
 339C C355 Normal serum [F]
 339D C420 Normal serum [M]
 339E C421 Normal serum [F]

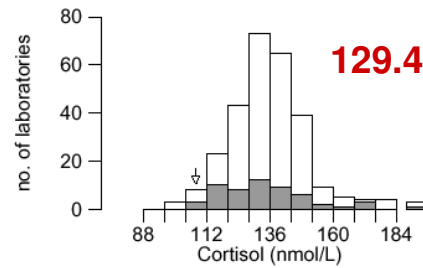
□ All methods
 ■ DPC Immulite 2000

Your A score is 117 ⚡
 Your B score is -10.7 ⚡
 Your C score is 7.7 ↔

The A limit is 200
 The B limit is +/- 10.0
 The C limit is 15.0

Specimen : 339A

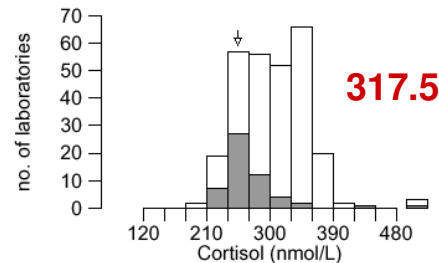
	n	Mean	SD	CV(%)
All methods	279	136	13	9.5
Abbott Architect	23	122	8	6.6
Bayer Advia:Centaur	76	144	13	9.2
Beckman Access	28	130	11	8.3
DPC Immulite 2000	55	134	17	12.4
Roche Elecsys	81	136	8	5.6
E170 Modular	61	136	7	5.3



Your result 112
 Target (ALTM) 135.7
 Your specimen:
 %bias -17.4 ⚡
 transformed bias -177
 Accuracy Index 177
 Your method mean 134.0
 DPC Immulite 2000

Specimen : 339B

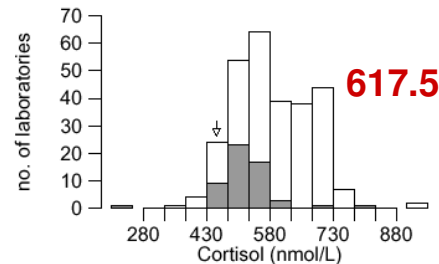
	n	Mean	SD	CV(%)
All methods	278	303	48	15.8
Abbott Architect	23	268	19	7.0
Bayer Advia:Centaur	76	310	26	8.4
Beckman Access	28	251	27	10.7
DPC Immulite 2000	54	267	29	10.9
Roche Elecsys	81	348	16	4.7
E170 Modular	61	348	15	4.3



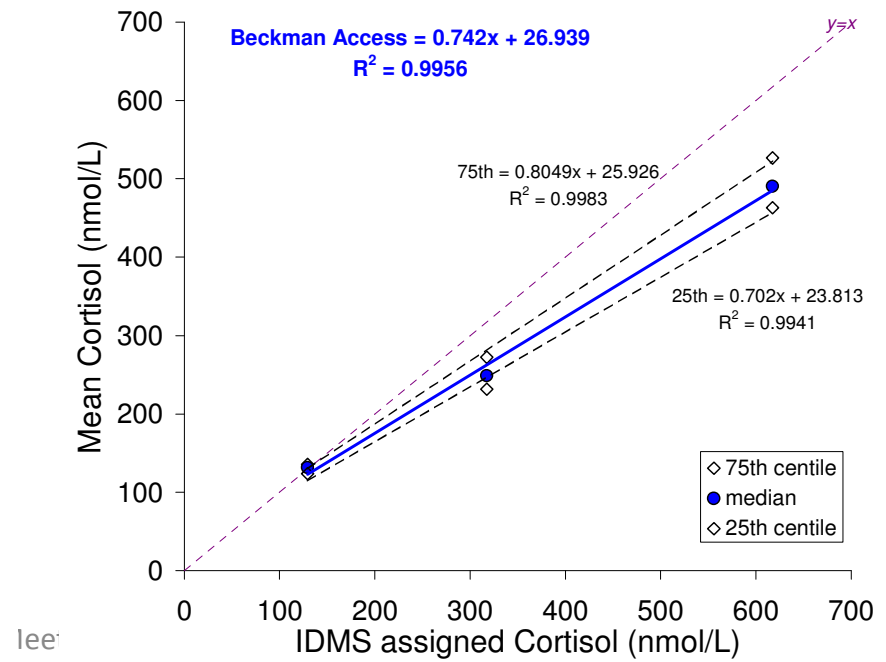
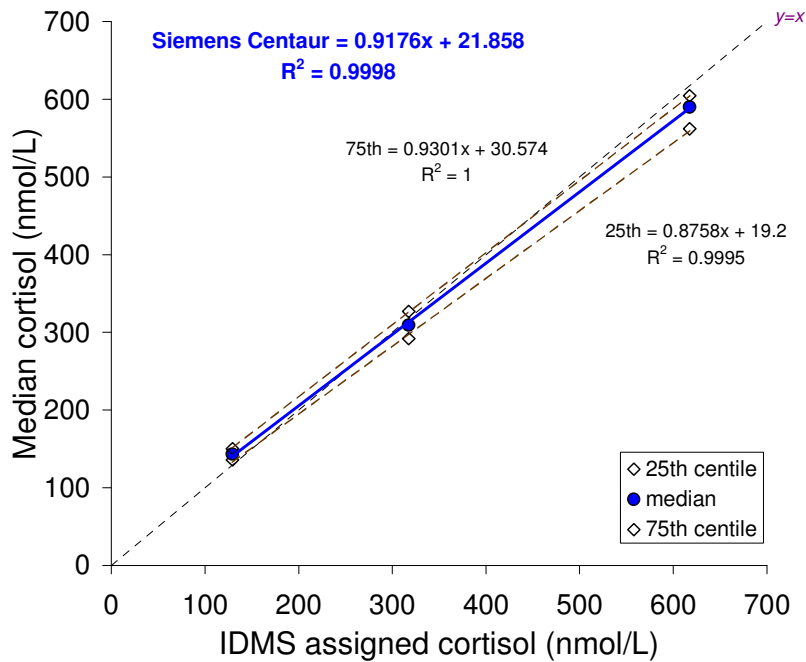
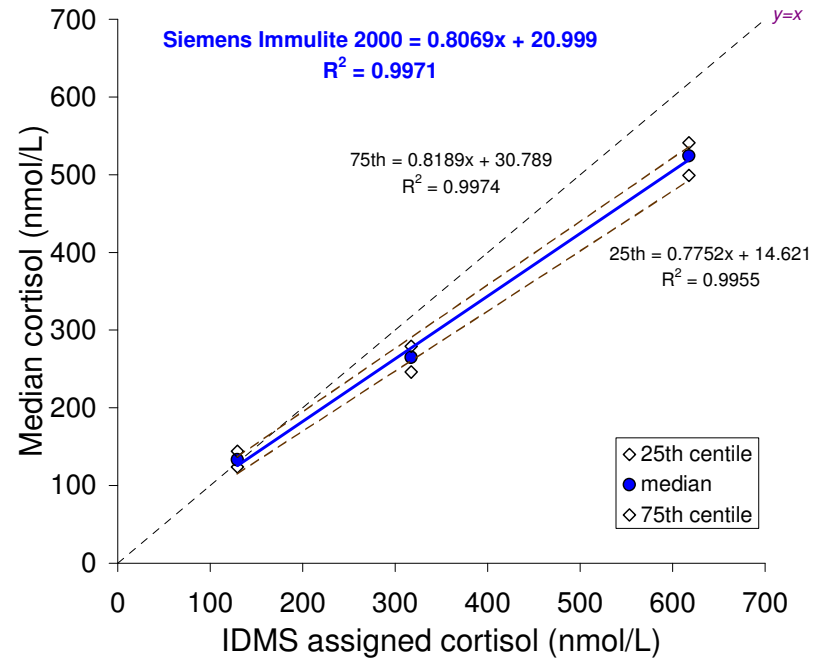
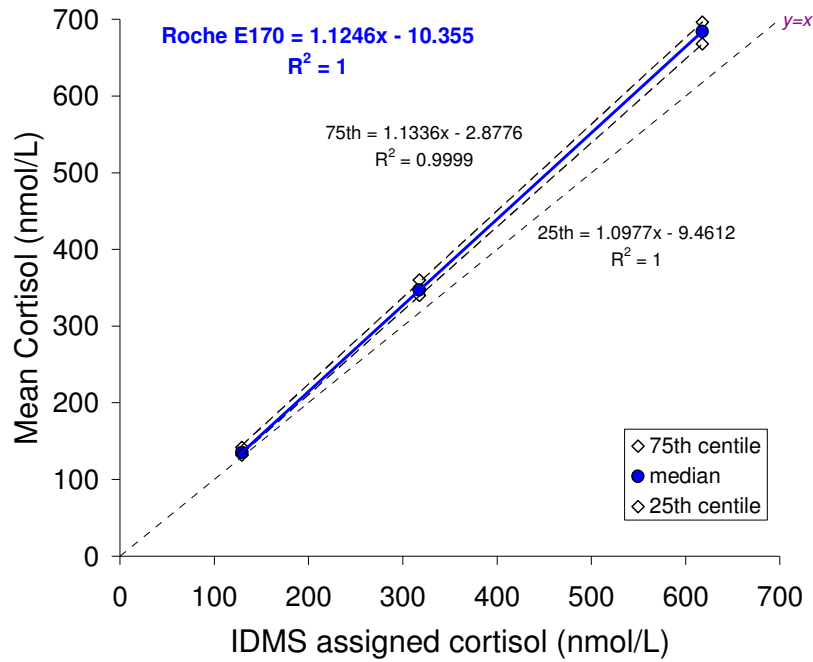
Your result 243
 Target (ALTM) 303.3
 Your specimen:
 %bias -19.9 ⚡
 transformed bias -235
 Accuracy Index 235
 Your method mean 267.1
 DPC Immulite 2000

Specimen : 339C

	n	Mean	SD	CV(%)
All methods	279	586	92	15.8
Abbott Architect	23	508	45	8.9
Bayer Advia:Centaur	76	587	38	6.5
Beckman Access	28	492	47	9.5
DPC Immulite 2000	55	519	40	7.6
Roche Elecsys	81	683	26	3.8
E170 Modular	61	684	24	3.6

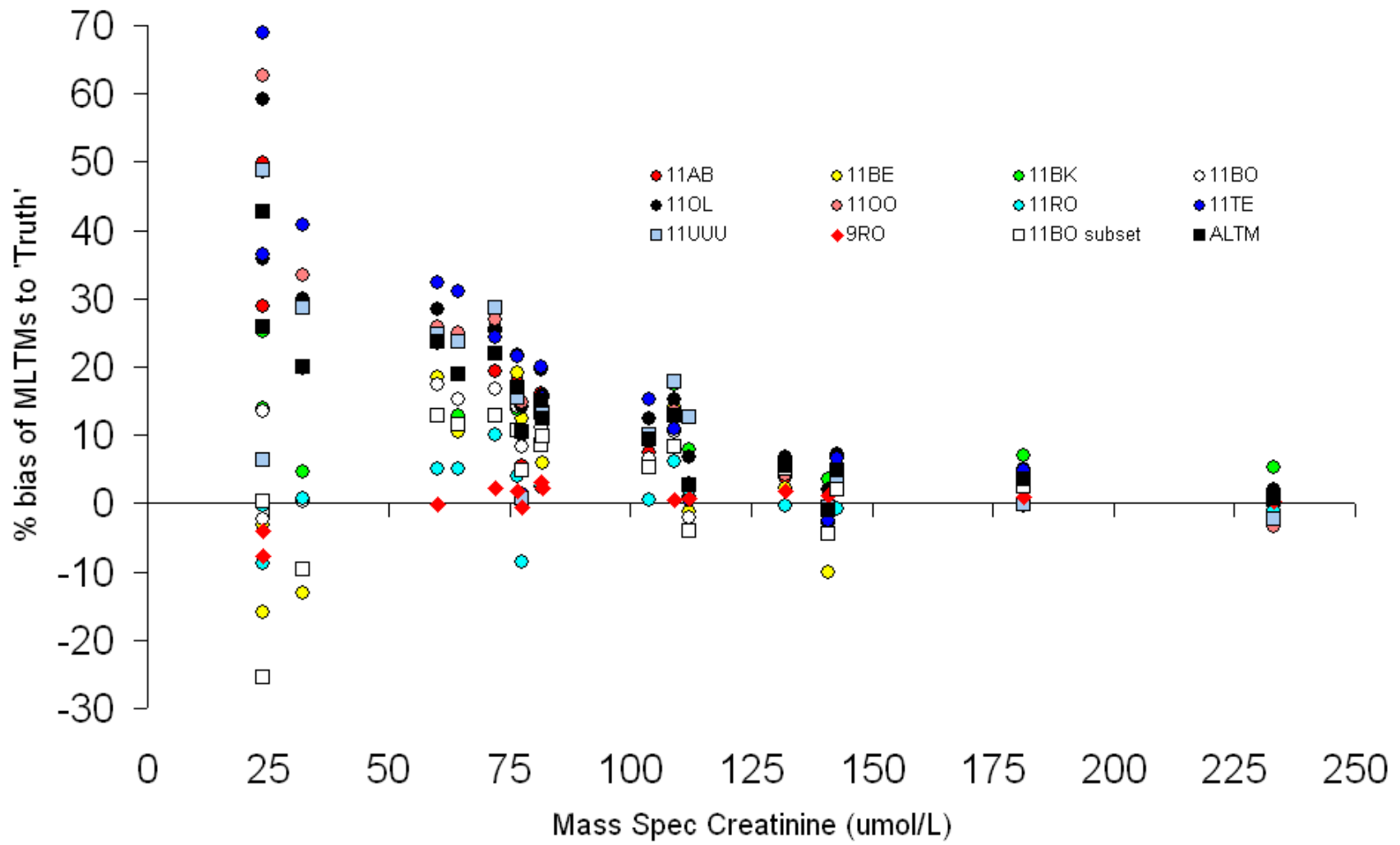


Your result 480
 Target (ALTM) 585.6
 Your specimen:
 %bias -18.0 ⚡
 transformed bias -187
 Accuracy Index 187
 Your method mean 519.3
 DPC Immulite 2000



UK NEQAS for Clinical Chemistry Creatinine Bias to IDMS exercise

(with thanks to Finlay MacKenzie)



Validating the Target Value

Perhaps the most effective way of examining the accuracy of a consensus target value is to perform regular recovery exercises, where a low endogenous analyte concentration pool is spiked with linearly related amounts of pure analyte, and all are distributed to participants at a single distribution.

Here are some examples which show ALTMs that are adequate and those that are not, and also reveal the wide variation seen in individual methods, some of which display concentration-related recovery.

Recovery studies - 1

UK NEQAS for Oestradiol
(separate Main & High-Level Schemes)

DIST	ANAL	SPEC	ADDED	ALTM	RECOV	AB13		AB7		AM12		BO5		CO10		DC11		SF1		
				<i>n=303</i>		<i>n</i>	<i>54</i>	<i>3</i>	<i>10</i>	<i>82</i>	<i>67</i>	<i>18</i>	<i>21</i>							
							mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec
354	E2	354A	0	98.7			100		129		96		92		110		85		99	
354	E2	354B	167	229.9	78.6		241	84.2	263	80.4	174	46.6	239	88.0	249	83.3	167	49.6	233	80.3
354	E2	354C	334	376.8	83.3		383	84.6	425	88.6	259	48.8	409	94.9	394	85.1	288	61.0	379	83.9
354	E2	354D	668	701.2	90.2		674	85.9	744	92.2	452	53.3	772	101.8	760	97.4	564	71.7	690	88.6
354	E2	354E	1336	1392.2	96.8		1285	88.6	1390	94.4	845	56.1	1576	111.1	1544	107.4	1160	80.5	1319	91.3
					87.2			85.8		88.9		51.2		98.9		93.3		65.7		86.0
DIST	ANAL	SPEC	ADDED	ALTM	RECOV	AB13		AB7		AM12		BO5		CO10		DC11		SF1		
				<i>n=120</i>		<i>n</i>	<i>20</i>	<i>3</i>	<i>7</i>	<i>31</i>	<i>33</i>	<i>15</i>	<i>10</i>							
							mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec
354	E2HI	354A	0	331.3			326		383		296		349		378		227		297	
354	E2HI	354B	3167	3412.6	97.3		3383	96.6	3459	97.1	2285	62.8	3717	106.3	3669	103.9	2812	81.6	3256	93.4
354	E2HI	354C	6334	6227.7	93.1		6349	95.1	6422	95.3	4266	62.7	6221	92.7	7034	105.1	5399	81.7	6075	91.2
354	E2HI	354D	12668	12500.4	96.1		12610	97.0	13600	104.3	8001	60.8	12573	96.5	13080	100.3	12062	93.4	12984	100.2
					95.5			96.2		98.9		62.1		98.5		103.1		85.6		94.9

Recovery studies - 2

UK NEQAS for Testosterone
(separate Male & Female matrices)

DIST	ANAL	SPEC	ADDED	ALTM	RECOV	AB13		AM12		B05		C010		DC11		FA1		MS2		SF1		
				<i>n=268</i>		<i>n</i>	<i>31</i>	<i>7</i>	<i>80</i>	<i>72</i>	<i>10</i>	<i>4</i>	<i>10</i>	<i>27</i>								
							mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec
354	FTES	354A	0	0.9			1.2		0.6		0.8		1.1		0.8		0.7		0.5		1.0	
354	FTES	354B	2.6	2.9	77.2		3.3	79.6	2.0	55.4	2.5	66.3	3.3	84.6	3.2	91.0	2.5	69.8	3.1	98.1	3.0	76.7
354	FTES	354C	5.2	5.0	77.7		5.7	84.9	3.8	60.7	4.5	72.2	5.1	76.8	5.2	83.9	4.7	77.9	5.7	99.1	5.1	77.5
					77.4			82.2		58.1		69.2		80.7		87.4		73.9		98.6		77.1
DIST	ANAL	SPEC	ADDED	ALTM	RECOV	AB13		AM12		B05		C010		DC11		FA1		MS2		SF1		
				<i>n=268</i>		<i>n</i>	<i>36</i>	<i>7</i>	<i>84</i>	<i>78</i>	<i>23</i>	<i>3</i>	<i>7</i>	<i>28</i>								
							mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec	mean	rec
354	MTES	354A	0	8.9			9.7		7.1		8.9		8.6		8.7		8.5		9.4		9.2	
354	MTES	354B	12.1	20.7	97.9		21.5	97.5	18.3	92.6	20.6	96.6	21.2	104.9	18.3	79.8	20.1	96.0	21.0	95.9	21.1	98.3
354	MTES	354C	24.2	31.7	94.3		34.0	100.2	30.4	96.4	31.9	94.9	31.0	92.8	27.1	76.1	28.9	84.3	33.0	97.5	33.5	100.4
					96.1			98.9		94.5		95.8		98.8		78.0		90.1		96.7		99.4

Role of Industry

Industry has a crucial role in the implementation of traceability!

- Openness and transparency with respect to the science of their assay systems
- Full engagement with established reference measurement systems through JCTLM, only using the highest order standards and employing reference laboratories that are collaborating in networks and participating in IFCC RELA
- Co-operation and funding assistance in programmes which prepare panels of single donation material with reference method assigned values, for the assessment of method trueness, and publishing their method's data in the IFU
- Full engagement with and participation in educational EQA programmes, so that changes in performance are immediately identified and acted upon

CERTIFICATE OF ANALYSIS

ERM® - DA451/IFCC

HUMAN SERUM					
Cortisol concentration in serum No.	Certified value ¹ nmol/L	Uncertainty ² nmol/L	Serum No.	Certified value ¹ nmol/L	Uncertainty ² nmol/L
1	351	14	18	146	6
2	432	17	19	166	7
3	288	11	20	83	4
4	152	6	21	89	4
5	329	13	22	180	7
6	278	11	23	387	15
7	515	20	24	384	15
8	163	7	25	315	12
9	287	11	26	215	9
10	230	9	27	497	19
11	334	13	28	299	12
12	251	10	29	265	11
13	430	17	30	114	5
14	626	24	31	764	29
15	246	10	32	623	24
16	211	8	33	264	10
17	356	14	34	390	15

1) Mean of two mean values independently obtained by two laboratories using a primary method of measurement (isotope-dilution GC-MS). The value is traceable to the international system of units (SI).

2) Estimated expanded uncertainty U with a coverage factor $k=2$, corresponding to a level of confidence of about 95 %, as defined in the Guide to the Expression of Uncertainty in Measurement (GUM), ISO, 1995. Uncertainty contributions arising from characterisation as well as from homogeneity and stability assessment were taken into consideration.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 50 μ L.

Accepted as an ERM®, Geel, May 2004

Latest revision: July 2008

Signed:



Prof. Dr. Hendrik Emons
Unit for Reference Materials
EC-DG JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

All following pages are an integral part of the certificate.

Page 1 of 3

Role of JCTLM

JCTLM has a crucial, pivotal role in providing clear guidance to industry and EQA providers on reference methods and reference materials, helping to ensure that there is transparency and comparability in the activities of both parties



Bureau International des Poids et Mesures

New search facility:
BIPM metrology portal



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- CIPM MRA
- COMMITTEES
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- SCIENTIFIC WORK
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- PUBLICATIONS
- DATABASES

> You are here: [committees](#) > [Joint Committees](#) > JCTLM

JCTLM: Joint Committee for Traceability in Laboratory Medicine

[Version française](#)

Database

- Direct access

Summary

- JCTLM-WG1: Reference Materials and Reference Procedures
- JCTLM-WG2: Reference Measurement Laboratories
- JCTLM-WG Review Teams and members
- Scope of activity for JCTLM Review Teams
- JCTLM Executive Committee
- JCTLM Executive Committee Procedures
- JCTLM Secretariat Procedures
- Criteria to assess the quality of nominated nucleic acid reference materials with stated nominal properties
- Metrological traceability in laboratory medicine
- Information on JCTLM member organizations

Open access

- JCTLM documents

The International Committee of Weights and Measures (CIPM), the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC) have agreed to cooperate to establish a Joint Committee for Traceability in Laboratory Medicine, with the acronym JCTLM.

The goal of the JCTLM is to provide a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in laboratory medicine and traceability to appropriate measurement standards.

[[Full declaration of cooperation](#)]



Chairman
IFCC: Prof. Mathias M. Müller
Austrian Society of Quality Assurance and Standardization
Hortlgasse 18/5
1090 Vienna
Austria

Secretariat
BIPM: Dr Robert Wielgosz
Bureau International des Poids et Mesures
Pavillon de Breteuil
F-92312 SÈVRES CEDEX
France

Contact form:

- JCTLM Database: Laboratory medicine and *in vitro* diagnostics**
Available higher order reference materials and reference measurement procedures for the assurance of the traceability of values assigned to calibrators and/or control materials for IVD devices
- Metrological traceability in laboratory medicine:** an overview



Summary

- JCTLM-WG1: Reference Materials and Reference Procedures:** Cycle VII call for nominations of reference materials and reference procedures for laboratory medicine and *in vitro* diagnostics – Closing date 30 April 2010
> [Cycle VII call for nominations](#) | [JCTLM-WG1 Quality Manual](#) | [Criteria for nominated nucleic acid reference materials](#) |
- JCTLM-WG2: Reference Measurement Laboratories:** Cycle V call for nominations of reference measurement services – Closing date 30 April 2010
> [Cycle V call for nominations](#) | [JCTLM-WG2 Quality Manual](#) | [IFCC EQAS for Reference Laboratories](#) |



Bureau International des Poids et Mesures

Database of higher-order reference materials, measurement methods/procedures and services



JCTLM Database
Laboratory medicine and *in vitro* diagnostics

> You are here : JCTLM-DB



JCTLM database: Laboratory medicine and *in vitro* diagnostics

JCTLM Database

- [Search Form](#)
- [General information](#)
- [List of reference materials no longer listed in the JCTLM Database](#)
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- [Contact us](#)

Highlights

- [Last updates](#)

JCTLM

- [Joint Committee for Traceability in Laboratory Medicine \(JCTLM\)](#)
- [JCTLM Working Group 1](#)
- [JCTLM Working Group 2](#)



Analyte keyword search for reference materials, measurement methods/procedures and services

Type an analyte name in part or full, e.g. cholesterol

Refine search by analyte category

Refine search by matrix category

Please select your requirement :

- Higher-order reference materials
- Reference measurement methods/procedures
- Reference measurement services

Reset ✕

Search →

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- Reference measurement services

Select an analyte category


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Select a matrix category

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http://www.bipm.org/utis/en/pdf/Traceability_in_LabMed.pdf

This document is particularly recommended!



Bureau International des Poids et Mesures

JCTLM Meeting 2008



Joint Committee for Traceability in Laboratory Medicine
**A Database of Higher Order Reference Materials
and Reference Measurement Procedures**

R.I. Wielgosz, BIPM
www.bipm.org

Role of Reference Laboratories




Reference laboratories (those that develop and maintain candidate reference methods registered with JCTLM, engage in networks and participate in IFCC RELA), have a crucial role to play in providing services to industry and to EQA Schemes.

Traceability in EQA cannot be implemented without them.

I would like to pay tribute to Professor Thienpont and her team for all the help offered to my Schemes during 23 years! Thank you Linda!

IFCC RELA

<http://www.dgkl-rfb.de:81/>



RELA Home

Welcome

login

Registration/
Account

RELA in progress

order RELA 2010

enter RELA 2010
results

former RELA results

Choose year... ▾

RELA 2009

All or choose Lab ... ▾

select lab analytes full address

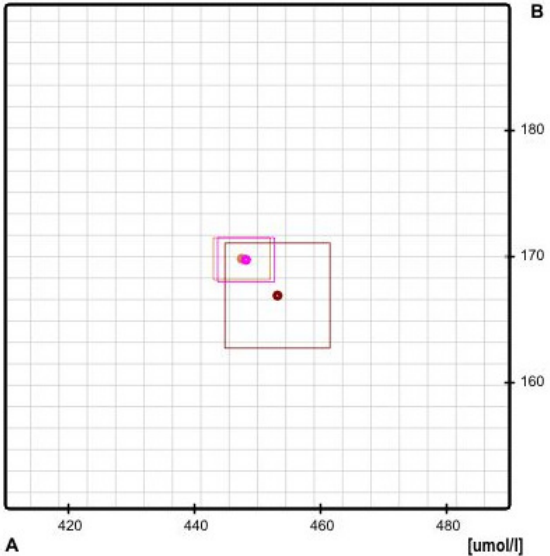
Creatinine ▾ show result plot

with limits of equivalence

For highlighting a specific result please click on the corresponding result line.

Labcode	A	e.u. A	B	e.u. B	Method
1	447.5	4.5	169.8	1.7	ID/LC/MS
12	453.2	8.31	166.9	4.155	kinetic spectrophotometric, 546 nm, 37°C
27	448.2	4.42	169.7	1.768	ID/GC/MS

Creatinine



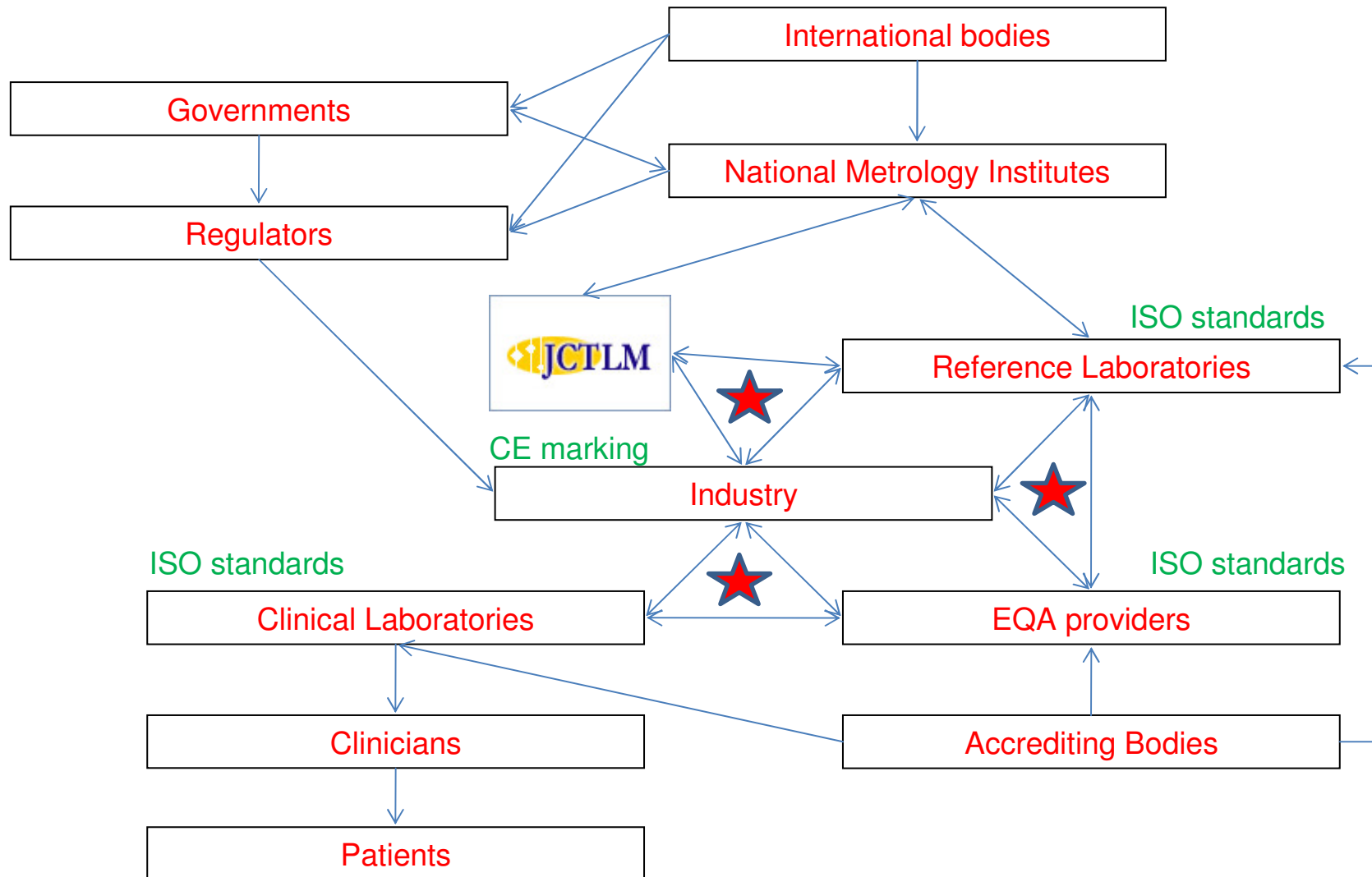
A B

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

Summary

- There are moral and professional imperatives that require laboratory medicine to meet the needs of its ultimate consumers; results of investigations must be accurate and comparable wherever and whenever they are produced
- Metrological Traceability is therefore a key concept that must be understood by all concerned, through education
- EQA provides continuous post market surveillance and is well placed to probe all aspects of analytical validity and to educate laboratories and other stakeholders
- Traceability can be implemented in EQA, but it may be costly and have major effects on Scheme logistics. It will obviously be constrained to those analytes where reference measurement systems exist
- It can only be implemented as part of a concerted effort by all stakeholders, engaging in a collaborative way, that transcends geographical, political and commercial boundaries

Partnerships





Thank you for your attention!

Jonathan Middle, PhD

UK NEQAS Organiser 1987 – 2009

Member IFCC C-TLM

www.jgmgc.co.uk drjgmiddle@gmail.com

