

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

- *Terms of Reference*
 - *Review Teams*
 - *Review Process*
 - *Results of Cycle I Reviews*
 - *Status of Cycle II Reviews*
 - *Assessment of Comparability of Listed Materials and Methods*
 - *Future Plans and Activities*
-

JOINT COMMITTEE on TRACEABILITY in LABORATORY MEDICINE



A global body, established in Paris on 12 June 2002, to meet the need for 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.

The Declaration of Cooperation between 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**) for establishment of the **JCTLM** can be found at <http://www.bipm.org/en/committees/jc/jctlm/declaration.html>

JCTLM - Structure

- **JCTLM Executive**

Chair: J. Thijssen (IFCC)

- *Priority setting*
- *Approval of WG's results*

- **JCTLM Working Groups: Task oriented**

1. Reference Materials and Reference Methods

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

2. Reference Laboratories - Networks

Co-Chairs: L. Siekmann (U. Bonn), L. Thienpont (U. Gent)

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.

JCTLM Reference Materials Nominations Template (1/2)

Unique Nomination Number	Date Nomination Filed	Analyte / Parameter				Basis for Traceability	
		Analyte Category	Analyte Name	CAS Number	Category I or II ?	Traceable to SI ?	Procedurally-defined (if so, name/cite procedure)

Matrix			RM								
Matrix Category	Matrix	Matrix JCTLM DB	Identifier / Number	Name	Availability (Duration)	Certifying Organization	Mode / approach used for value assignment (if not clearly stated in certificate)	Comments	Issued by NMI with Certificate	Certificate from other RM provider ?	RM listed in BIPM Database?

Concentration or Concentration Range of Analyte Certified / Assigned Value			Range of Expanded Uncertainty for Analyte Certified/Assigned Value				Information for Assessing Commutability				
From	To	Unit	From	To	Unit	Lev. of conf. (%)	Physical form of RM matrix	RM fortified with analyte or naturally incurred	Applicable analyte characteristics (e.g., isoform(s); free/bound, total)	Other relevant factors (list)	Citation of specific publication / reference if available

JCTLM Reference Materials Nominations Template (2/2)

Congruent with other critical factors in ISO 15194 (list other relevant factors)?						Additional Comments	RM Documentation for publication via JCTLM DB		Contact information for publication via JCTLM DB					
Expression of Uncertainty							Hyperlink to Comparability Assessment Studies Among listed RMs	Other relevant publications	Producer	Country	Website	email address	Phone number	Fax number

Contact Information for Additional Details				Recommended for publication in JCTLM DB ?	FOR REVIEW COMMITTEE USE		Review Word Document
Name	email address	Phone number	How to obtain certificate		Does RM value-assignment approach meet traceability requirements of IVDD industry and regulatory community ?	Additional Reviewer Comments	

Nominated Reference Methods and Reference Materials

(Cycle I, Sept 2002 – March 2004)

	Reference Methods	Reference Materials
	~75	~ 300
Coagulation Factor		28
Drugs	3	84
Electrolytes	20	64
Enzymes	6	8
Hormones	25	16
Metab. & Substrates	22	62
Nucleic Acids		4
Proteins	3	51

Actually a few additional methods and materials were considered in each area. All Review Team Chairs were encouraged to actively solicit additional nominations as needed.

Priority Analyte Areas for Cycle I Review Process (Sept 2002 – March 2004)

Review Teams established with worldwide representation from Lab Accreditation Organizations, NMIs, Professional Societies, and IVD Industry in order to facilitate a fair and transparent review process.

Electrolytes

Metabolites and Substrates

Nucleic Acids

Hormones

Enzymes

Proteins

Drugs

Coagulation Factors

Quality Systems and Implementation Protocols

Additional Priority Areas for Cycle II Review Process (April 2004 - Dec 2004)

Blood Grouping/ Typing

Blood Gases

Microbial Serology

Non-Electrolyte Metals

Vitamins and Micronutrients

JCTLM Highest Priority Analyte Categories & Review Team Leaders

Analyte Category

Review Team Leaders

(With representative examples)

Coagulation Factors

Elaine Gray, NIBSC

Antithrombin

Fibrinogen

Drugs [therapeutic and “of abuse”]

Andre Henrion, PTB

Codeine

Valproic Acid

Cocaine

THC-COOH

Electrolytes

Richard Miller, Dade Behring

Calcium

Potassium

Sodium

Enzymes

Mauro Panteghini, Azienda Ospedaliera “Spedali Civili”

AMYLASE

CK

GGT

JCTLM Highest Priority Analyte Categories & Review Team Chairs – cont'd

Analyte Category

(With representative examples)

Review Team Chair

Metabolites and Substrates

Cholesterol

Creatinine

Glucose

Michael Welch, NIST

Nucleic Acids

Hepatitis A virus RNA,

Hepatitis B virus DNA

Helen Parkes, LGC

Non-Peptide Hormones

Cortisol

Estradiol-17 β

Thyroxine

Heinz Schimmel, IRMM

Proteins

Albumin

Troponin-I

PSA

David Sogin, Abbott Laboratories

New Analyte Category Areas & Review Team Leaders

- **Blood Grouping/ Typing** – Susan Thorpe, NIBSC
- **Blood Gases** – Susan Blonshine, NCCLS
- **Microbial Serology** – Morag Ferguson, NIBSC
- **Non-Electrolyte Metals** – L. 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)**

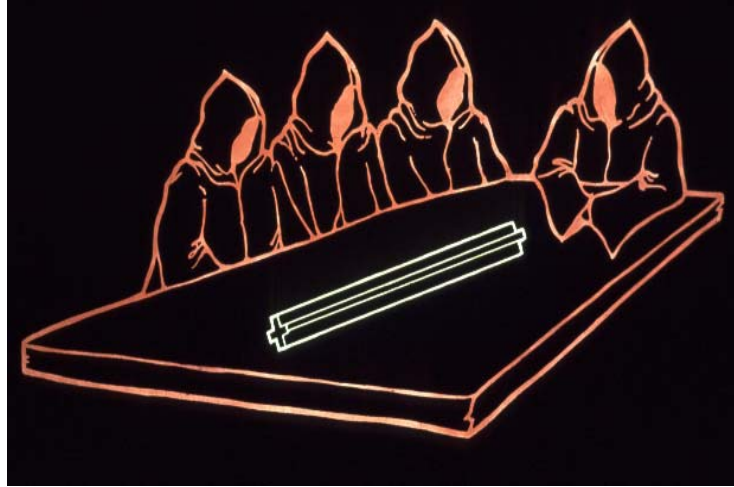
Joint Committee on the Traceability of Laboratory Medicine List of Higher Order Reference Materials and Reference Measurement Procedures

Analyte Categories and Review Teams

Metabolites and Substrates
Cholesterol; Creatinine; Glucose

Michael Welch, National Institute of Standards and
Technology (NIST)
Xu Bei, National Research Center for Certified
Reference Material
Kazuo Fujihashi, Japan Association of Clinical
Reagents Industries
Neil Greenberg, Ortho-Clinical Diagnostics
Andre Henrion, Physikalisch-Technische
Bundesanstalt (PTB)
Steve Wolf, Beckman Coulter, Inc.

NOT !!!!!



Benchmarked Against Applicable Normative Standards

Presentation of **reference measurement procedures** (EN 12286:1998 + 12286/A1:2000; ISO/FDIS 15193)

BUT RATHER!!!!

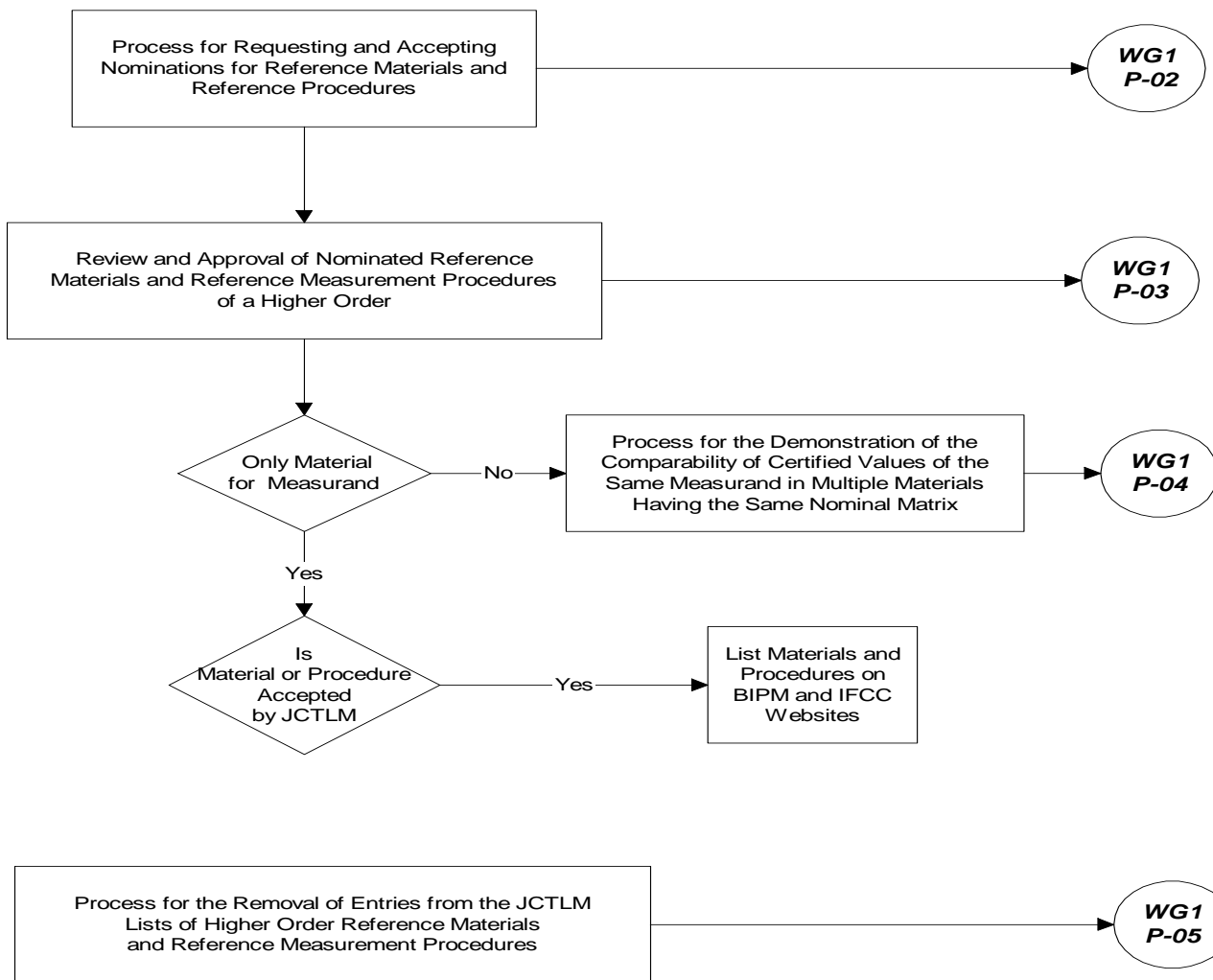
Description of **reference materials** (EN 12287:1999, ISO/FDIS 15194)

Metrological **traceability** of values assigned to calibrators and control materials (prEN ISO/FDIS 17511)

Metrological **traceability** of values for catalytic concentration of **enzymes** assigned to calibrators and control materials (prEN ISO/FDIS 18153)

Outline - WG1-P-01

Procedure Code



Classification Scheme

used During Review Cycle I

- **Review Teams sorted all nominated Reference Materials and Reference Measurement Procedures based on their assessment of compliance with relevant ISO Standards**
 - α list **Fully Compliant**
 - β list **Provisionally Acceptable**
 - γ list **Does Not Meet Requirements**
- **α and β category nominations merged into a single list and submitted for JCTLM Executive consideration (without distinction). Two Lists to be established {see next slide}**
- **Each Review Team will keep track of the nominations by category and solicit missing and/or clarify information regarding all β category nominations to determine if these nominations should remain on the List for 2005**

Initial Provisional Lists 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 that 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.

Initial Provisional Lists of Higher Order Reference Materials and Reference Measurement Procedures published 01 April 2004

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 that are traceable to the SI units. [*Electrolytes, Drugs, Metabolites and Substrates, Non-Peptide Hormones, Enzymes and some Proteins*]

approximately **100** Reference Measurement Procedure entries for **58** different health status markers

approximately **150** Reference Material entries for **96** measurands

<http://www.bipm.org/en/committees/jc/jctlm/jctlm-db/>

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

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.

- 10 CRMs for Coagulation Factors
- 7 CRMs for Proteins

Hereafter, Lists I and II to be updated in April of each year

Seven CRMs for Proteins to be published on List II

Reference Materials							
Information about Material				Contact Information	References		Comments
Analyte	Matrix	Material Name and/or ID #	Estimated * Availability (months, as of Jan 2004) HIDE	- Producer - Country - Website - Email Address - Phone Number - Fax Number	Commutability Study Information and/or Citations	Other Relevant Publications	Hyperlink to Comparability Assessment Studies Comments
alphafoetoprotein	purified	BCR-486		IRMM Belgium www.irmm.jrc.be/irmm.html E-mail:bcr.sales@irmm.jrc.be Tel: 32-14-571721 Fax: 32-14-590406			
angiotensin I	angiotensin I acetate	SRM 998		NIST USA http://ts.nist.gov/ts/htdocs/230/232/232.htm Email:srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730			http://patapsco.nist.gov/srmcatalog/certificates/view_cert2.gif?m?certificate=998
apolipoprotein A I	human serum	BCR-393		IRMM Belgium www.irmm.jrc.be/irmm.html E-mail:bcr.sales@irmm.jrc.be Tel: 32-14-571721 Fax: 32-14-590406			
apolipoprotein A II	human serum	BCR-394		IRMM Belgium www.irmm.jrc.be/irmm.html E-mail:bcr.sales@irmm.jrc.be Tel: 32-14-571721 Fax: 32-14-590406			
carbohydrate deficient transferrin	human serum	ME 30830 ME 30840		GTFCh/ Medichem or SFTA/Medichem UK http://www.lgcpromochem.com/home/home_en.aspx christian.zeine@lgcpromochem.com Tel: 44(0)1264 6987 275			
prostate specific antigen	purified	BCR-613		IRMM Belgium www.irmm.jrc.be/irmm.html E-mail:bcr.sales@irmm.jrc.be Tel: 32-14-571721 Fax: 32-14-590406			
thyroglobulin (human)	purified	BCR-457		IRMM Belgium www.irmm.jrc.be/irmm.html E-mail:bcr.sales@irmm.jrc.be Tel: 32-14-571721 Fax: 32-14-590406			

Ten CRMs for Coagulation Factors to be published on List II

Reference Materials							
Information about Material			Contact Information	References		Comments	
Analyte	Matrix	Material Name and/or ID #	- Producer - Country - Website - Email Address - Phone Number - Fax Number	Commutability Study Information and/or Citations	Other Relevant Publications	Hyperlink to Comparability Assessment Studies Among Listed RMs	Comments
Antithrombin	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Coagulation Factor II	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Coagulation Factor IX	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Coagulation Factor VII	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Coagulation Factor VIII	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Coagulation Factor X	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Fibrinogen	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Protein C	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
Protein S	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants
von Willebrand Factor	Iyophilised human plasma	SSC Lot#2	ISTH/NIBSC UK www.nibsc.ac.uk thubbard@nibsc.ac.uk Tel: +44 1707 641318 Fax: +44 1707 647227		http://www.med.unc.edu/isth/coagstandnewpage.htm		Calibrated directly against the WHO international standard, intended for use by diagnostic manufacturers for calibration of kits and calibrants

JCTLM Database Portal

under development

Analyte Name

potassium

e.g. type an analyte name in part or full, or a CAS number

Matrix

Blood serum 

- All
- High Purity Material
- Calibration Solution
- Whole Blood
- Blood Serum**
- Urine
- Other

User Requirement



Reference Material




Reference Measurement Procedure



Reference Laboratory

Reference Materials				
Information about Material				Contact Information
Analyte	Matrix	Material Name and/or ID #	Estimated * Availability (months, as of Jan 2004)	<ul style="list-style-type: none"> - Producer - Country - Website - Email Address - Phone Number - Fax Number



References			Comments
Commutability Study Information and/or Citations	Other Relevant Publications	Hyperlink to Comparability Assessment Studies	

Link to List I published on BIPM website for [Electrolytes, Enzymes, Drugs, Metabolites and Substrates, Non-Peptide Hormones, some Proteins](#)

Results of Search: Reference Materials for High Purity Cholesterol

Reference Materials							
Information about Material			Contact Information	References	References		
Analyte	Matrix	Material Name and/or ID #	<ul style="list-style-type: none"> - Producer - Country - Website - Email Address - Phone Number - Fax Number 	Commutability Study Information and/or Citations	Other Relevant Publications	Hyperlink to Comparability Assessment Studies	Comments
cholesterol	neat cholesterol crystalline material	GBW09203b	NRCCRM China Tel: 086-10-64221811 Fax: 086-10-64213149 Email: crmservice@nrccrm.com.cn	Primary calibrator for higher order reference methods			
cholesterol	neat cholesterol crystalline material	SRM 911b	NIST USA http://ts.nist.gov/ts/htdocs/230/232/232.htm Email: srminfo@nist.gov	Primary calibrator for higher order reference methods			

Results of Search: Reference Materials for Cholesterol in Serum

Reference Materials							
Information about Material			Contact Information	References	References		
Analyte	Matrix	Material Name and/or ID #	<ul style="list-style-type: none"> - Producer - Country - Website - Email Address - Phone Number - Fax Number 	Commutability Study Information and/or Citations	Other Relevant Publications	Hyperlink to Comparability Assessment Studies	Comments
cholesterol	human serum	JCCRM 211	HECTEF Japan http://www.in8.co.jp/hectef/start_e.htm Tel: 81-44-813-0055 Fax: 81-44-813-0224			NIST study presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France	
cholesterol	human serum (frozen)	SRM 1951b	NIST USA http://ts.nist.gov/ts/htdocs/230/232/232.htm Email: srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730	Material prepared following NCCLS Document C37-A "Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline" Method used for certification:		Previous lot (1951a) was measured in NIST study presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France	
cholesterol	human serum (lyophilized)	SRM 1952a	NIST USA http://ts.nist.gov/ts/htdocs/230/232/232.htm Email: srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730		Method used for certification: Anal Chem 61, 1718-1723 (1989)	NIST study presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France	
cholesterol	human serum (lyophilized)	SRM 968c	NIST USA http://ts.nist.gov/ts/htdocs/230/232/232.htm Email: srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730		Method used for certification: Anal Chem 61, 1718-1723 (1989)	NIST study presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France	
cholesterol	human serum (lyophilized)	SRM 909b	NIST USA http://ts.nist.gov/ts/htdocs/230/232/232.htm Email: srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730		Certification process described: Fresenius' J. Anal. Chem. 361:2 71-80 (1998); Method used for certification: Anal Chem 61, 1718-1723	NIST study presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France	

Results of search

Certified Reference Materials for Potassium in Serum

Analyte	Matrix	Material Name and/or ID #	- Producer - Country - Website - Email Address - Phone Number - Fax Number	Commutability Study Information and/or Citations	Other Relevant Publications	Hyperlink to Comparability Assessment Studies Among Listed RMs	Comments
potassium	human serum	SRM 909b Human Serum	NIST USA http://www.nist.gov/srm Email: srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730			See summary of Comparability Assessment for Potassium in Human Serum CRMs on JCTLM List I at http://www1.bipm.org/utills/en/pdf/jctlm_preamble.pdf (originally presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France)	
potassium	human serum	SRM 956b Electrolytes in Frozen Human Serum	NIST USA http://www.nist.gov/srm Email: srminfo@nist.gov Tel: (301)975-6776 Fax: (301)948-3730	Material Prepared following NCCLS C29A2 Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method -	Also see Clin. Chem., Aug 1992; 38: 1459 - 1465.	See summary of Comparability Assessment for Potassium in Human Serum CRMs on JCTLM List I at http://www1.bipm.org/utills/en/pdf/jctlm_preamble.pdf (originally presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France)	
potassium	human serum	JCCRM 111	JCCRM Japan hctefum@mri.biglobe.ne.jp Tel: 0032-14-5-71-721	Material Prepared following NCCLS C29A2 Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method -		See summary of Comparability Assessment for Potassium in Human Serum CRMs on JCTLM List I at http://www1.bipm.org/utills/en/pdf/jctlm_preamble.pdf (originally presented at JCTLM Meeting, June 20, 2003, BIPM, Sevres, France)	

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
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Results of search

Reference Measurement Procedures for Cholesterol in Serum/Plasma

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	lyophilized, fresh, or frozen human serum or plasma	ID/GC/MS	Siekmann et al., Z. anal. Chem. 279, 145-146 (1976)	PTB - National Key Comparison for Accreditation
cholesterol	CDCAbell-Kendall method for cholesterol	lyophilized, fresh or frozen human serum	Spectrophotometry	Cooper, GR, et al, Clin Chem 32: 921-929, 1986	Clin Chem 36, 370-375 (1990)
cholesterol	NIST definitive method for serum cholesterol	lyophilized, fresh, or frozen serum	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	lyophilized, fresh, or frozen serum	ID/GC/MS	Clin Chem 39,1001-6 (1993) [=part II of Clin Chem 39,993-1000 (1993)]; Eur J Clin Chem Clin Biochem 34, 853-60 (1996); Clin Chem 42, 531-5 (1996)	EUROMET 563

Results of the search for Potassium

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
potassium	NIST/CDC/AACC Flame Atomic Emission Method for Serum Potassium	human serum	Flame Atomic Emission Spectroscopy	NBS Special Publication 260-63 (http://ts.nist.gov/ts/hdocs/230/232/SP_PUBLICATIONS/documents/SP260-63.pdf)	See NBS Special publication 260-63 (http://ts.nist.gov/ts/hdocs/230/232/SP_PUBLICATIONS/documents/SP260-63.pdf)
potassium	NIST ID-TIMS Method for Serum Potassium	human serum	IDMS	NBS Special Publication 260-63 (http://ts.nist.gov/ts/hdocs/230/232/SP_PUBLICATIONS/documents/SP260-63.pdf)	See NBS Special publication 260-63 (http://ts.nist.gov/ts/hdocs/230/232/SP_PUBLICATIONS/documents/SP260-63.pdf)
potassium	NIST ID-ICP/MS Method serum potassium	human serum; lyophilized, fresh or frozen	ID/ICP-MS	J. Anal. At. Spectrom. 17, 469-477 (2002)	
potassium	Ion Chromatographic Reference Method for Potassium	human serum; lyophilized, fresh or frozen	Ion chromatography	J Chromatogr A 706,443-50 (1995); Clin Biochem 29, 501-8 (1996); J Chromatogr A 789, 557-568 (1997); Ann Clin Biochem 36, 80-5 (1999); Clin Chem 44, 849-57 (1998)	

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

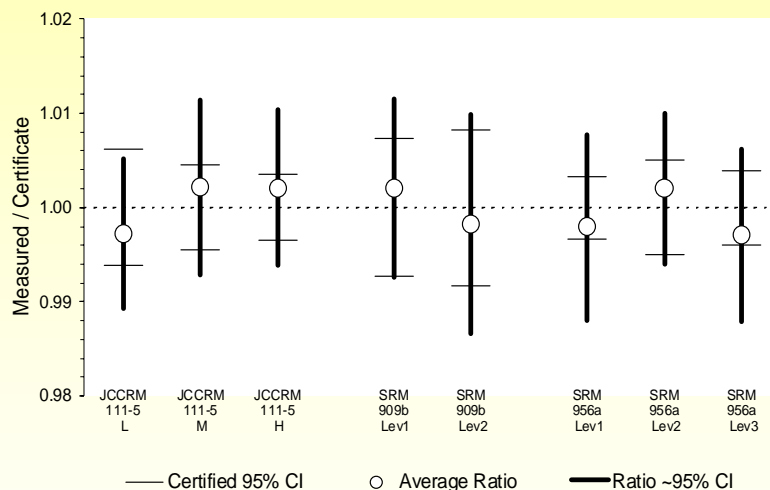


Fig 2: Scattergram Display

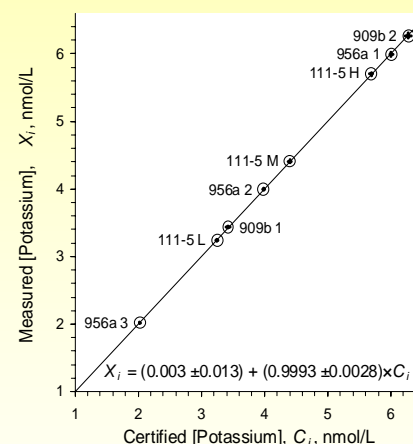
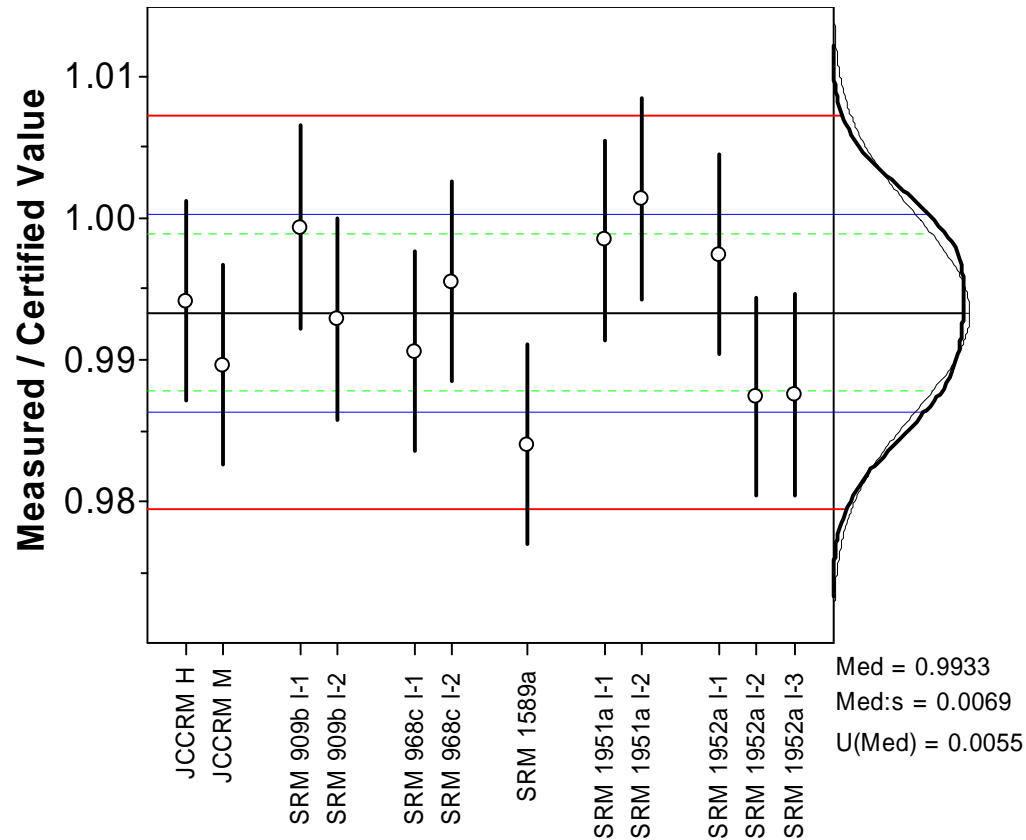
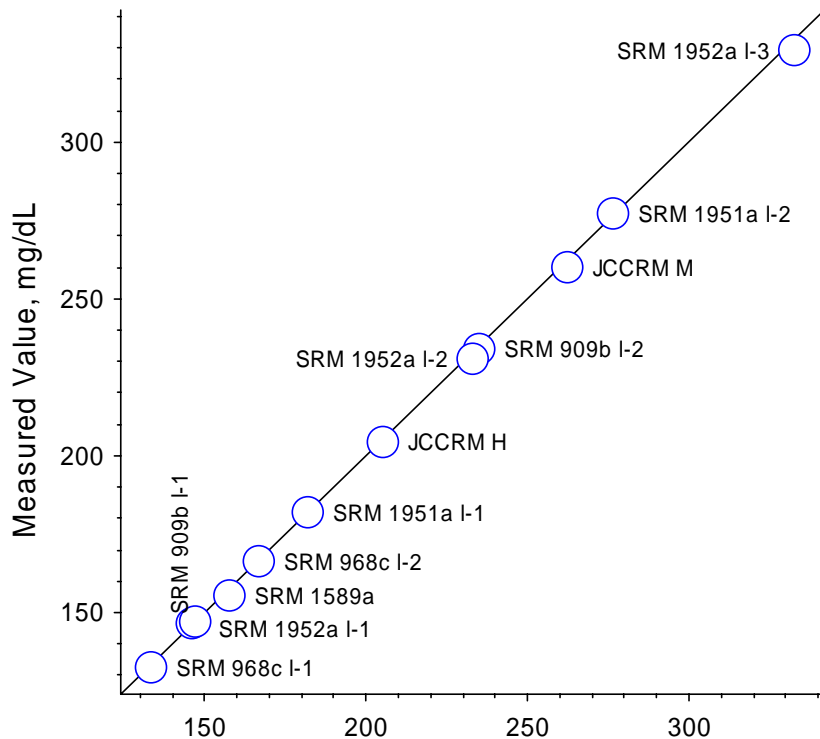


Fig 1: The vertical axis reports the ratio between the measured and certified values of each CRM, X/C_i . The dark vertical lines represent the approximate 95% CI about the ratios. The light horizontal lines represent the certified 95% CIs. The dotted line represents the expected ratio for the suite 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



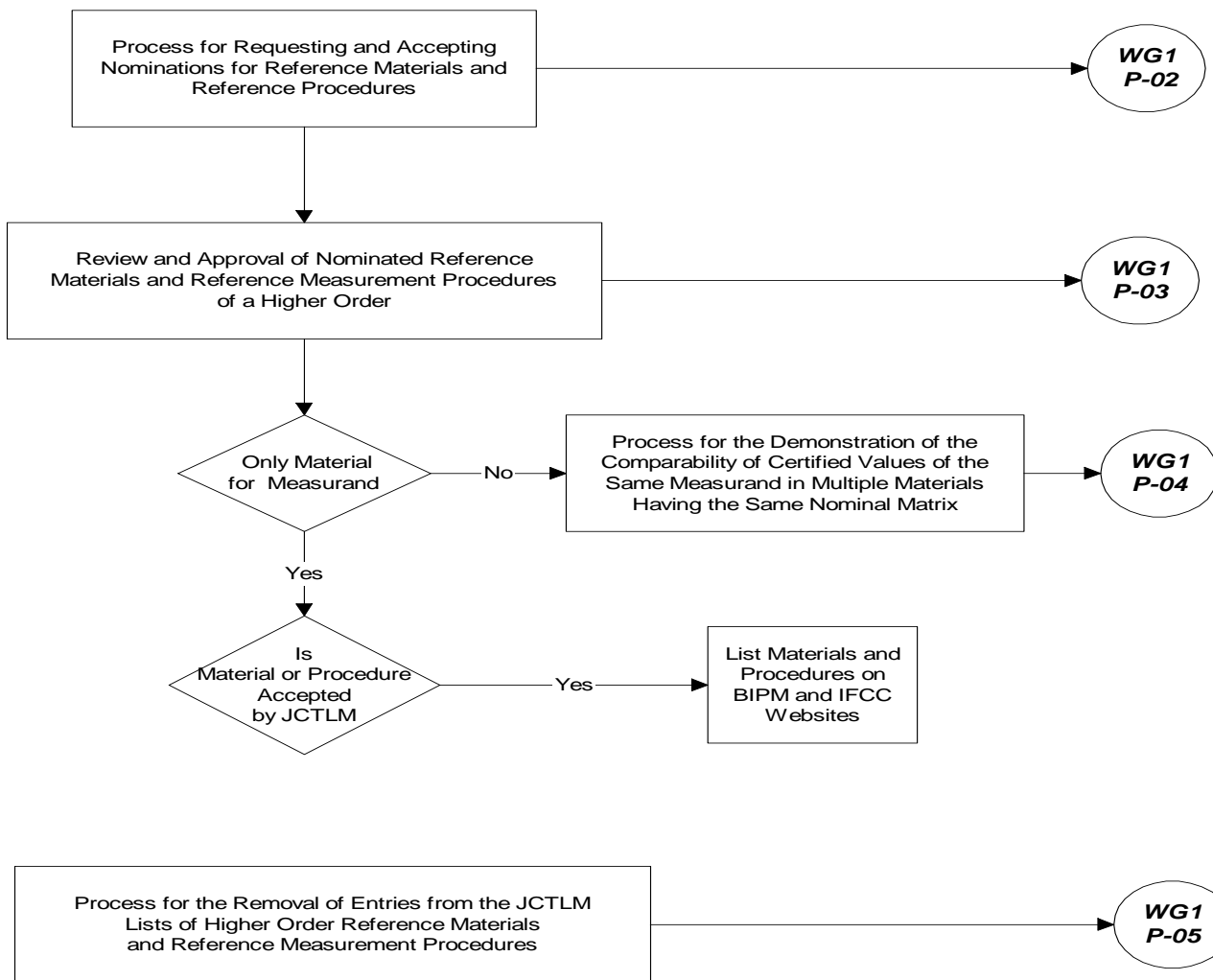
⇒ CRM comparability independent of analyte level

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

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

Outline - WG1-P-01

Procedure Code



Nominated Reference Methods and Reference Materials

(Cycle II, April 2004 – December, 2004)

	Reference Methods	Reference Materials
	<i>~75</i>	<i>~75</i>
Blood Gases	1	3
Blood Grouping/ Typing	0	3
Coagulation Factors		
Drugs	1	0
Electrolytes	3	
Enzymes	0	7
Non-Peptide Hormones	2	0
Metab. & Substrates	8	0
Microbial Serology	8	6
Non-Electrolyte Metals	50	43
Nucleic Acids	0	0
Proteins	0	2
Vitamins	2	9

JCTLM WG I Action Items

based on discussions during JCTLM Executive Meeting 01 March, 2004

- Publish List I based on Cycle I nominations–
for Reference Materials and Reference Laboratory Procedures, with descriptive Preamble, 01 April, 2004
- **Modify Preamble and publish List II based on Cycle I nominations–**
for Reference Materials during the last quarter of 2004 after further discussions among the Working Group]
- **Proceed with open call for Cycle II nominations in original 8 plus the 5 new categories by 01 April, 2004**
- **Complete WG-I Quality Manual and present to JCTLM Executive for Adoption by August 1, 2004**
- **Process and review nominations received during Cycle II**
- **Update Lists I and II, 01 April 2005; begin thorough QA process**



Thanks for your attention !!!

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<http://www.cstl.nist.gov/nist839/jctlm.htm>

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