IFCC Scientific Division Update for General Conference Madrid 2016

Ian S.Young

Queen's University Belfast

Chair, IFCC-SD

Name	Position	Country	Term	Time in Office
I. Young	Chair	UK	2nd	2014 01 - 2016 12
P. Gillery	Vice-Chair	FR	2nd	2014 01 - 2016 12
J. Passarelli	Secretary	US	1st	2015 01 - 2017 12
T. Nobori	Member	JP	1st	2015 01 - 2017 12
G. Merlini	Member	IT	2nd	2014 01 - 2016 12
C.Cobbaert	Member	NE	2nd	2015 01 - 2017 12
J.F. Pierson-Perry	Corporate Rep	US	1st	2015 01 – 2017 12
H. Schimmel	IRMM Consultant	BE		
D. Bunk	NIST Consultant	US		
C. Burns	NIBSC Cousultant	UK		
G. Myers	Chair JCTLM	US		

IFCC SD

- Mission and objectives
- How SD is structured and how it works
- Achievements and work programme
- Future activities

IFCC SD

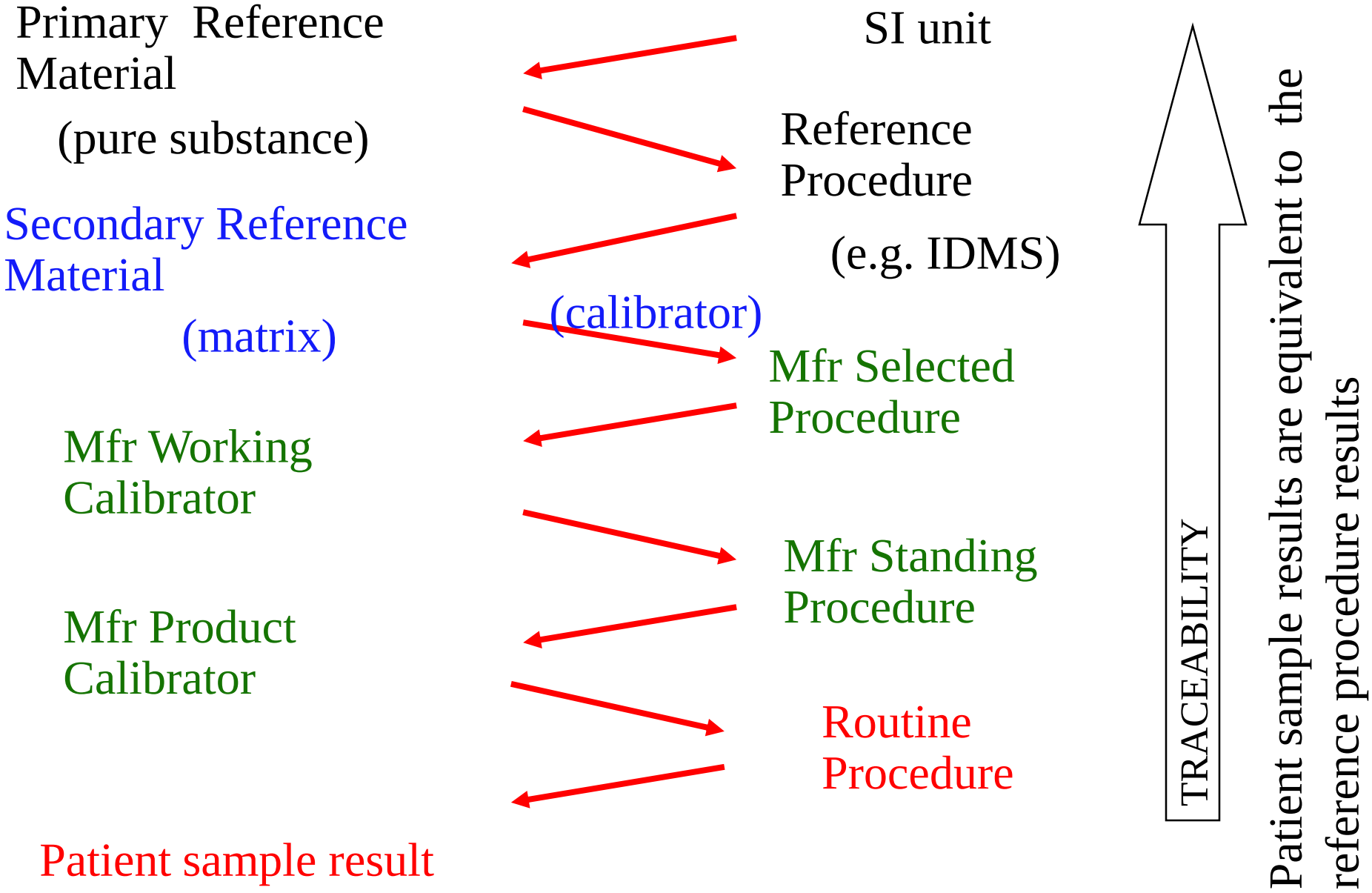
- Mission and objectives

IFCC SD

Mission: to advance the science of Clinical Chemistry and to apply it to the practice of Clinical Laboratory Medicine

- By identifying technical innovations and diagnostic strategies and assisting the transfer of these to the profession
- By promoting the standardization of laboratory tests and the comparability of patient results through the development of reference measurement systems, or harmonization activities where this is not currently possible
- By establishing standards for scientific and technical aspects of good laboratory practice

Traceability (based on ISO 17511)



IFCC-SD – Working in Partnership

- IFCC Divisions
- Corporate members
- Metrology institutions
- Governmental bodies and non-Governmental organisations
- Other professional bodies
- Clinicians and clinical organisations

IFCC SD

- Mission and objectives
- How SD is structured and how it works

Scientific Division

Committees	Working Groups
Theme orientated	Task orientated
Appointed Chair plus four/five elected members	Appointed Chair plus unlimited members
Corresponding members	

IFCC SD

- Mission and objectives
- How SD is structured and how it works
- Achievements and work programme

IFCC SD – some key achievements

- More than 150 scientists and clinicians from all IFCC regions involved as members of Cs / WGs
- SD symposia at most major international congresses
- Bergmeyer conferences
- Key publications

SD-Committees

8.2.6.	Nomenclature, Properties and Units (C-NPU) in collaboration with International Union of Pure and Applied Chemistry (IUPAC)	R.Flatman (AUS)
8.2.11.	Molecular Diagnostics (C-MD)	D.Payne (US)
8.2.21.	Reference Systems of Enzymes (C-RSE)	F. Ceriotti (IT)
8.2.23.	Traceability in Laboratory Medicine (C-TLM)	L.Siekman (DE)
8.2.24.	Reference Intervals and Decision Limits (C-RIDL)	Y.Ozarda (TR)
8.2.25.	Standardization of Thyroid Function Tests (C-STFT)	L. Thienpont (BE)

Committee on Nomenclature, Properties and Units
Robert Flatman (AUS)

- **Current Projects**
- Transfer and maintenance of the NPU generic database on the IFCC site
- Mapping of the IFCC-IUPAC laboratory coding system to SNOMED CT
- Development of an international vocabulary for nominal examinations in scientific communication

Committee on Molecular Dlagnostics
Debs Payne (US)

- **Current Projects**
- Establish an International Network of IFCC Reference Centres in Molecular Diagnostics
- Standardise formats for reporting of molecular diagnostic results

Committee on Reference Systems of Enzymes
Ferruccio Ceriotti (IT)

- Development of a reference measurement procedure for Pancreatic Lipase
- A recertification campaign for a primary reference material for LD, CK and ALT in cooperation with IRMM
- A certification campaign for a primary reference material for ALP in cooperation with IRMM

Committee on Traceability in Laboratory Medicine

Lothar Siekmann (DE)

- To support activities regarding Traceability in Laboratory Medicine
- To support reference laboratories in the context of complete reference systems by establishing an External Quality Assessment Scheme (EQAS) for reference laboratories in order to monitor their competence
- To promote establishment and maintenance of IFCC reference laboratory networks for clinically relevant measurands

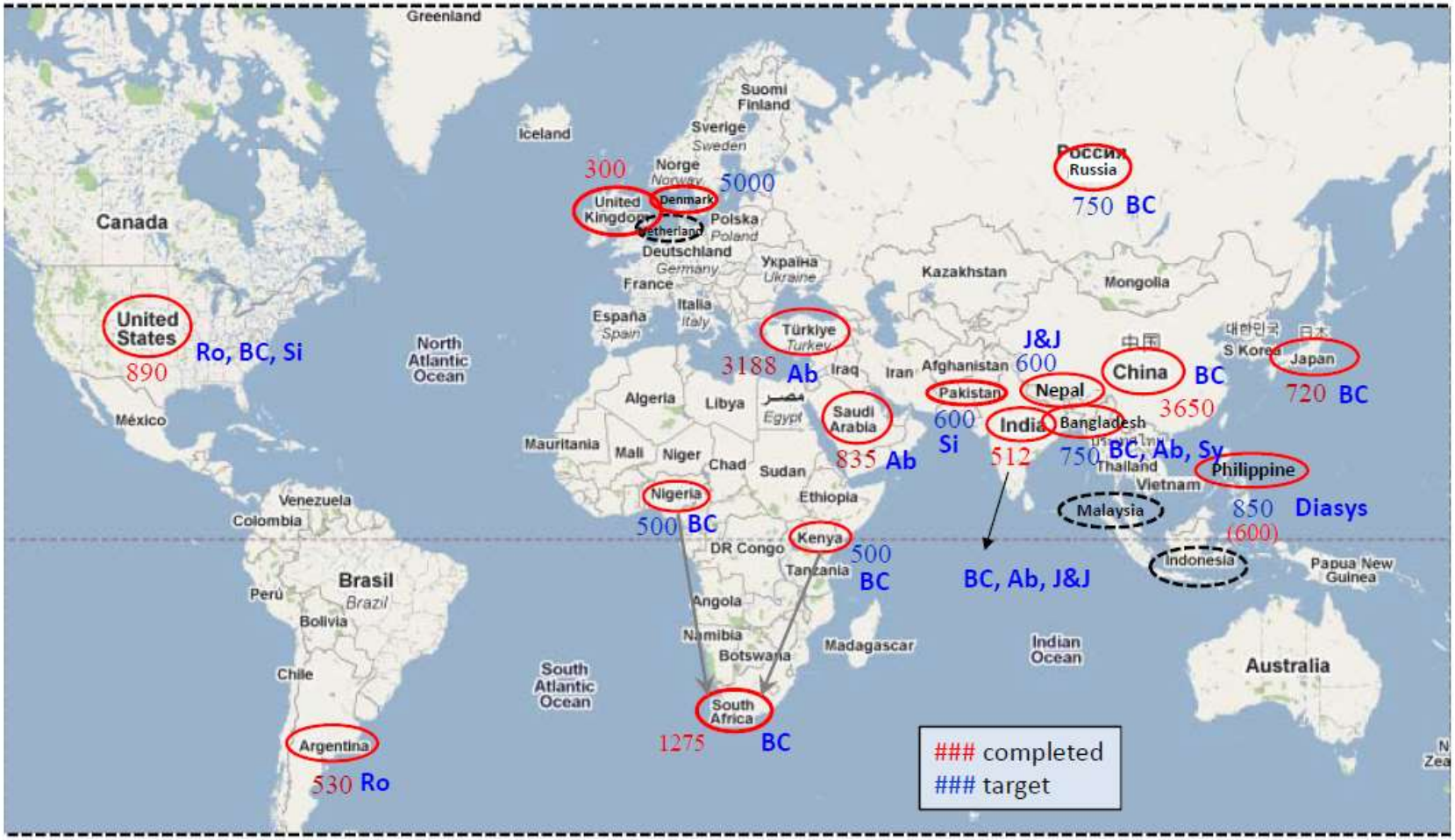
Reference Intervals and Decision Limits

Yesim Ozarda (TR)

- To make available reference intervals and decision limits that respect the requirements of international directives
- To compare alternative approaches to establishment of reference intervals and to make recommendations about the applicability of such approaches

The 18 countries collaborating in the global study

Rev: 2014/6/7



BC: Beckman Coulter; Ab: Abbott; Ro: Roche; Si: Siemens;
Sy: Sysmex; J&J: Jonson and Johnson; Diasys;

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

Reference Intervals and Decision Limits
Kiyoshi Ichihara (JP)

- Ichihara K, Ozarda Y, Klee G, Straseski J, Baumann N, Ishikura K; Committee on Reference Intervals and Decision Limits, International Federation for Clinical Chemistry and Laboratory Medicine.
- Utility of a panel of sera for the alignment of test results in the worldwide multicenter study on reference values
- Clin Chem Lab Med. 2013 May;51(5):1007-25. doi: 10.1515/cclm-2013-0248

SD Working Groups

8.3.35	Standardisation of Haemoglobin A2 (WG-HbA2)	R. Paleari (IT)
8.3.36	Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT)	J.Wielders (NL)
8.3.39	Standardisation of Albumin Assay in Urine (WG-SAU)	L.Bachmann (US)
8.3.40	Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A)	S.Wittfooth (FI)
8.3.42	Standardisation of Insulin Assays (WG-SIA)	M. Steffes (US)
8.3.43	Standardisation of Troponin I (WG-TNI)	D.Bunk (US)

SD Working Groups

8.3.45	Harmonisation of Autoantibody Tests (WG-HAT)	J. Sheldon (UK)
8.3.47	Clinical Quantitative Mass Spectrometry Proteomics (WG-cMSP)	S.Lehmann (FR)
8.3.48	Serum Parathyroid Hormone (WG-sPTH)	C.Sturgeon (UK)
8.3.49	CSF Proteins (WG-CSFP)	K.Blennow (SE)
8.3.50	Standardization of Bone Marker Assays (WG-SBMA)	H.Morris (AU)
8.3.51	Commutability (WG-COMM)	G.Miller (US)

WG – Carbohydrate Deficient Transferrin

J. Wielders (NL)

- **Terms of Reference**
- Definition of the measurand and standardisation of the nomenclature
- Preparation of reference material and selection of reference method
- Establishment of appropriate reference intervals
- Development of guidelines for clinical use of CDT assays

Carbohydrate deficient transferrin (CDT)

- CDT is the generic term that refers to the transferrin glycoforms whose concentration in blood is temporarily increased by sustained alcohol consumption

Normal human serum
(abstinence)

CDT < 1.5-2.0 % of total Tf

P0 Absence of asialo-Tf

Chronic alcohol abuse
(50-80 g/day)

CDT > 1.5 % of total Tf

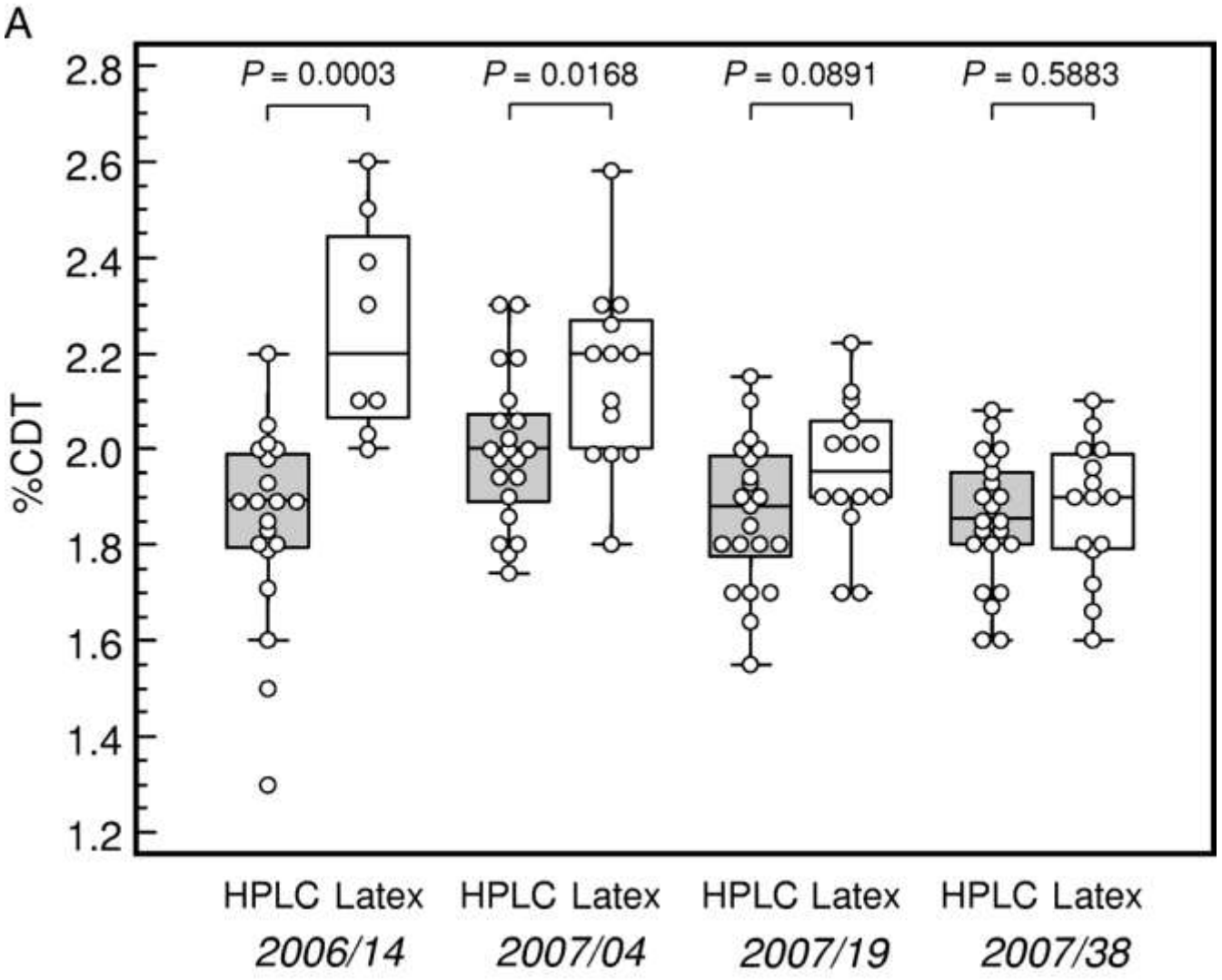
⇨ *disialo-Tf (P2)* ⇗ *5-10x*

P0 Presence of asialo-Tf

⇨ *Specific biomarker*

Stibler H., Allqulander C., Borg S., Kjellin KG., Acta Med Scand 204 (1978)49

Need for CDT standardization



	Harmonization potential					
	Patient panel P1 and P3				Spiked panel S3	
Method	P1 before	P1 after	P3 before	P3 after	S3 before	S3 after
Bio-Rad	1.12	1.23	3.69	3.99	4.22	4.58
Siemens N Latex	1.85	1.34	4.09	3.80	3.87	3.60
Sebia	0.66	1.31	3.46	3.70	3.42	3.66
Candidate reference	1.16	1.16	3.83	3.83	4.27	4.27
Mean	**1.20**	**1.26**	**3.77**	**3.83**	**3.94**	**4.03**
Intermethod CV	**40%**	**4%**	**7%**	**3%**	**10%**	**12%**

Table 2: Calibration potential of candidate reference materials applied to mean results obtained in EQA laboratories with three different samples.

Development of New Projects

SD horizon scanning

Third party approach

Assessment of need
Development and submission of formal proposal
Agreement on terms of reference

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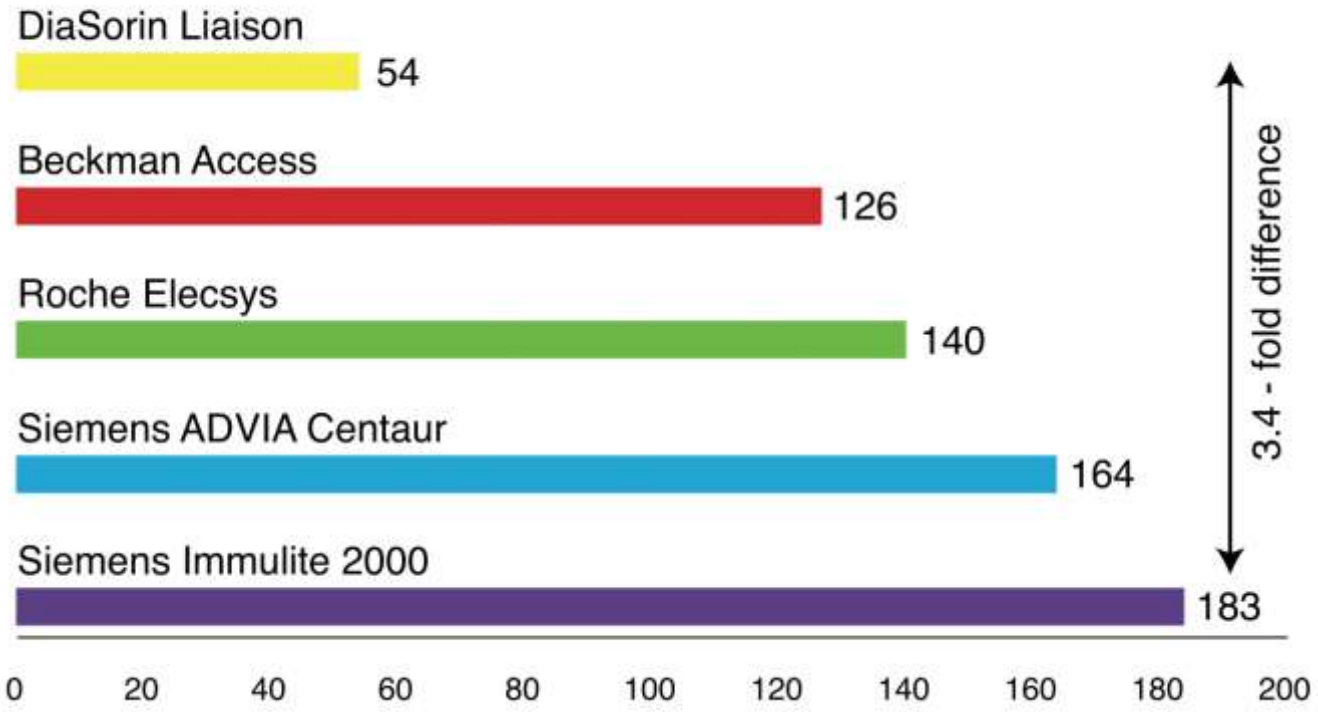
Approval by SD and EB
Establishment of WG or C

↓

Work cycle with ongoing review

PTH results - single patient



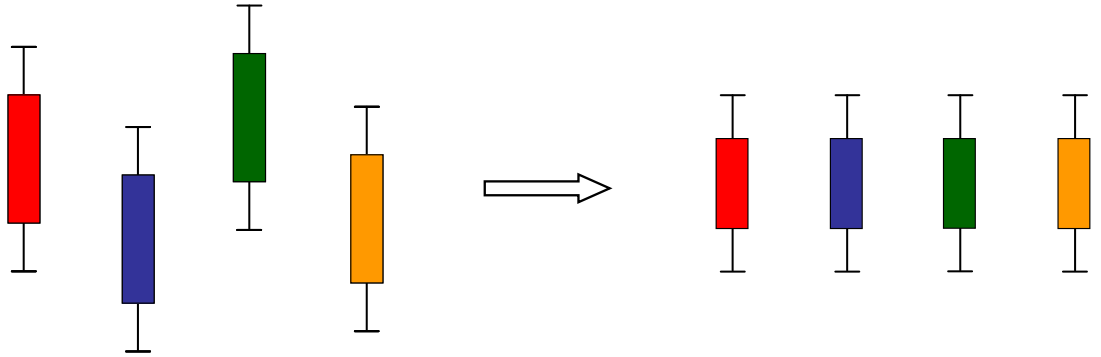
Results in pmol/L.
1 pmol/L ~ 9.5 ng/L

In the patients studied, differences ranged from 1.4-fold to 4.2-fold (mean 2.8-fold) although manufacturers' reference ranges are similar.

Almond, Walker & Ellis. Ann Clin Biochem 2012; 69: 43-7

International Consortium for Harmonization of Clinical Laboratory Results

Harmonization.net



AACC

http://www.ifcc.org/ifcc-scientific-division/

Becoming involved in the work of SD

- Apply for positions on SD or C's
- Become a corresponding member of a C
- Become a member of a WG
- Propose a new WG or C

On behalf of SD

Thank you!

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