Activities of JCTLM Working Group I

on Reference Materials and Reference Measurement Procedures

An Update

".... the traceability of values assigned to calibrators and control materials must be assured through available reference measurement procedures and/or reference materials of a higher order ..."

Annex 1 (3) 2nd para

Willie E. May (NIST) and Heinz Schimmel (IRMM)
Co-Chairs

OUTLINE

- *WG-I Terms of Reference*
- *Review Team Structure*
- *Review Process*
- *Overview of Cycle I Reviews*
- *Overview of Cycle II Review Process*
- *Comparability Assessment for Listed Materials and Methods*
- *Future Plans and Activities*

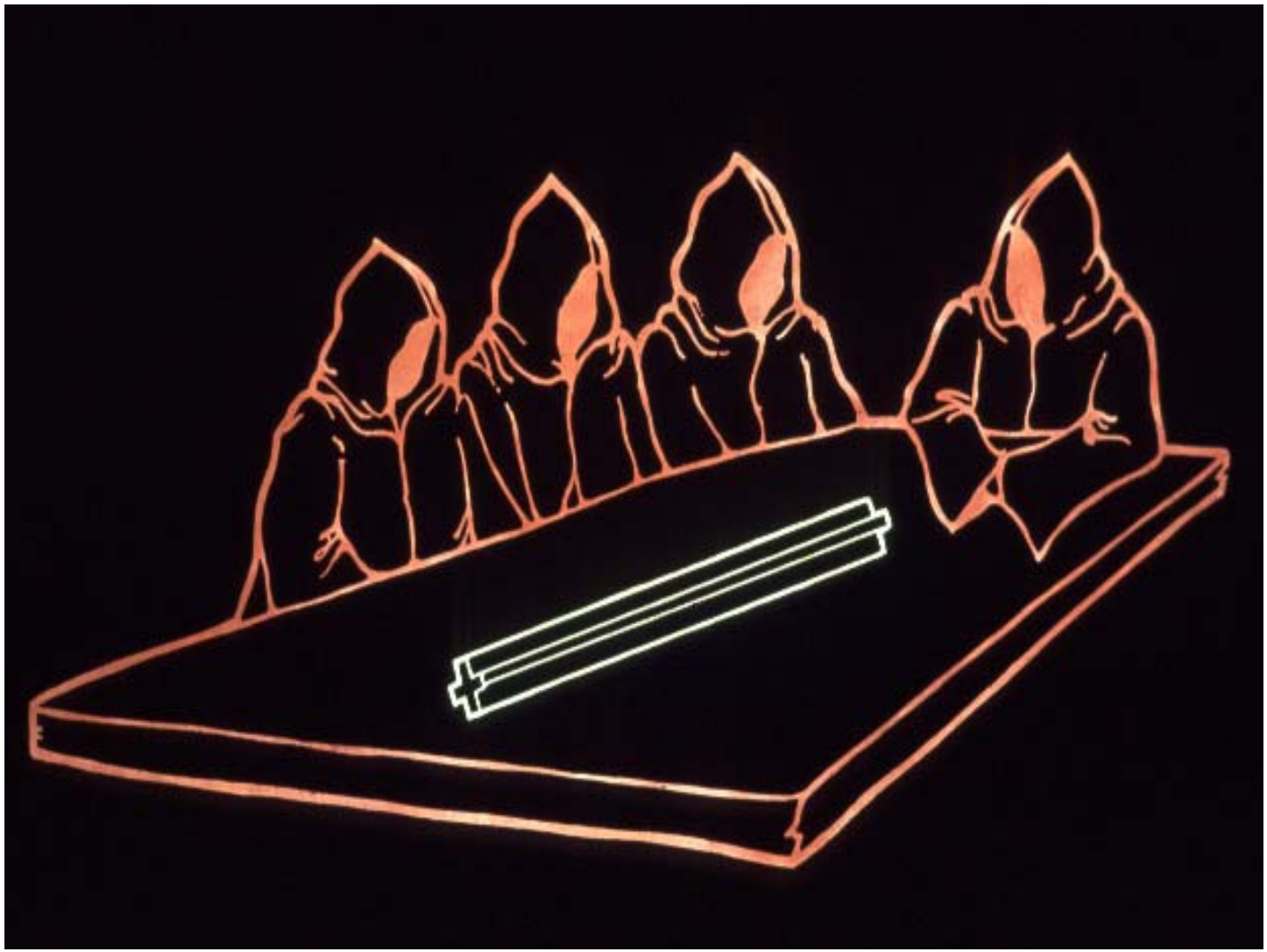
JCTLM Working Group I on Reference Materials and Reference Measurement Procedures

Co-Chairs: W.E. May (NIST), H. Schimmel (IRMM)

Charged with:

- **establishing a process for identifying, and reviewing against agreed upon criteria "higher order" Certified Reference Materials and Reference Measurement Procedures** required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.
- **publishing a List** of "higher order" Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.

NOT !!!!!



Priority Analyte Areas

Review Teams established with worldwide representation in order to facilitate a fair and transparent review process

- *Lab Accreditation Organizations*
- *National Metrology Institutes*
- *Professional Societies, such as AACC, EDMA, JACC, etc.*
- *the IVD Industry*

Review Team Areas:

Blood Grouping/ Typing
Blood Gases
Coagulation Factors
Drugs
Electrolytes
Enzymes
Non-Peptide Hormones
Metabolites and Substrates
Microbial Serology
Non-Electrolyte Metals
Nucleic Acids
Proteins
Vitamins and Micronutrients

Covered in Cycle I and forward
Covered in Cycle II and forward

JCTLM Measurand-Based Review Teams

Coagulation Factors	Elaine Gray, **NIBSC,** United Kingdom
Drugs	Andre Henrion, **PTB,** Germany
Electrolytes	Richard Miller, **Dade Behring**, United States
Enzymes	Mauro Panteghini, **University of Milan**, Italy
Metabolites/Substrates	Michael Welch, **NIST**, United States
Nucleic Acids	Helen Parkes, **LGC**, United Kingdom
Non-Peptide Hormones	Heinz Schimmel, **IRMM,** European Union
Proteins	David Sogin, **Abbott Laboratories,** United States
Blood Group Substances	Susan Thorpe, **NIBSC,** United Kingdom
Viral Markers	Morag Ferguson, **NIBSC**, United Kingdom
Vitamins	Katherine Sharpless, **NIST**, United States
Non-electrolyte Metals	Lee Yu, **NIST,** United States
Blood Gases	Merged with Electrolytes, November 3, 2005
Quality System	Craig M Jackson, **HDC,** United States

JCTLM Highest Priority Analyte Categories & Review Team Leaders

Analyte Category	Review Team Leaders
Coagulation Factors	Elaine Gray, NIBSC
Drugs [therapeutic and "of abuse"]	Andre Henrion, PTB
Electrolytes	Richard Miller, Dade Behring
Enzymes	Mauro Panteghini, Università degli Studi di Milano
Metabolites and Substrates	Michael Welch, NIST
Nucleic Acids	Helen Parkes, LGC
Non-Peptide Hormones	Heinz Schimmel, IRMM
Proteins	David Sogin, Abbott Laboratories
Blood Grouping/ Typing	Susan Thorpe, NIBSC
Blood Gases	……
Microbial Serology	Morag Ferguson, NIBSC
Non-Electrolyte Metals	Lee Yu, NIST
Vitamins	Katherine Sharpless, NIST

The Electrolytes Review Team

- **Dr. W. Külpmann, MH-Hannover (Germany)**
- **Dr. S. Long, NIST (USA)**
- **Dr. P. D'Orazio, IL (USA)**
- **Dr H. Schimmel, IRMM (Belgium)**
- **Dr. L. Penberthy, Flinders Med. Ctr. (Australia)**
- **C. Jain, Beckman (USA)**
- **Dr. K. Kuwa, Univ. Tskuba (Japan)**
- **Dr. L. Ma, NRCCRM, (China)**
- **R. Miller Dade Behring (USA)**

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members	
Microbial Serology	**Morag Ferguson**	**Thomas Ciesiolka**	**Claude Giroud**
	National Institute for Biological Standards and Control / /Division of Endocrinology (NIBSC)	Roche Diagnostics GmbH	Bio-Rad Laboratories
	UK	Germany	92430 Marnes-la-Coquette - France

Toshiaki Mizuochi	**C. Micha Nübling**	**Sjoerd Rijpkema**	**Wolfgang Philipp**
Department of Safety Research on Blood and Biological Products	Paul-Ehrlich-Institut	National Institute for Biological Standards and Control/Division of Bacteriology	IRMM
National Institute of Infectious Diseases	Division of Virology	UK	Geel, Belgium B-2440
Tokyo 162-8640 Japan	Germany		

Ian Sharp	**David Sogin**
Deputy Director of Evaluations and Standards Laboratory	Abbott Laboratoies Diagnostics Division
London, NW9 5EQ UK	Abbott Park, IL 60035-6015

Members of Working Group 1 of JCTLM: REFERENCE MATERIALS AND REFERENCE PROCEDURES			
Analyte Category	**Review Team Chair**	**Review Team Members**	
Metabolites and Substrates	**Michael Welch**	**Xu Bei**	**Norihiko Kayahara**
	NIST	National Research Center for Certified Reference Material	Kyowa Medex Co., Ltd.
	Gaithersburg, MD 20899-8392	Beijing 100013 PR China	Tokyo 104-6004,JAPAN

Neil Greenberg	**Andre Henrion**	**Steve Wolf**	**Mary Kimberly**
Ortho Clinical Diagnostics, a Johnson and Johnson Co.	PTB	Beckman Coulter, Inc.	CDC
Rochester, NY 14626-5101	Braunschweig, Germany D-38116	Brea, CA 92821-6208	Chamblee, GA 30341-3742

Relevant ISO Standards

- **ISO 17511** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

- **ISO 15193** Presentation of reference measurement procedures

- **ISO 15194** Description of reference materials

- **ISO 18153** Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

List of Higher Order Reference Materials and Reference Measurement Procedures

I. **Certified Reference Materials and Reference Measurement Procedures** for well-defined chemical entities or internationally recognized reference method-defined measurands, such as enzymes. Reference Materials included in this category are those whose certified values are traceable to the SI units. [***Electrolytes, Drugs, Metabolites and Substrates, Non-Peptide Hormones, Enzymes and*** *some* ***Proteins***]

II. **Reference Materials** that are value-assigned using an internationally agreed upon protocol e.g., reference materials for ***Blood Typing, Coagulation Factors, Microbial Serology, Nucleic Acids, and some Proteins.*** The values of the measurands in the reference materials on this List are not SI-traceable and/or no internationally-recognized reference measurement procedures exist.

JCTLM Lists of Reference Materials and Methods -

List I

Certified Reference Materials and Reference Measurement Methods for well-defined chemical entities or internationally recognized reference method-defined measurands.

Reference materials and measurement methods included in this category are those that provide values that are traceable to the SI units. Examples are: electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, vitamins, non-electrolyte metals and some proteins.

Source – Preamble to JCTLM Quality System

JCTLM LIST of "Higher Order" RMs and RMPs

Initially Published 1 April 2004, the Current List contained :

Certified Reference Materials and Reference Measurement Methods
for well-defined chemical entities or internationally recognized reference method defined measurands, such as enzymes.

approximately **100** Reference Measurement Procedure entries for **~60** different health status markers

approximately **150** Reference Material entries for **~95** measurands

JCTLM Lists of Reference Materials and Methods, Cont'd -

List II.

Reference Materials for which values of the measurands are not SI-traceable but are assigned by or traceable to an internationally agreed upon protocol,

Examples include: reference materials for blood typing, coagulation factors, microbial serology, nucleic acids, and some proteins and purified substances.

List II also contains a group of purified substances which due to the absence of reference measurement procedures should not be directly used for calibration of routine methods unless commutability is established and/or matrix effect independent internationally recognized standardized value transfer protocols to commutable samples are applied.

Source – Preamble to JCTLM Quality System

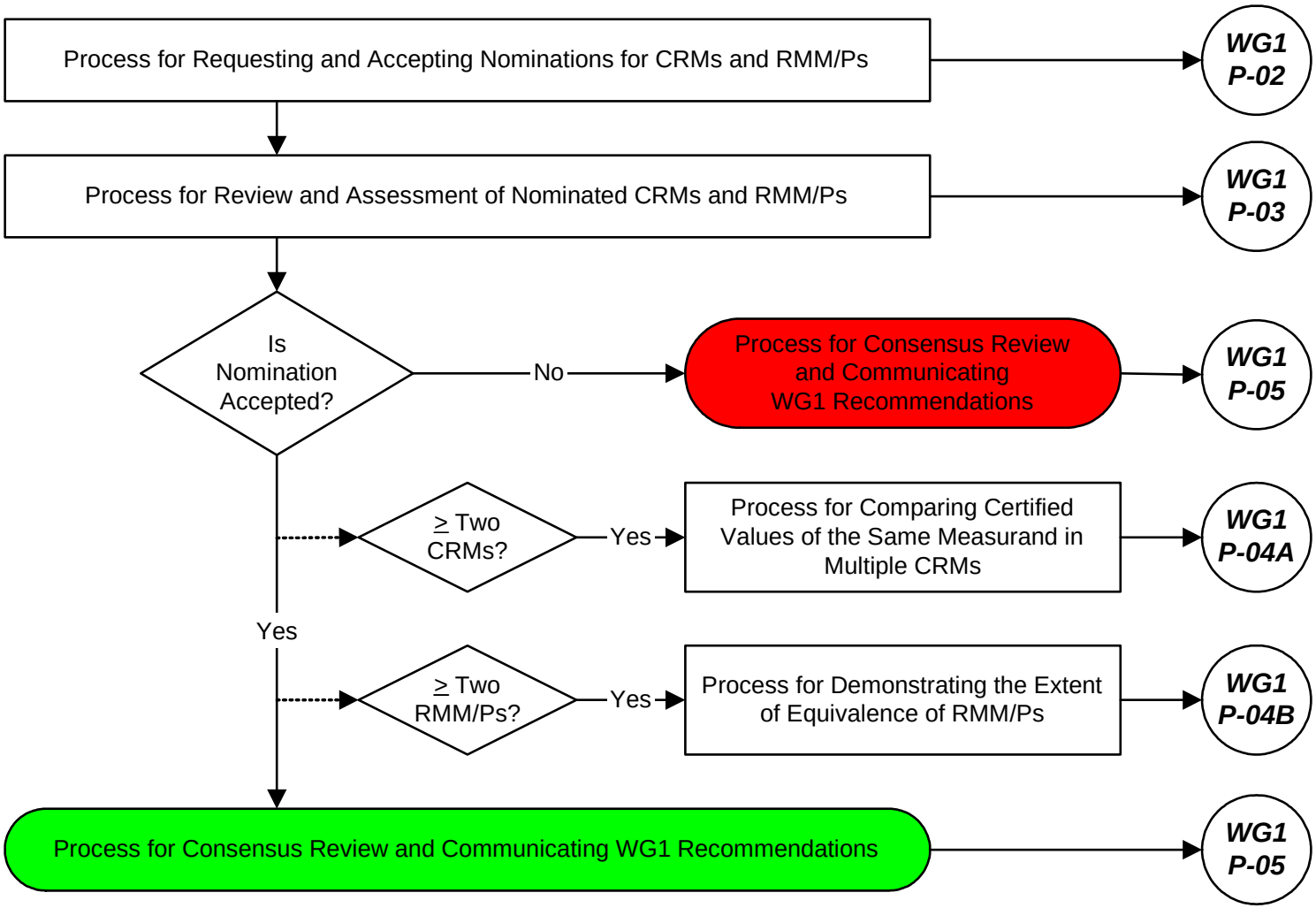
List updated in April 2005 to include – based on Cycle I nominations:

Reference Materials that were value-assigned using an internationally agreed upon protocol

- **CRMs for 10 Coagulation Factors**
- **CRMs for 7 Proteins**

Hereafter, List to be updated in April of each year

But Rather: JCTLM WG1 Review Process Roadmap



Members of Working Group 1 of JCTLM					
REFERENCE MATERIALS AND REFERENCE					
Analyte Category	Review Team Chair	Review Team			
Quality Systems	Craig Jackson	David Duewer	Richard Miller	Robert Wielgosz	Katherine Sharpless
	San Diego, CA 92121-435	NIST	Dade Behring	Bureau International des Poids et Mesures	NIST
		Gaithersburg, MD	Newark, DE 19714-	F-92312 Sevres Cedex	Gaithersburg, MD 20899

Overview of Cycle I Nomination Process

Category	Number of Nominations Submitted		Number Published in Cycle I	
	Reference Materials	Reference Measurement Procedures	Reference Materials	Reference Measurement Procedures
Drugs	84	3	23	3
Electrolytes	65	21	24	21
Enzymes	20	7	11	6
Metabolites and Substrates	67	34	39	28
Non-Peptide Hormones	15	25	14	21
Nucleic Acids	5	--	--	--
Proteins	110	20	42	19
Coagulation Factor	28	--	10	--
TOTAL Number	*394*	*110*	*163*	*98*

•If a Reference Measurement Procedure (RMP) was for “n” analytes, it was counted as “n” RMPs
•For Cycle I from List I **AND** List II)

Overview of Cycle II Nomination Process

Category	Number of Nominations Submitted		Number Recommended for Publication	
	Reference Materials	Reference Measurement Procedures	Reference Materials	Reference Measurement Procedures
Blood Gases	1	1	0	0
Drugs		2		0
Electrolytes	5	2	5	2
Enzymes	0	0	0	0
Metabolites and Substrates	2	10	0	7
Non-Electrolyte Metals	43	50	30	15
Non-Peptide Hormones	0	1	0	1
Nucleic Acids	0	0	0	0
Vitamins	8	2	7	0
Proteins	4	0	1	0
Blood Groupings	3	0	0	0
Coagulation Factor	6	0	2	0
Microbial Serology	10	8	0	0
Other	6	2	3	0
TOTAL Number	*88*	*78*	**48 (33)**	**25 (16)**

Approval of Cycle II Reference Materials and Reference Measurement Procedures Nominations

- **Recommended Cycle II Nominations**
- **Deferred Cycle II Nominations**

Comparability Assessment Studies

- All Listed Reference Materials and Reference Methods need to be Tested to assess comparability
  - **to assess veracity of the Normative Standards-Based Review Process**
  - **to assess bias that could be introduced by random selection/use of any of the materials/methods on the List**

Cycle I- Materials Comparability Assessment Needs

Analyte	Matrix	Number of RMs listed	RMs ID	Producer
17b-estradiol	human serum	3	BCR-576 BCR-577 BCR-578	IRMM IRMM IRMM
benzoylecgonine	human urine	2	SRM 1511 SRM 1508a	NIST NIST
calcium	human serum	3	BCR-304 SRM 909b SRM956b	IRMM NIST NIST
chloride	human serum	2	SRM 909b JCCRM 111	NIST JCRRM
cholesterol	cholesterol crystalline material; neat	2	GBW09203b SRM 911b	NRCCRM NIST
cholesterol	human serum	5	JCRRM 211 SRM 1951b SRM 1952a SRM 968c SRM 909b	HECTEF NIST NIST NIST NIST
codeine	human urine	2	SRM 1511 SRM 2381	NIST NIST
cortisol	human serum	3	BCR-192 BCR-193 IRMM 451	IRMM IRMM IRMM
creatinine	human serum	4	BCR-573 BCR-574 BCR-575 SRM 909b	IRMM IRMM IRMM NIST

Cycle I- Materials Comparability Assessment Needs

ethanol	water	3	LGC 5401 LGC 5402 LGC 5403	LGC LGC LGC
lithium	human serum	3	BCR-304 SRM 909b SRM 956b	IRMM NIST NIST
magnesium	human serum	3	BCR-304 SRM 909b SRM 956b	IRMM NIST NIST
morphine	human urine	3	SRM 1511 SRM 2381 SRM 2382	NIST NIST NIST
potassium	human serum	3	SRM 909b SRM 956b JCCRM 111	NIST NIST JCRRM
sodium	human serum	3	SRM 909b SRM 956b JCCRM 111	NIST NIST JCRRM
THC-9-COOH	human urine	2	SRM 1511 SRM 1507b	NIST NIST
triglycerides	human serum	2	JCRRM 223 SRM 909b	HECTEF NIST
urea	urea crystalline material; neat	2	SRM 912a GBW09201	NIST NRCCRM
uric acid	uric acid crystalline material; neat	2	SRM 913a GBW09202	NIST NRCCRM

All Listed Reference Materials will be assessed for comparability by a reference measurement procedure under repeatability conditions:

- **to assess** veracity of the Normative Standards-Based Review Process
- To establish bias **that could be introduced by randomly selecting any material from the List**

Example: Potassium in Human Serum CRMs on provisional JCTLM List 1 were assessed for comparability by a single laboratory (NIST) using a reference measurement procedure under repeatability conditions.

Fig 1: Ratio Display

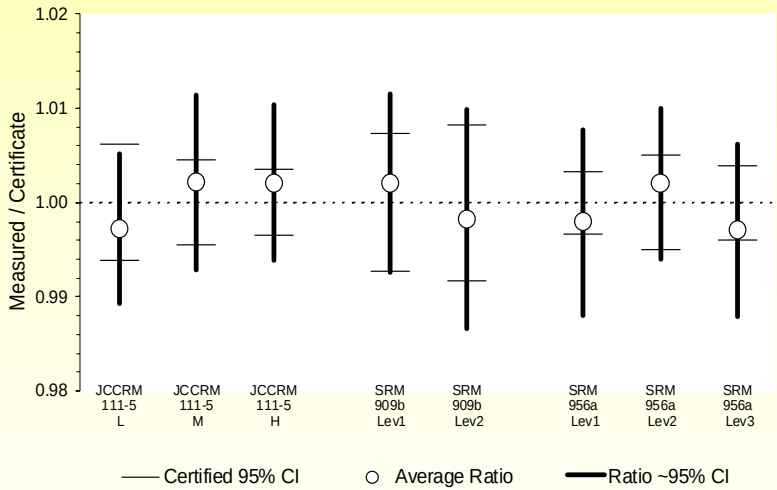


Fig 2: Scattergram Display

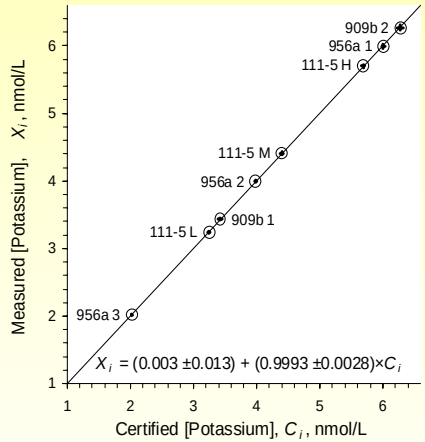
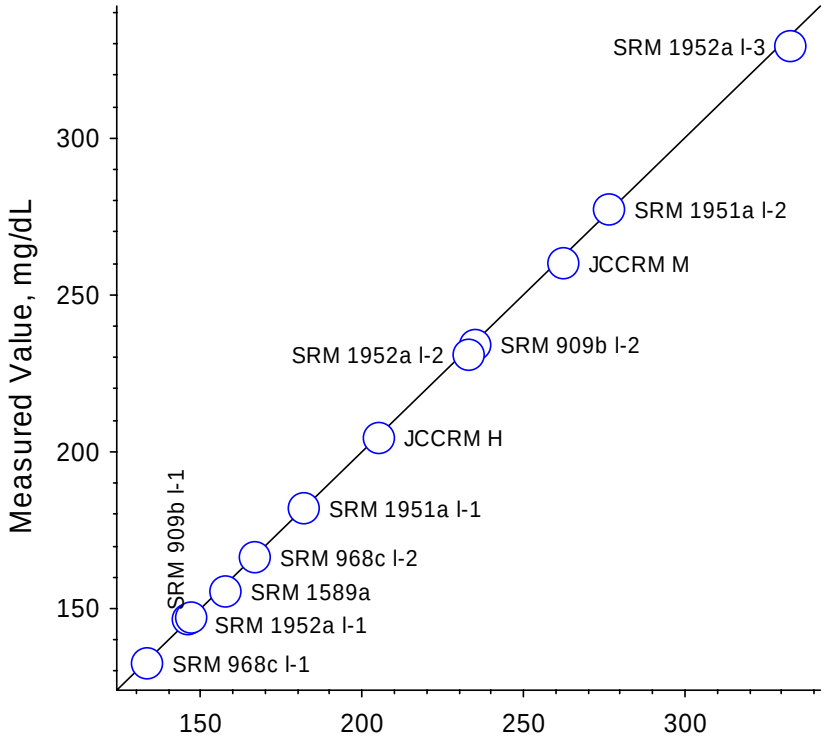
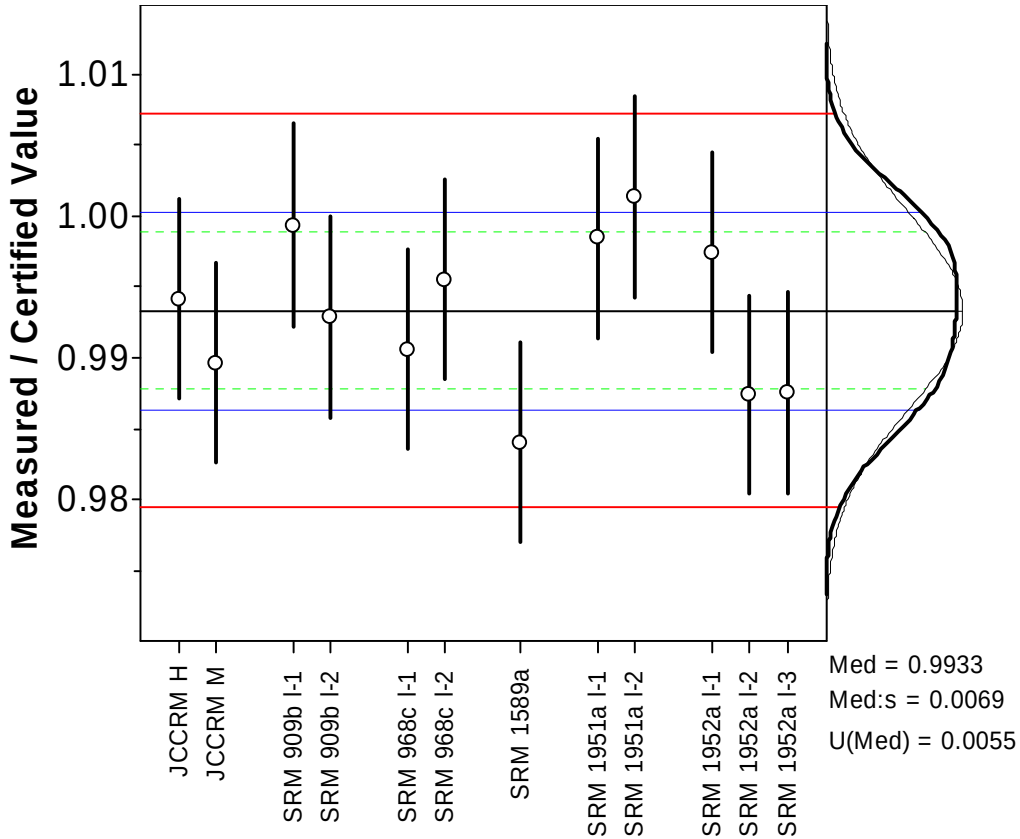


Fig 1: The vertical axis reports the ratio between the measured and certified values of each CRM, X_i/C_i. The dark vertical lines represent the approximate 95% CI about the ratios. The light horizontal lines represent the certified 95% CIs. The dotted line represents the expected ratio for the suite of all materials given the observed identity between the measured and certified values. (CI = Confidence Interval)

Fig 2: The data demonstrate that these CRMs are comparable over a wide concentration range. The horizontal axis reports the certified values, C_i; the vertical reports the average measured values, X_i. Each level of each CRM is displayed as approximate 95% CIs along both axes. The intersection of these intervals is bounded by an open circle to aid visual inspection.

Comparability of Cholesterol in Serum CRMs on JCTLM LIST





⇨ CRM comparability independent of analyte level

The measured/certified ratios for this set of CRMs are:

- ~ normally distributed
- with a standard deviation of ~0.7%

1-Apr-2004

Reference Measurement Procedures

Analyte Name	Procedure Name and/or ID #	Applicable Matrices	Measurement Principle	Reference Procedure Citation(s) or Document(s)	Reference Procedure Comparability Assessment Studies
calcium	NIST ID-TIMS Method for Serum Calcium	human serum	IDMS	NBS Special Publication 260-36 (http://ts.nist.gov/ts/htdocs/230/232/SP_PUBLICATIONS/documents/SP260-36.pdf)	See NBS Special publication 260-63 (http://ts.nist.gov/ts/htdocs/230/232/SP_PUBLICATIONS/documents/SP260-63.pdf)
calcium	NIST/CDC/AACC Flame Atomic Absorbtion Method for Serum Calcium	human serum	atomic absorbtion	Clin Chem 19(10) 1208-1213; NBS special publication 260-36; Clin Chem 16: 998-1007; J Clin Chem Clin Biochem 19: 395-412.	
calcium	NIST ID-ICP/MS Method for Serum Calcium	human serum; lyophilized, fresh or frozen	ID/ICP-MS	J. Anal. At. Spectrom. 17, 469-477 (2002)	CCQM-K14; see http://kcdb.bipm.org/appendixB/
calcium	Ion Chromatographic Reference Method for Serum Calcium	human serum; lyophilized, fresh or frozen	Ion chromatography	Anal Chem 66, 2404-8 (1994); Clin Biochem 29, 501-8 (1996); J Chromatogr A 789, 557-568 (1997); Eur J Clin Chem Clin Biochem 35, 297-300 (1997); Scand J Clin Lab Invest 58, 229-40 (1998)	

Ca	SI	blood serum	freeze-dried or frozen serum	Inorg-012	Analysis of Ca by ICP-OES	LGC	ICP-OES	Gravimetric preparation of primary standard using neat chemical
Ca	SI	blood serum	freeze-dried or frozen serum	Inorg-012	Isotope dilution of Ca by ICP-MS	LGC	Isotope dilution ICP-MS	Gravimetric preparation of primary standard using neat chemical

1-Apr-2004

Reference Measurement Procedures

Analyte Name	Procedure Name and/or ID #	Applicable Matrices	Measurement Principle	Reference Procedure Citation(s) or Document(s)	Reference Procedure Comparability Assessment Studies
creatinine	DGKC definitive Method for Serum Creatinine	human serum or plasma; lyophilized, fresh, or frozen	ID/GC/MS	Siekmann et al., J.Clin.Chem.Clin.Biochem. 23 (1985) 137-144	See CCQM-P9 results in CCQM-K12 Report at http://kcdb.bipm.org/appendixB/appbresults/ccqm-k12/ccqm-k12_final_report.pdf
creatinine	DGKC definitive Method for Urine Creatinine	human urine; lyophilized, fresh, or frozen	ID/GC/MS	Siekmann et al., J.Clin.Chem.Clin.Biochem. 23 (1985) 137-144	See CCQM-P9 results in CCQM-K12 Report at http://kcdb.bipm.org/appendixB/appbresults/ccqm-k12/ccqm-k12_final_report.pdf
creatinine	NIST definitive method for serum creatinine	human serum; lyophilized, fresh or frozen	ID/GC/MS	Anal Chem 58, 1681-1685 (1986)	CCQM-K12; http://kcdb.bipm.org/appendixB/appbresults/ccqm-k12/ccqm-k12_final_report.pdf
creatinine	U. Of Ghent reference method for creatinine	human serum; lyophilized, fresh or frozen	ID/GC/MS	Clin Chem 39,1001-6 (1993), Clin Chem 39,993-1000 (1993)]; Eur J Clin Chem Clin Biochem 34,853-60 (1996); Clin Chem 41,995-1003 (1995)	EUROMET 563

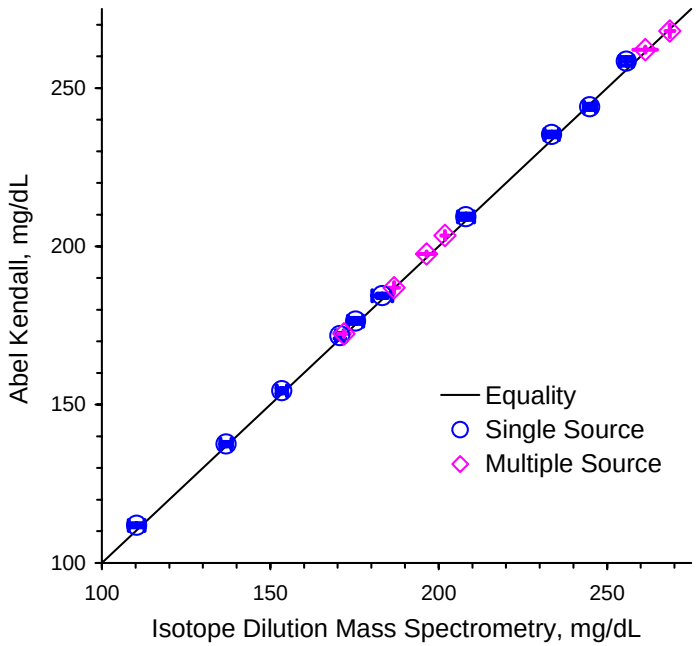
Creatinine	SI	blood serum	lyophilized or frozen serum	Org-022	Isotope dilution of creatinine by LCMS	LGC	Isotope dilution LCMS	Gravimetric preparation of primary standard using SRM 914a

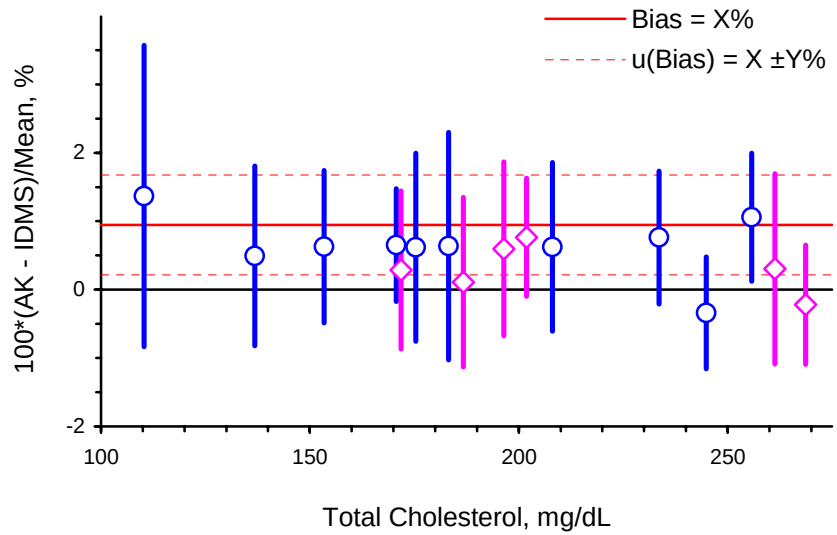
Reference Measurement Procedures

Analyte Name	Procedure Name and/or ID #	Applicable Matrices	Measurement Principle	Reference Procedure Citation(s) or Document(s)	Reference Procedure Comparability Assessment Studies
cholesterol	DGKC definitive Method for Serum Cholesterol	human serum or plasma; lyophilized, fresh, or frozen	ID/GC/MS	Siekmann et al., Z. anal. Chem. 279, 145-146 (1976)	See CCQM-P6 results in CCQM-K6 Report at http://kcdb.bipm.org/appendixB/appbresults/ccqm-k6/ccqm-k6_final_report.pdf
cholesterol	CDCAbell-Kendall method for cholesterol	human serum; lyophilized, fresh, or frozen	Spectrophotometry	Cooper, GR, et al, Clin Chem 32: 921-929, 1986	Clin Chem 36, 370-375 (1990)
cholesterol	NIST definitive method for serum cholesterol	human serum; lyophilized, fresh or frozen	ID/GC/MS	Anal Chem 61, 1718-1723 (1989)	CCQM-K6; http://kcdb.bipm.org/appendixB/appbresults/ccqm-k6/ccqm-k6_final_report.pdf; Clin Chem 36, 370-375 (1990)
cholesterol	U. Of Ghent reference method for cholesterol	human serum; lyophilized, fresh or frozen	ID/GC/MS	Clin Chem 39,1001-6 (1993), Clin Chem 39,993-1000 (1993)]; Eur J Clin Chem Clin Biochem 34, 853-60 (1996); Clin Chem 42, 531-5 (1996)	EUROMET 563

olites & rates	cholesterol	SI	blood serum	lyophilized or frozen serum	Org-005	Isotope dilution of cholesterol by LCMS	LGC	Isotope dilution LCMS	Gravimetric preparation of primary standard using SRM 911b		1

Assessment of Comparability of two RMM/Ps for Total Cholesterol in Liquid Frozen Serum





Measurements performed at NIST and CDC; publication to be forthcoming

Future Activities

- annual call for new nominations
  - Cycle III to commence February, 2006
- ongoing assessments of quality and utility of information in database
  - Involve NMIs in materials and methods comparisons
  - Methods vs Implementation procedures
  - Formal review of database contents on 3-year cycle
- publicize and improve visibility of activities

Members of Working Group 1 of JCTLM REFERENCE MATERIALS AND REFERENCE PROCEDURES			
Analyte Category	**Review Team Chair**	**Review Team Members**	
Blood Groupings	**Susan Thorpe**	**John Allan**	**Sheryl Kochman**
	National Institute for Biological Standards and Control - Division of Haematology (NIBSC)	Diagnostics Scotland	Food and Drug Administration (FDA)
	UK	Scotland	Rockville, MD 20852-1448

Toshiaki Mizuochi	**Kathleen Reis**	**Marion Scott**
Department of Safety Research on Blood and Biological Products	Ortho-Clinical Diagnostics	International Blood Group Reference Laboratory
National Institute of Infectious Diseases	New Jersey 08869	Bristol BS10 5ND, UK
Tokyo 162-8640, Japan		

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members		
		NEW		
Coagulation Factor	Elaine Gray	Claus Opper (or designate)	John Lloyd	Craig Jackson
	National Institute for Biological Standards & Control (NIBSC)	Dade Behring	Haemostasis Laboratory, Haematology Division	San Diego, CA 92121
	UK	Marburg, Germany	Institute of Medical and Veterinary Science, University of South Australia	
			Adelaide, Australia	

Barry Woodhmas	Koji Suzuki	Steve Kitchen	Steffen Rosen
Scientific Diector, Serbio (Diagnostica Stago)	Department of Molecular Pathobiology, Mie University School	Department of Coagulation, Sheffield Haemophilia and Thrombosis Centre	Rossix
92635 Gennevillier Cedex, France	Tsu-city, Mie 514-8507, Japan	Royal Hallamshire Hospital, Glossop Road	S-431 53 Molndal Sweden
		Sheffield S10 2JF UK	

Katsuyuki Fukutake
Professor and Chairman of Laboratory Medicine
Tokyo, Japan

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members	
Drugs	**Andre Henrion**	**Bridin Brady**	**Lohri Phelan**
	PTB	State Laboratory	Beckman Coulter, Inc.
	Braunschweig, Germany D-	Dublin 15, Ireland	Brea, CA 92821-6208

David Sogin	Michael Welch	Richard White	Christian Zeine
Abbott Laboratoies Diagnostics Division	NIST	Dade Behring	LGC Promochem GmbH
Abbott Park, IL 60035-6015	Gaithersburg, MD 20899	Cupertino, CA 95014-2036	46485 Wesel, Germany

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members		
Electrolytes	**Richard Miller**	**Paul D'Orazo**	**Chandra Jain**	**Wolf Kulpmann**
	Dade Behring	Instrumentation Laboratory	Beckman Coulter, Inc.	Medical University Klin. Chemie
	Newark, DE 19714-6101	Lexington, MA 02421	Brea, CA 92822-8000	Hannover, D-30625, Germany

Katsuhiko Kuwa	**Ma Liandi**	**Stanley Lo**	**Stephen Long**
University of Tsukuba	National Research Center for Certified Reference Materials	Children's Hospital of Wisconsin	NIST
Tsukuba, Japan	P.R.China	Milwaukee, WI 53226-3518, USA	Gaithersburg, MD 20899-8391

Lloyd Penberthy	**Heinz Schimmel**
RCPA Quality Assurance Programs Pty Ltd	IRMM
Adelaide, S. Australia 5043	Geel, Belgium B-2440

Continuation Proposed	**Removal Requested**

Members of Working Group 1 of JCTLM:
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members		
Enzymes	Mauro Panteghini	Ferruccio Ceriotti	Wenxiang Chen	Kazuo Fujihashi
	Cattedra di Biochimica Clinica e Biologia Molecolare Clinica	Diagnostica e Ricerca San Raffaele S.p.A.	National Center for Clinical Laboratories, Ministry of Health	Japan Association of Clinical Reagents Industries
	Università degli Studi di Milano	20132 Milano, ITALY	Beijing 100730,China	Tokyo, Japan 103-0026
	20157 Milano, *Italy*			

NEW

Gerhard Schumann	Steve Wolf	Hideo Misaki
Klin. Chem.	Beckman Coulter, Inc.	KAINOS Lab. Inc
D-30623 Hannover, Germany	Brea, CA 92821-6208	Izu-city, Shizuoka, 410-2501

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM: REFERENCE MATERIALS AND REFERENCE PROCEDURES			
Analyte Category	**Review Team Chair**	**Review Team Members**	
Metabolites and Substrates	**Michael Welch**	**Xu Bei**	**Norihiko Kayahara**
	NIST	National Research Center for Certified Reference Material	Kyowa Medex Co., Ltd.
	Gaithersburg, MD 20899-8392	Beijing 100013 PR China	Tokyo 104-6004,JAPAN

Neil Greenberg	**Andre Henrion**	**Steve Wolf**	**Mary Kimberly**
Ortho Clinical Diagnostics, a Johnson and Johnson Co.	PTB	Beckman Coulter, Inc.	CDC
Rochester, NY 14626-5101	Braunschweig, Germany D-38116	Brea, CA 92821-6208	Chamblee, GA 30341-3742

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members	
Microbial Serology	**Morag Ferguson**	**Thomas Ciesiolka**	**Claude Giroud**
	National Institute for Biological Standards and Control / /Division of Endocrinology (NIBSC)	Roche Diagnostics GmbH	Bio-Rad Laboratories
	UK	Germany	92430 Marnes-la-Coquette - France

Toshiaki Mizuochi	**C. Micha Nübling**	**Sjoerd Rijpkema**	**Wolfgang Philipp**
Department of Safety Research on Blood and Biological Products	Paul-Ehrlich-Institut	National Institute for Biological Standards and Control/Division of Bacteriology	IRMM
National Institute of Infectious Diseases	Division of Virology	UK	Geel, Belgium B-2440
Tokyo 162-8640 Japan	Germany		

Ian Sharp	**David Sogin**
Deputy Director of Evaluations and Standards Laboratory	Abbott Laboratoies Diagnostics Division
London, NW9 5EQ UK	Abbott Park, IL 60035-6015

Continuation Proposed	Removal Requested

** Review team members have not been verified.

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members	
Non-Electrolyte Metals	Lee Yu	Koichi Chiba	Peter Evans
	NIST	National Metrology Institute of Japan	LGC Ltd
	Gaithersburg, MD 20899-8391	Tsukuba-shi 305-8563, JAPAN	0LY

Neil Greenberg	Andrea Held	Heinrich Kipphardt	Patrick J. Parsons
Ortho-Clinical Diagnostics	IRMM	BAM	New York State Department of Health
Rochester, NY 14626-5101	Geel, Belgium B-2440	D-12489 Berlin, Germany	Albany, NY 12201-0509

Enrico Rizzio	Detlef Schiel	Ralph Sturgeon	Xingrong Zhang
IMGC, Unit of Radiochemistry and Spectroscopy	PTB	NRC-Canada	Tsinghua University
12-27100 Pavia, Italy	38116	Ottawa Canada	Beijing 100084 P.R. China

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members	
Hormones (non-peptide)	Heinz Schimmel	Wenxiang Chen	Daniel Ehresmann
	IRMM	National Center for Clinical Laboratories, Ministry of Health	Beckman Coulter, Inc.
	Geel, Belgium B-2440	Beijing 100730,China	Chaska, MN 55318-1084

NEW

Ken Kapsner	Lothar Siekmann	David Sogin	Michael Welch (Susan Tai)
Beckman Coulter, Inc.	Institute of Clinical Biochemistry	Abbott Laboratoies Diagnostics Division	NIST
Chaska, MN 55318-	University of Bonn	Abbott Park, IL 60035-6015	Gaithersburg, MD 20899
	Bonn, Germany D-53127		

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM

REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members		
Nucleic Acids	Helen Parkes	Steve Gutman	Tomoshige Hori	Philip Minor
	LGC Ltd	FDA	Japan Bioindustry Association	National Institute for Biological Standardization and Control (NIBSC)
	Middlesex, UK TW11 0LY	Rockville, MD 20850	Tokyo 104-0032, Japan	U.K. EN6 3QG

		NEW	NEW
Heinz Schimmel	Vincent Vilker	Morag Ferguson	Roberta Madej
IRMM	NIST	National Institute for Biological Standardization and Control (NIBSC)	Roche Molecular Systems
Geel, Belgium B-2440	Gaithersburg, MD 20899-8310	Herts, EN6 3QG, UK	Pleasanton, CA 94588, US

NEW	NEW	NEW
Paul Wallace	Devery Howerton	Joan Gordon
Quality Control in Molecular Diagnostics (QCMD)	Centre for Disease Control (CDC)	Maine Molecular QC, Inc
Glasgow G20 0SP, UK	MS G-23, 4770 Buford Hwy, Atlanta GA 30341-3717	Scarborough, ME 04074

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM:
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members		
Proteins	**David Sogin**	**David Bunk**	**Katsuhiko Yamamoto**	**Chandra Jain**
	Abbott Laboratoies Diagnostics Division	NIST	Fujirebio Inc.	Beckman Coulter, Inc.
	Abbott Park, IL 60035-6015	Gaithersburg, MD 20899	Tokyo 192-0031,JAPAN	Brea, CA 92822-8000

A. Myron Johnson	**Richard Miller**	**Mauro Panteghini**	**Brian Rafferty**
University of North Carolina	Dade Behring	Cattedra di Biochimica Clinica e Biologia Molecolare Clinica	Biological Standards and Control / /Division of Endocrinology (NIBSC)
Chapel Hill, NC 27599-7516	Newark, DE 19714-6101	Università degli Studi di Milano	UK
		20157 Milano, *Italy*	

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM					
REFERENCE MATERIALS AND REFERENCE					
Analyte Category	Review Team Chair	Review Team			
Quality Systems	Craig Jackson	David Duewer	Richard Miller	Robert Wielgosz	Katherine Sharpless
	San Diego, CA 92121-435	NIST	Dade Behring	Bureau International des Poids et Mesures	NIST
		Gaithersburg, MD	Newark, DE 19714-	F-92312 Sevres Cedex	Gaithersburg, MD 20899

Continuation Proposed	Removal Requested

Members of Working Group 1 of JCTLM
REFERENCE MATERIALS AND REFERENCE PROCEDURES

Analyte Category	Review Team Chair	Review Team Members	
Vitamin	Katherine Sharpless	Thomas Ciesiolka	Malcolm Hamilton
	NIST	Roche Diagnostics GmbH	Good Hope NHS Trust
	Gaithersburg, MD 20899	D- 82377 Penzberg, Germany	Sutton Coldfield B77 7RR UK

Masayuki Totani	Ben Twombly	Franz Ulberth
Graduate School of Human Life Science	Catachem, Inc.	IRMM
Showa Women's University	Bridgeport, CT 06606	Geel, Belgium B-2440
Tokyo, 154-8533 Japan		

Continuation Proposed	Removal Requested

Thanks for your attention !!!

For further information:

willie.may@nist.gov

heinz.schimmel@cec.eu.int

http://www.bipm.org/en/committees/jc/jctlm