Bureau International des Poids et Mesures

JCTLM SYMPOISUM 2007

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

Joint Committee for **Traceability** in Laboratory Medicine

- What is it?
- Why is it important?
- How is it implemented?
- How does the JCTLM help?

What Is Metrological Traceability?

- Definition VIM:1993, 6.10

Metrological traceability - property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

NOTES

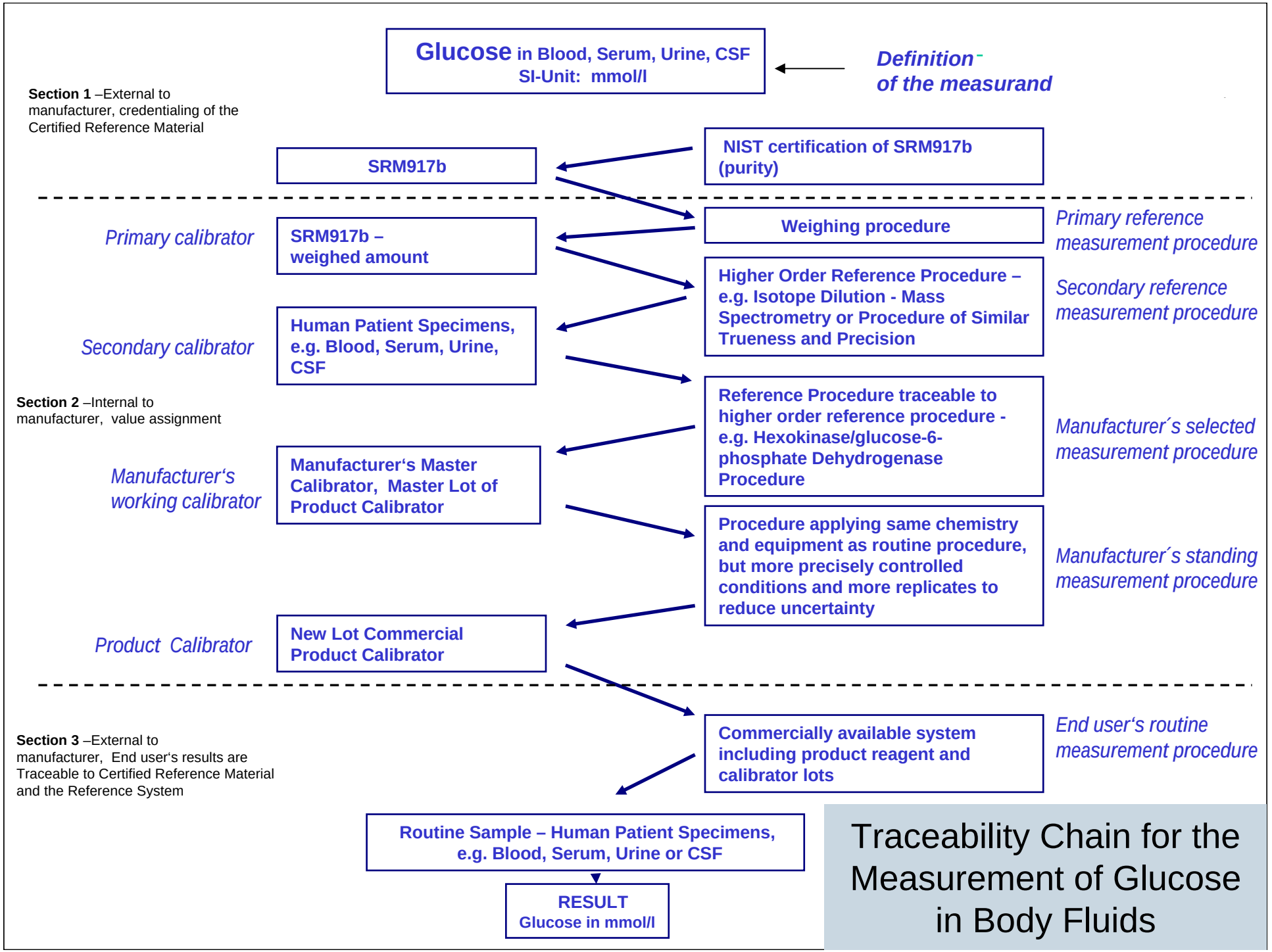
1 The concept is often expressed by the adjective **traceable**.

2 The unbroken chain of comparisons is called a **traceability chain**.

Uncertainty Definition

VIM 1993, 3.9

- **uncertainty of measurement** - parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand


Glucose in Blood, Serum, Urine, CSF
SI-Unit: mmol/l
Definition of the measurand
Section 1 –External to manufacturer, credentialing of the Certified Reference Material
SRM917b
NIST certification of SRM917b (purity)
Primary calibrator
SRM917b – weighed amount
Weighing procedure
Primary reference measurement procedure
Higher Order Reference Procedure – e.g. Isotope Dilution - Mass Spectrometry or Procedure of Similar Trueness and Precision
Secondary reference measurement procedure
Secondary calibrator
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
Section 2 –Internal to manufacturer, value assignment
Reference Procedure traceable to higher order reference procedure - e.g. Hexokinase/glucose-6-phosphate Dehydrogenase Procedure
Manufacturer´s selected measurement procedure
Manufacturer‘s working calibrator
Manufacturer‘s Master Calibrator, Master Lot of Product Calibrator
Procedure applying same chemistry and equipment as routine procedure, but more precisely controlled conditions and more replicates to reduce uncertainty
Manufacturer´s standing measurement procedure
Product Calibrator
New Lot Commercial Product Calibrator
Section 3 –External to manufacturer, End user‘s results are Traceable to Certified Reference Material and the Reference System
Commercially available system including product reagent and calibrator lots
End user‘s routine measurement procedure
Routine Sample – Human Patient Specimens, e.g. Blood, Serum, Urine or CSF
RESULT
Glucose in mmol/l
Traceability Chain for the Measurement of Glucose in Body Fluids

The Importance of Metrological Traceability

- Why has traceability become important
  - Clinical Considerations
  - Legislative and Standardization Efforts
- Ensuring Metrological Traceability
  - The Traceability Chain
  - Commutability
  - Uncertainty

Why Traceability

- Evidence Based Medicine is becoming more and more prominent in the practice of clinical laboratory science
  - Glucose
  - PSA
  - HbA1c
  - Creatinine (GFR calculations)
- All of these analytes have specific cutoffs that are independent of the assay used.
- To correctly utilize these cutoffs, the assays for the analyte in question must be comparable.

Comparability

- For the above types of clinical guidelines to be effective, the results from clinical laboratories must be comparable
- To be comparable they must to “traceable”
  - i.e. a traceability chain to the same materials and methods, commutable with patient sera and an uncertainty within clinical guidelines

Regulatory Requirements

- **IVD Directive (IVD Manufacturers)**

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

- **ISO 18159 (Clinical Laboratories)**

  “A program for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that measurements are traceable to the SI units or by reference to a natural constant”….

  “The laboratory shall determine the uncertainty of its measurements, where relevant and possible”.

- **ISO 17025 has similar requirements**

What has JCTLM delivered?

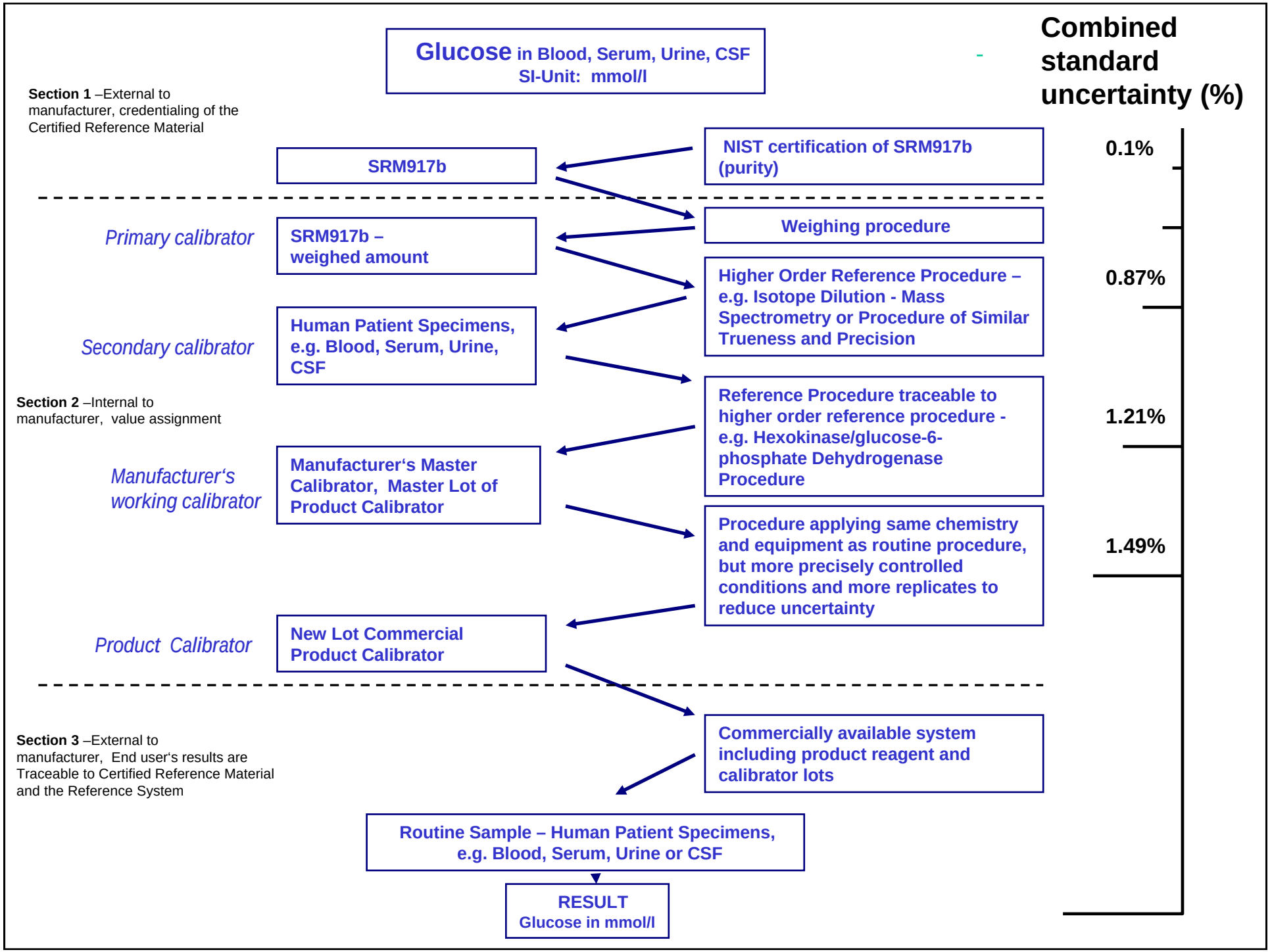
A Quality assured database of:

a) Higher Order Reference Materials
b) Reference Measurement Procedures
c) Laboratory Reference Measurement Services (2007)

http://www.bipm.org/jctlm/

For use by (primarily)

a) IVD industry
b) Regulators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0.1%
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0.87%
Secondary calibrator
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
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Reference Procedure traceable to higher order reference procedure - e.g. Hexokinase/glucose-6-phosphate Dehydrogenase Procedure
1.21%
Manufacturer‘s working calibrator
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1.49%
Product Calibrator
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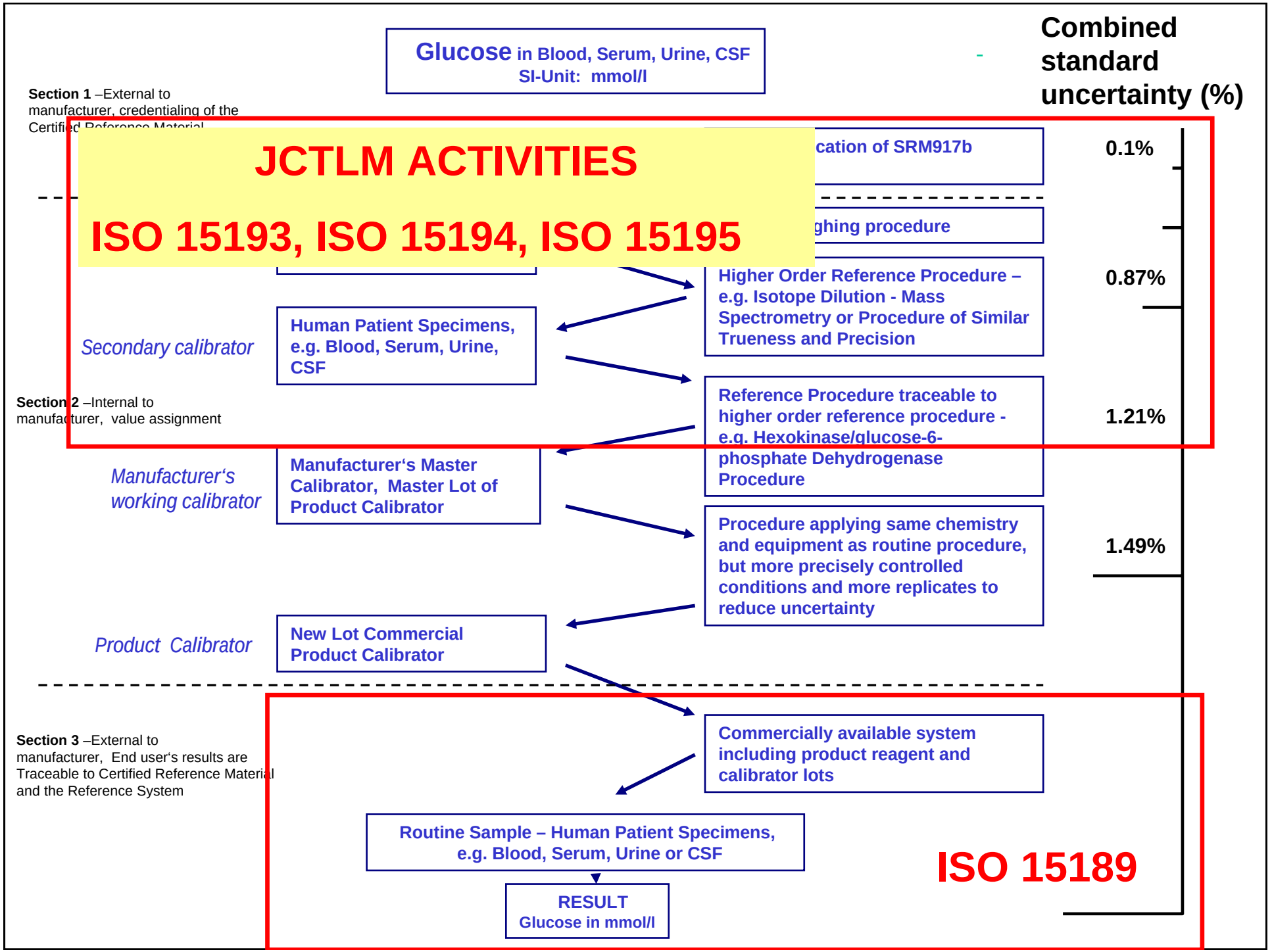
Commercially available system including product reagent and calibrator lots
Routine Sample – Human Patient Specimens, e.g. Blood, Serum, Urine or CSF
RESULT
Glucose in mmol/l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JCTLM ACTIVITIES
ISO 15193, ISO 15194, ISO 15195
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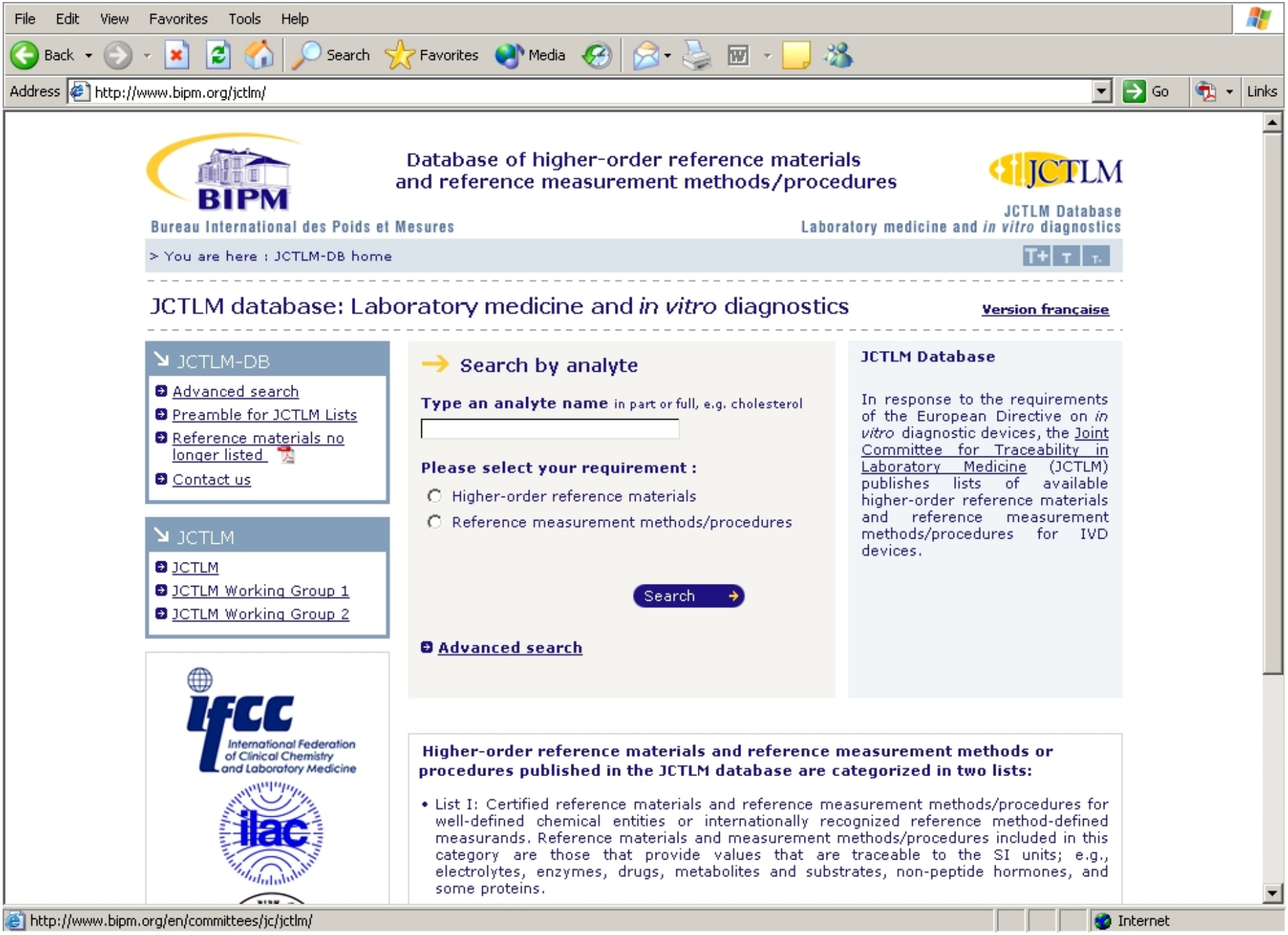
RESULT
Glucose in mmol/l
ISO 15189


File Edit View Favorites Tools Help
Back Search Favorites Media
Address http://www.bipm.org/jctlm/
Go Links
BIPM
Bureau International des Poids et Mesures
Database of higher-order reference materials
and reference measurement methods/procedures
JCTLM
JCTLM Database
Laboratory medicine and in vitro diagnostics
> You are here : JCTLM-DB home
JCTLM database: Laboratory medicine and in vitro diagnostics
Version française
JCTLM-DB
Advanced search
Preamble for JCTLM Lists
Reference materials no longer listed
Contact us
JCTLM
JCTLM
JCTLM Working Group 1
JCTLM Working Group 2
ifcc
International Federation of Clinical Chemistry and Laboratory Medicine
ilac
Search by analyte
Type an analyte name in part or full, e.g. cholesterol
Please select your requirement :
Higher-order reference materials
Reference measurement methods/procedures
Search
Advanced search
JCTLM Database
In response to the requirements of the European Directive on in vitro diagnostic devices, the Joint Committee for Traceability in Laboratory Medicine (JCTLM) publishes lists of available higher-order reference materials and reference measurement methods/procedures for IVD devices.
Higher-order reference materials and reference measurement methods or procedures published in the JCTLM database are categorized in two lists:
• List I: Certified reference materials and reference measurement methods/procedures for well-defined chemical entities or internationally recognized reference method-defined measurands. Reference materials and measurement methods/procedures included in this category are those that provide values that are traceable to the SI units; e.g., electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, and some proteins.
http://www.bipm.org/en/committees/jc/jctlm/
Internet

Operational Structure

- **Executive Committee**
- **Working Groups**

1. **Reference Materials and Reference Methods**

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

   Compilation of existing RMPs and CRMs (Lists)

2. **Reference Laboratories - Networks**

   Chairs: L. Siekmann, L. Thienpont (IFCC)

   Guidelines for reference laboratories

   Identification of networks

Relevant ISO Standards for higher order RMs and RMPs

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

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

ISO 15193 **Presentation of reference measurement procedures**

ISO 15194 **Description of reference materials**

ISO 15195 **Reference Measurement Laboratories**

JCTLM WG1 Review Process

INTERNATIONAL STANDARD

ISO 15194

First edition
2002-10-01

In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Description of reference materials

Dispositifs médicaux de diagnostic in vitro — Mesure des grandeurs dans les échantillons d'origine biologique — Description des matériaux de référence

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Reference number
ISO 15194:2002(E)

JCTLM WG1 Review Process (ISO 15194)

5 Description of a reference material

5.1 Elements of a description

The description of a reference material of higher metrological order shall comprise at least the elements listed as mandatory (M) in Table 1.

NOTE: The order of the elements listed in Table 1 may be changed and additional elements, such as an abstract, may be added as appropriate.

Table 1: Main elements (clauses) of a report describing a reference material of higher metrological order

Element	Type [1]		Subclause in this European Standard
	M	O	
Title page	I		
Contents list		I	
Foreword	I		
Warning and safety precautions	N		5.2
Introduction		I	5.3
Title of report	N		
Scope	N		5.4
Definitions		N	
Symbols and abbreviations		N	
Terminology		N	5.5
Justification for choice of reference material	I		5.6
General characteristics	I		5.7
Specific characteristics	I		5.8
Validation	I		5.9
Intended function	I		5.10
Instructions for use	I		5.11
Supplier	I		5.12
Bibliography		I	5.13
Annexes		I	5.14
Dates	I		5.15

[1] Symbols for type of element in a European Standard:
M mandatory, O optional;
I informative, N normative.

JCTLM-WG1 Quality Manual:
Reference Materials and Reference Procedures

↘	**Preamble**		PDF	2006/01/31
↘	**WG1-P-00**	Quality Policy	PDF	2006/01/30
↘	**WG1-P-01**	Outline of JCTLM procedures	PDF	2006/01/31
↘	**WG1-P-02**	Reference material and procedure nomination requests	PDF	2006/01/31
↘	**WG1-P-02-F-01 & F-02**	Reference material and procedure nomination templates	XLS	2006/01/30
↘	**WG1-P-02-F-01 EXAMPLE**	Reference material nomination example	XLS	2006/01/30
↘	**WG1-P-02-F-02 EXAMPLE**	Reference procedure nomination example	XLS	2006/01/30
↘	**WG1-P-02-I-01**	Instructions for completing nomination templates	PDF	2006/01/31
↘	**WG1-P-03**	Review and approval of nominations	PDF	2006/01/30
↘	**WG1-P-03-F-03**	Review report form	DOC	2006/01/30
↘	**WG1-P-04A**	Multiple CRM comparison process	PDF	2006/01/30
↘	**WG1-P-04B**	Multiple reference method/procedure comparison process	PDF	2006/01/30
↘	**WG1-P-05**	Consensus review and communication of recommendations	PDF	2006/01/30
↘	**WG1-P-06**	Membership of JCTLM WG1 Review Teams	PDF	2006/01/31
↘	**WG1-P-06-F-01**	Review Team membership form	DOC	2006/01/30
↘	**WG1-P-07**	Process for changing the WG1 Quality System procedures	PDF	2006/01/31
↘	**WG1-P-07-F-01**	Procedure change request form	DOC	2006/01/30
↘	**WG1-P-08**	Process for changing WG Review Teams	PDF	2006/01/30
↘	**WG1-P-09**	Appeals process	PDF	2006/01/30

LIST I

published initially on 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 **123** Reference Measurement Procedure entries for **75** different health status markers

approximately **211** Reference Material entries for **128** measurands

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

JCTLM LIST 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.

Initially published in January, 2005, now includes

- 12 CRMs for Coagulation Factors
- 7 CRMs for Proteins

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

Summary of Cycles I & II Nominations and Approvals

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	84	5	23	3
Electrolytes	70	23	29	23
Enzymes	20	7	11	6
Metabolites and Substrates	69	44	39	35
Non-Electrolyte Metals	43	50	30	15
Non-Peptide Hormones	15	26	14	22
Nucleic Acids	5	0	0	0
Vitamins	8	2	7	0
Proteins	114	20	43	19
Blood Groupings	3	0	0	0
Coagulation Factor	34	0	12	0
Microbial Serology	10	8	0	0
Other	6	2	3	0
TOTAL Number	*482*	*188*	211	123

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

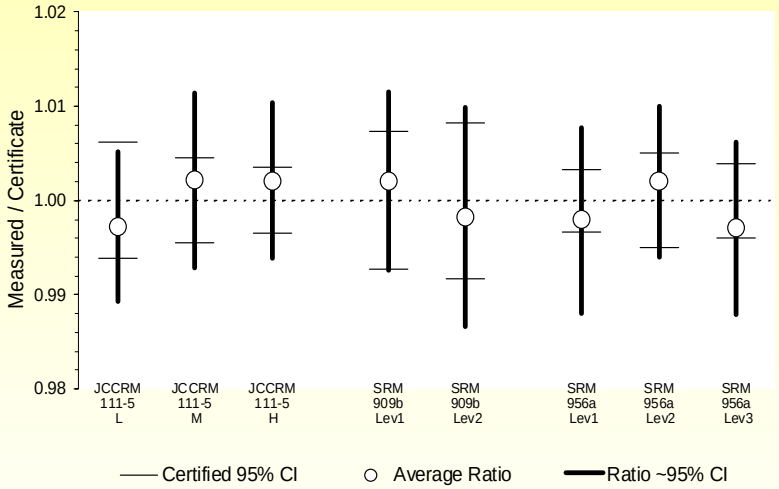


Fig 2: Scattergram Display

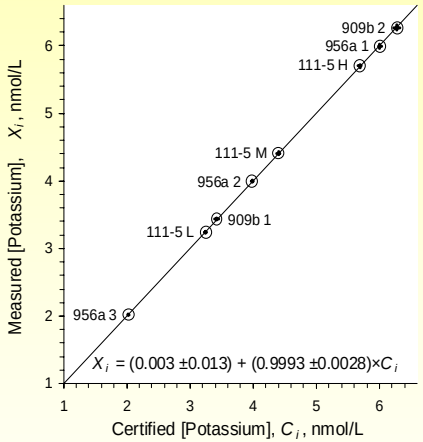
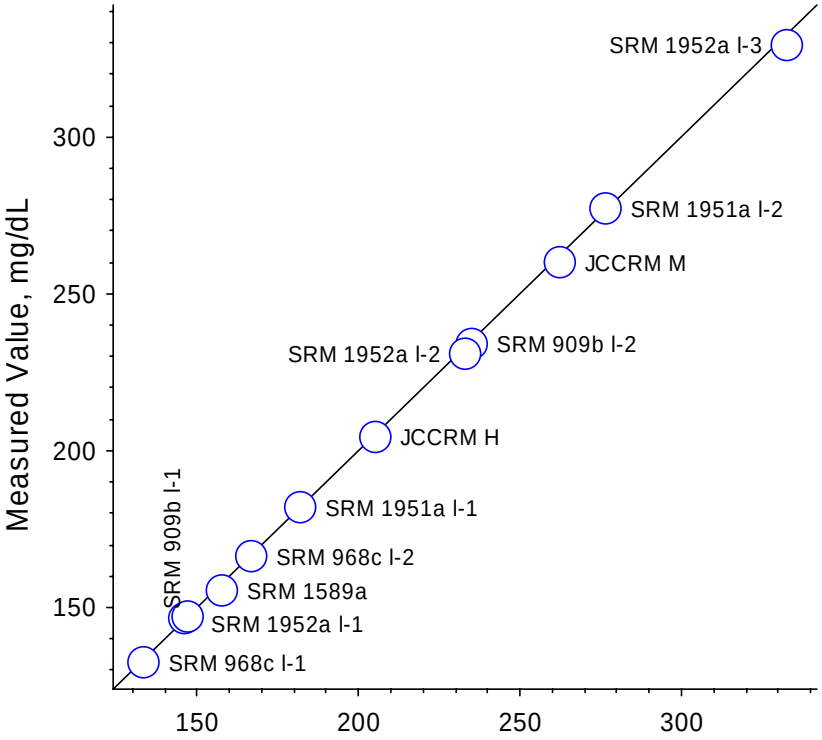
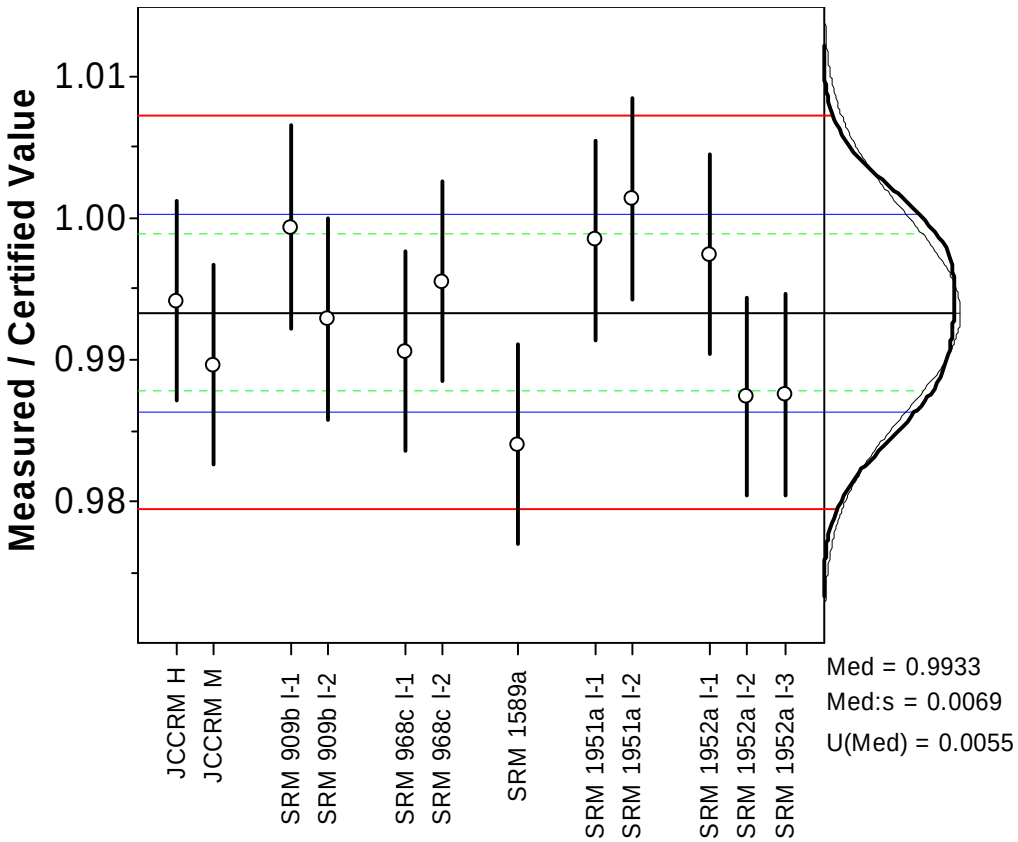


Fig 1: The vertical axis reports the ratio between the measured and certified values of each CRM, X_i/C_i. The dark vertical lines represent the approximate 95% CI about the ratios. The light horizontal lines represent the certified 95% CIs. The dotted line represents the expected ratio for the suite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

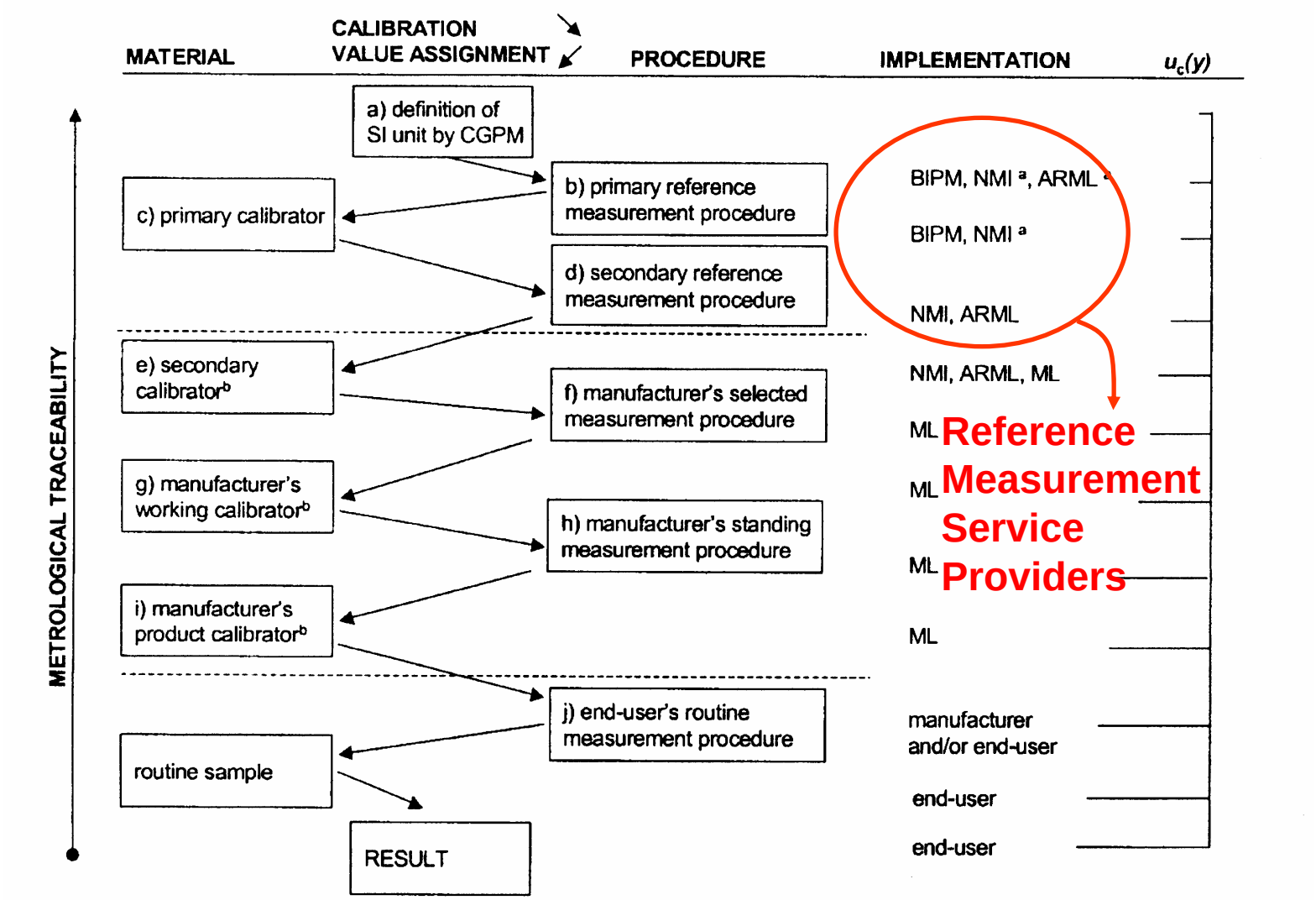
- ~ normally distributed
- with a standard deviation of ~0.7%

JCTLM Working Group II -
Reference Measurement Services

Assessed on basis of:

- Metrological level of the reference procedures used (compliance with JCTLM WG1 RMPs)
- Accreditation to ISO 17025 and ISO 15195 as a calibration laboratory and/or CIPM-MRA process
- Ongoing performance in inter-laboratory comparisons

SI traceability - Primary Calibrators (ISO 17511)



JCTLM Working Group II -

Reference Measurement Services for Laboratory Medicine

Cycle I Call for nominations (Closing date 30 April 2006)

JCTLM-WG2 Procedure Manual:
Reference Measurement Services

		Title	File type	Last update
↘	**WG2-P-00**	Outline of calibration hierarchy in laboratory medicine	PDF	2006/01/30
↘	**WG2-P-01**	Overview of JCTLM WG2 procedures	PDF	2006/01/30
↘	**WG2-P-02**	Nomination process for reference measurement laboratory services	PDF	2006/01/31
↘	**WG1-P-02-F-01**	Template for nomination of reference laboratory measurement services		2006/01/30
↘	**WG2-P-03A**	Review of NMI measurement services	PDF	2006/01/30
↘	**WG2-P-03B**	Review of measurement services from accredited laboratories	PDF	2006/01/30
↘	**WG2-P-03C**	Review of measurement services from laboratories preparing for accreditation	PDF	2006/01/30
↘	**WG2-P-04**	Listing reference measurement laboratory services	PDF	2006/01/30
↘	**WG2-P-05**	De-listing reference measurement laboratory services	PDF	2006/01/30

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

DGKL Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V.

eference Institute of Bioanalysis

Reference Laboratories in Laboratory Medicine

Registration Form for Ring Trial RELA 01/2004

Reference Laboratory Address:

Organisation:	Laboratory
Name of person responsible:	Name
Street:	
City:	
Post Code:	
State:	
Country:	
Phone:	
Fax:	
e-mail:	

Please return by August 15, 2004 to:

Dr. R. Kruse,
Dr. W. Geilenkeuser
DGKL
Im Mühlenbach 52 a
D-53127 Bonn - Germany

Fax: +49-228-211529
E-mail: info@dgkl-rfb.de

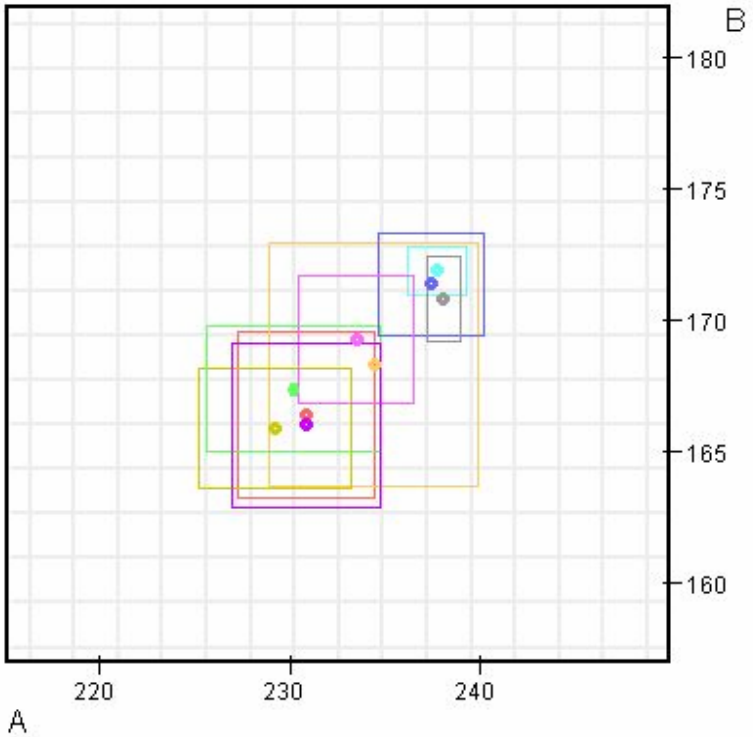
Please switch to next table (Measurands) !

	A	B	C
11			
12	Measurand	Participation please indicate "X"	Number of Vials
13			
14			
15			
16	METABOLITES & SUBSTRATES		
17	Total Cholesterol		
18	Total Glycerol		
19	Creatinine	x	2 x 5
20	Uric Acid		
21	Urea		
22	Glucose		
23	Total Bilirubine		
24			
25	ELECTROLYTES		
26	Sodium		
27	Potassium	x	2 x 5
28	Chloride		
29	Calcium		
30	Lithium		
31	Magnesium		
32			
33	ENZYMES		
34	ALT		
35	AST		
36	CK		
37	LDH		
38	GGT		
39	Amylase		
40			
41	Total Protein		
42			
43	HORMONES		
44	Aldosterone		
45	Cortisol	x	2 x 5
46	Progesterone		
47	Testosterone		
48	Estradiol-17ß		
49	Estriol (non-conjugates)		
50	Total Thyroxine (TT4)		
51	Total Tri-iodothyronine (TT3)		
52	17-Hydroxyprogesterone		
53			
54	THERAP.DRUGS		
55	Digoxin	x	2 x 5
56	Digitoxin		
57	Theophyllin		

IFCC EQAS, Inter-laboratory comparisons for Reference Measurement Laboratories

RELA 1/2003

Total cholesterol [mg/dl]

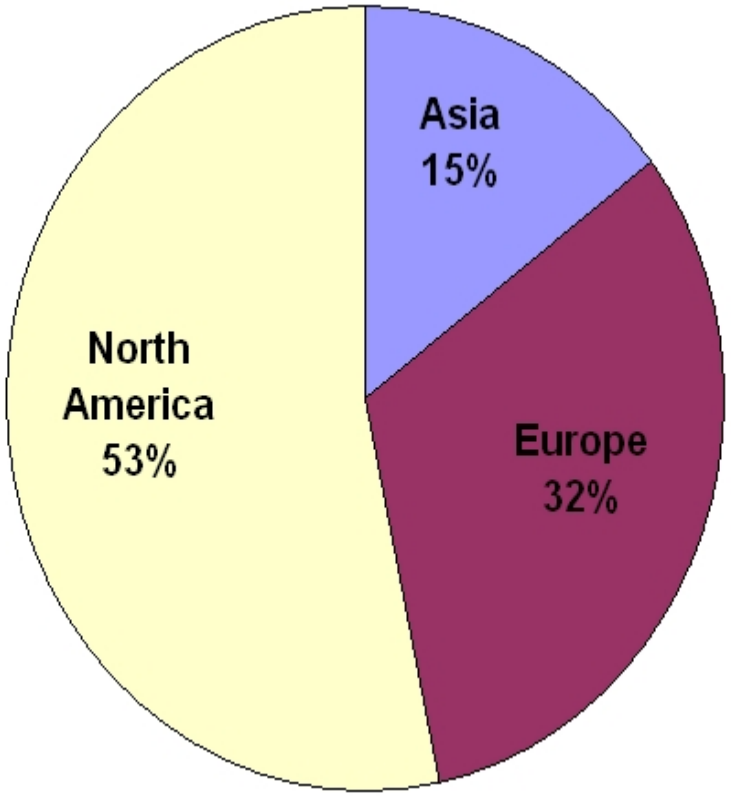


Lab	A	p.e.u.	B	p.e.u.	method
01	230,888	3,572	166,409	3,175	ID-MS
05	234,43	5,523	168,31	4,641	ID-MS
08	229,227	4,028	165,907	2,262	ID-MS
11	230,2	4,613	167,4	2,369	ID-MS
12	237,8	1,558	171,9	0,890	spectrometry (Abell-Kendall)
16	237,490	2,764	171,389	1,962	spectrometry (Abell-Kendall)
18	233,5	3,08	169,3	2,42	HPLC
19	238,1	0,860	170,8	1,610	spectrometry (Abell-Kendall)
27	230,888	3,919	166,023	3,105	ID-MS

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

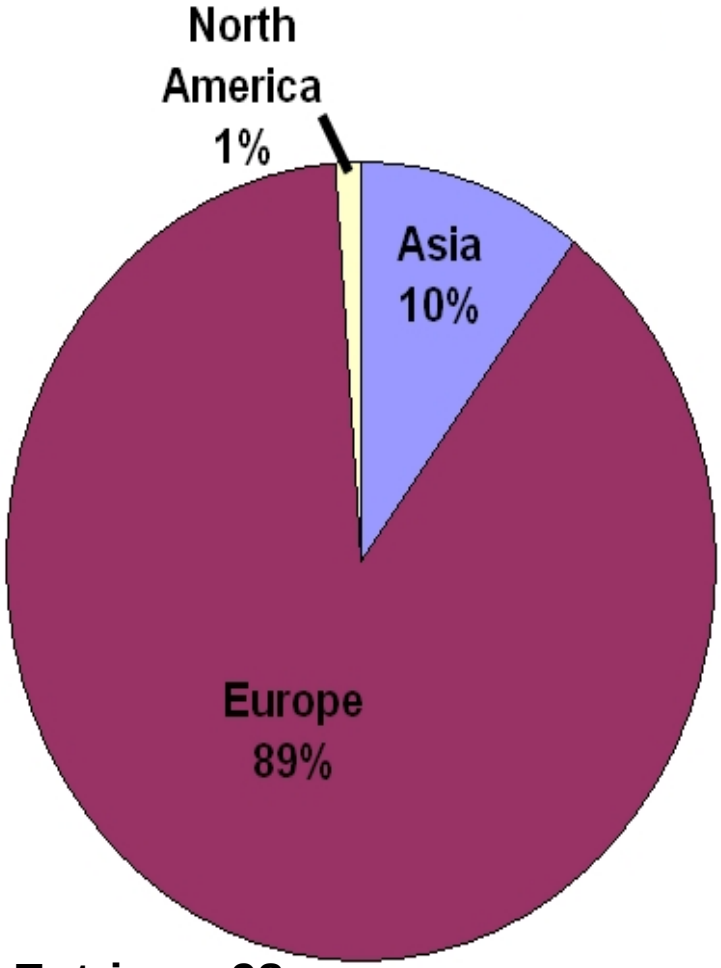
JCTLM Database: Summary of entries by Region of Origin

Certified Reference Materials



Entries = 202

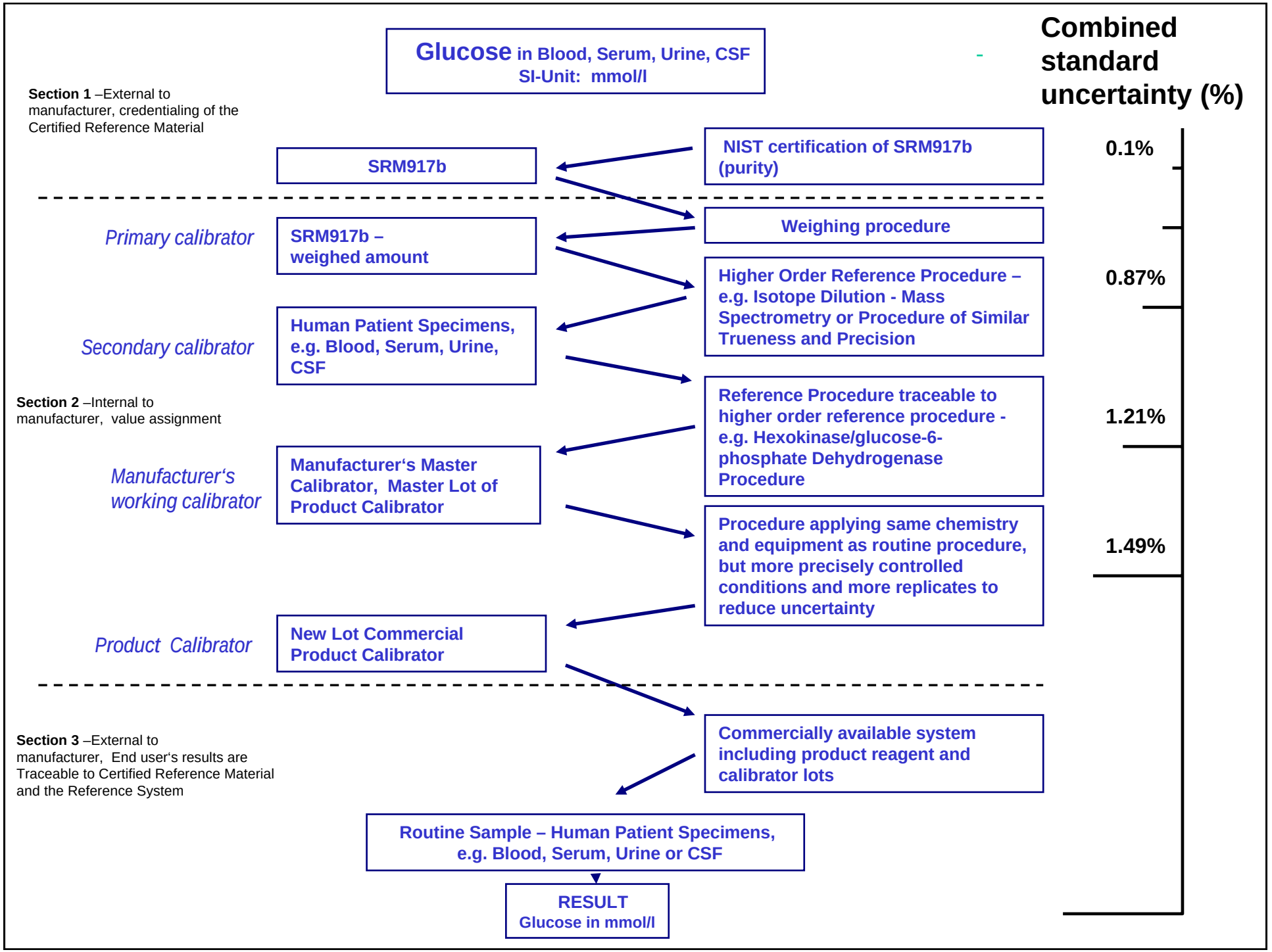
Reference Measurement Services



Entries = 98

Establishing and validating a traceable measurement system

SI traceability Example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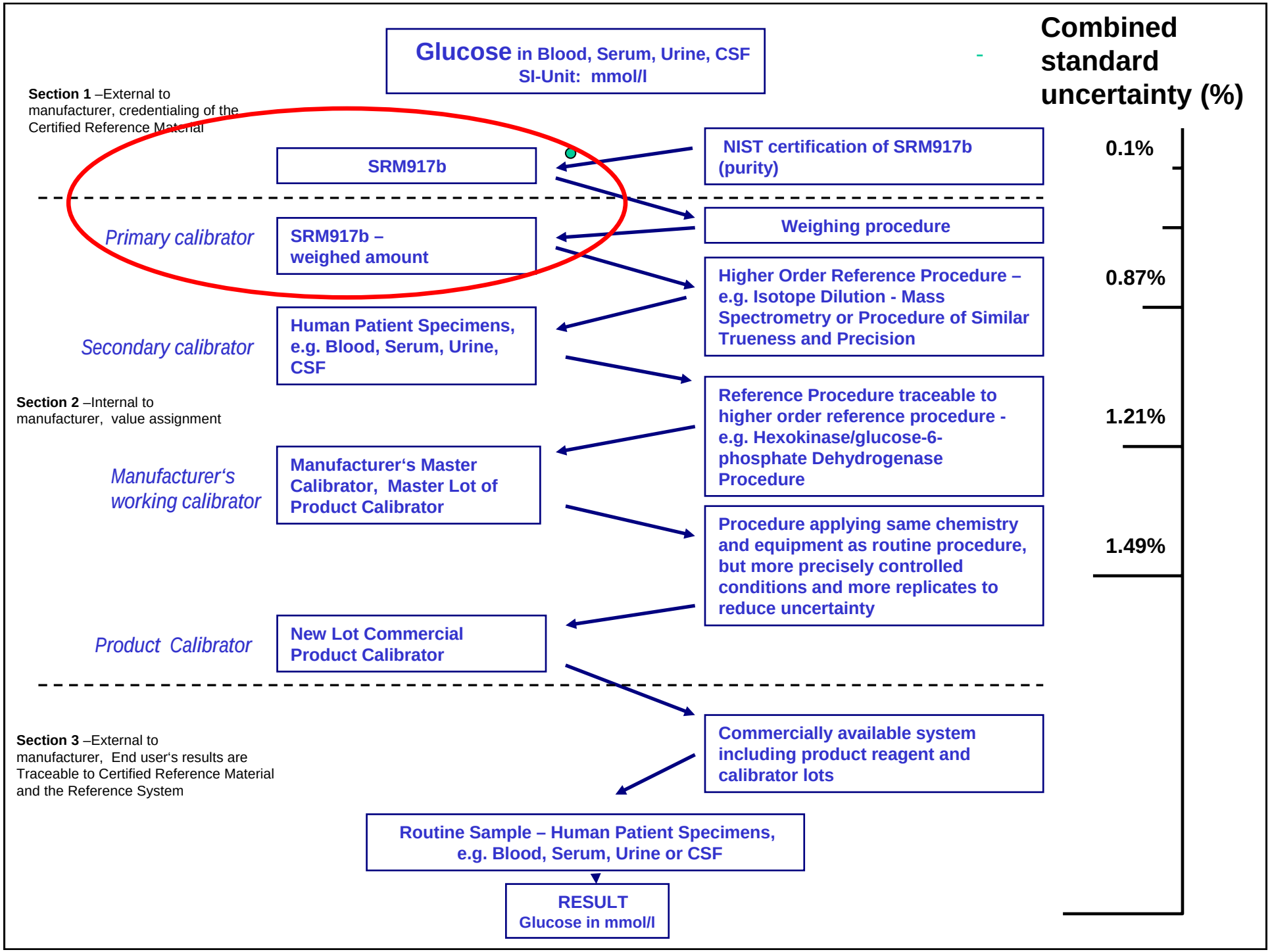
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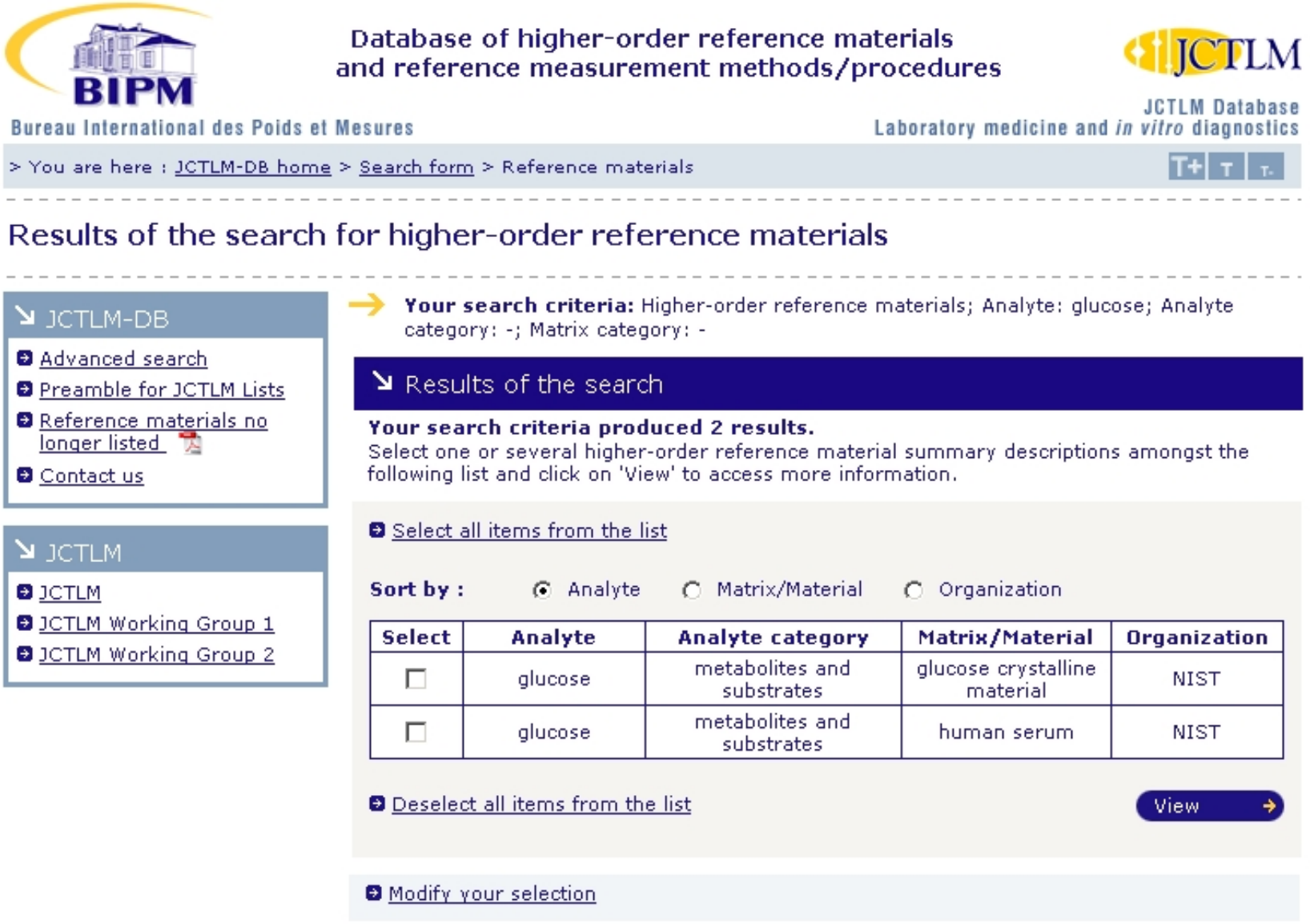
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
Section 2 –Internal to manufacturer, value assignment
Reference Procedure traceable to higher order reference procedure - e.g. Hexokinase/glucose-6-phosphate Dehydrogenase Procedure
1.21%
Manufacturer‘s working calibrator
Manufacturer‘s Master Calibrator, Master Lot of Product Calibrator
Procedure applying same chemistry and equipment as routine procedure, but more precisely controlled conditions and more replicates to reduce uncertainty
1.49%
Product Calibrator
New Lot Commercial Product Calibrator
Section 3 –External to manufacturer, End user‘s results are Traceable to Certified Reference Material and the Reference System
Commercially available system including product reagent and calibrator lots
Routine Sample – Human Patient Specimens, e.g. Blood, Serum, Urine or CSF
RESULT
Glucose in mmol/l

JCTLM Database: Glucose Reference Materials



JCTLM Database: Glucose Reference Materials

Results of the search

glucose in glucose crystalline material

National Institute of Standards and Technology (NIST), United States

Phone: +1 301 975 6776
Fax: +1 301 948 3730
Email: srminfo@nist.gov
Web: http://www.nist.gov/srm

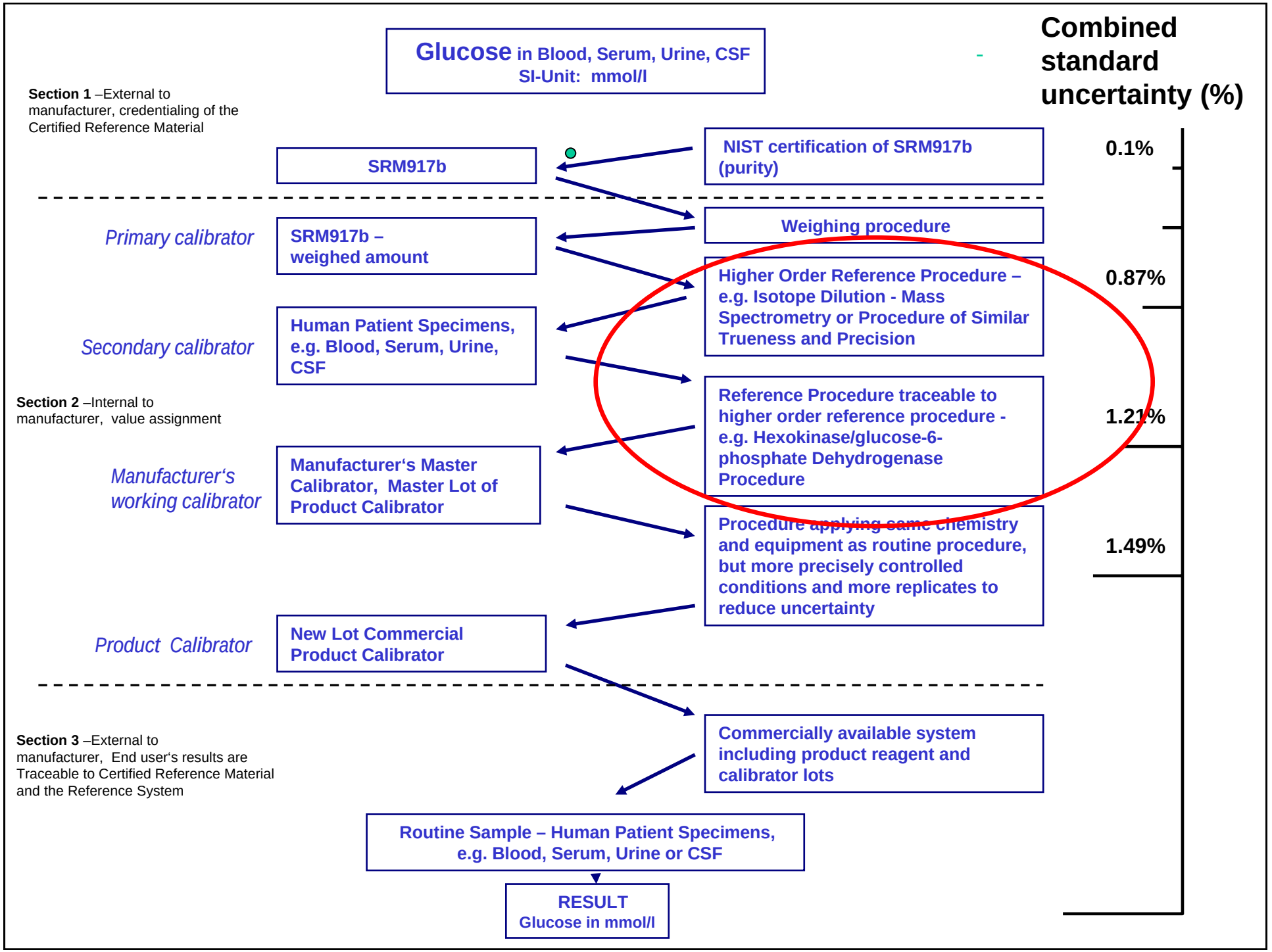
Name of the reference material	SRM 917b, D-glucose (dextrose)
Quantity	Mass fraction
Analyte certified/assigned value	99.7 %
Expanded uncertainty (level of confidence 95%)	0.2 %
Reference(s) on commutability	Not applicable: a high-purity material used as a primary calibrator for higher order reference methods
Traceability	SI
CRM listing	List I

glucose in human serum

National Institute of Standards and Technology (NIST), United States

Phone: +1 301 975 6776
Fax: +1 301 948 3730
Email: srminfo@nist.gov
Web: http://www.nist.gov/srm

Name of the reference material	SRM 965a, glucose in frozen human serum
Quantity	Amount-of-substance concentration
Analyte certified/assigned value	1.918 mmol/l to 16.24 mmol/l
Expanded uncertainty (level of confidence 95%)	0.02 mmol/l to 0.19 mmol/l
Other relevant publication(s)	Method used for certification: *Biomed. Mass Spectrom.*, 1982, **9**, 395-405
Traceability	SI
CRM listing	List I


Glucose in Blood, Serum, Urine, CSF
SI-Unit: mmol/l
Combined standard uncertainty (%)
Section 1 –External to manufacturer, credentialing of the Certified Reference Material
SRM917b
NIST certification of SRM917b (purity)
0.1%
Weighing procedure
Primary calibrator
SRM917b – weighed amount
Higher Order Reference Procedure – e.g. Isotope Dilution - Mass Spectrometry or Procedure of Similar Trueness and Precision
0.87%
Secondary calibrator
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
Section 2 –Internal to manufacturer, value assignment
Reference Procedure traceable to higher order reference procedure - e.g. Hexokinase/glucose-6-phosphate Dehydrogenase Procedure
1.21%
Manufacturer's working calibrator
Manufacturer's Master Calibrator, Master Lot of Product Calibrator
Procedure applying same chemistry and equipment as routine procedure, but more precisely controlled conditions and more replicates to reduce uncertainty
1.49%
Product Calibrator
New Lot Commercial Product Calibrator
Section 3 –External to manufacturer, End user's results are Traceable to Certified Reference Material and the Reference System
Commercially available system including product reagent and calibrator lots
Routine Sample – Human Patient Specimens, e.g. Blood, Serum, Urine or CSF
RESULT
Glucose in mmol/l

Comparison of NMI capabilities for Glucose in Serum Measurements

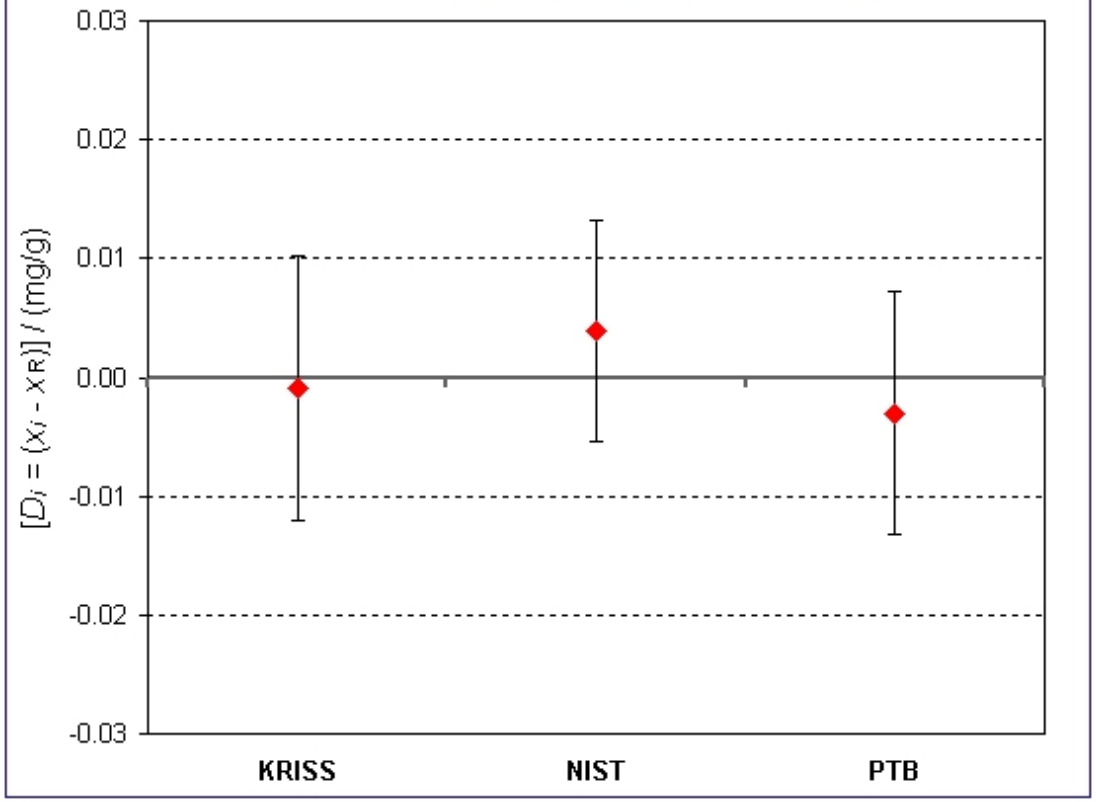
CCQM-K11

Results

Laboratory individual measurements | Equivalence statements | Degrees of equivalence | **Graph(s) of equivalence**

MEASURAND : Mass fraction of glucose in human serum
Material I : physiological range

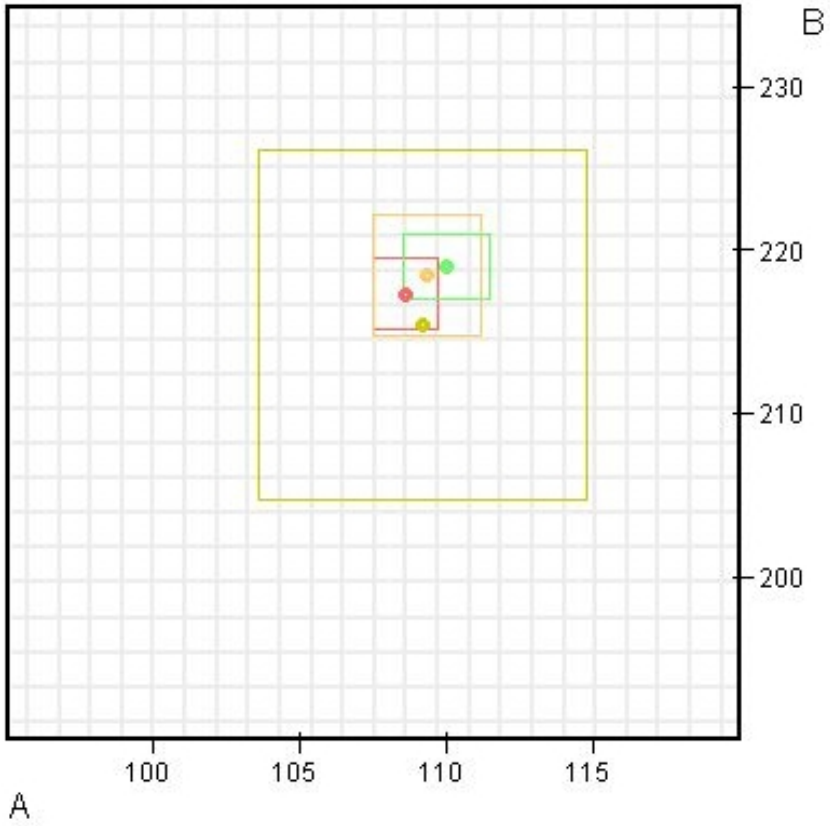
Degrees of equivalence D_i and expanded uncertainty U_i (95% level of confidence) expressed in mg/g; x_R = 0.7762 mg/g, U_R = 0.0088 mg/g



IFCC EQUAS results for two different reference methods for glucose in serum

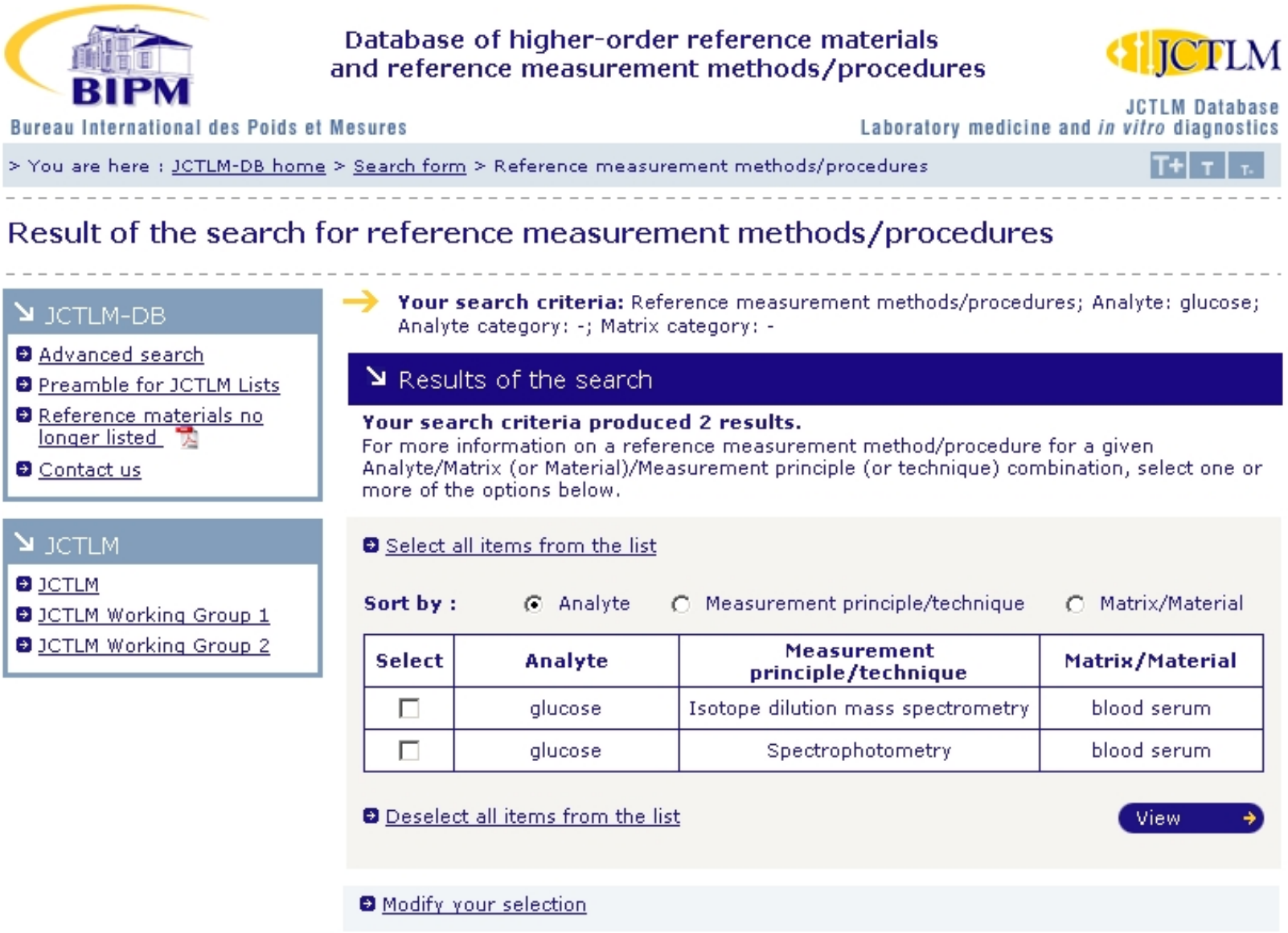
RELA 2004

Glucose [mg/dl]



Lab	A	p.e.u.	B	p.e.u.	method
03	108,612	1,081	217,297	2,162	ID-MS
05	109,36	1,86	218,41	3,71	ID-MS
24	109,2	5,59	215,4	10,75	spectrometry
27	110,0	1,45	219,0	1,97	ID-MS

JCTLM Database: Reference Methods for Glucose



JCTLM Database: Reference Methods for Glucose

↘ Results of the search

Isotope dilution mass spectrometry methods for glucose in blood serum	
‣ NIST definitive method for serum glucose	
Applicable matrice(s)	lyophilized, fresh, or frozen human serum
Full description of technique(s)	ID/GC/MS
Quantity	Amount-of-substance concentration
Applicable range	2 mmol/l to 20 mmol/l
Expected uncertainty (level of confidence 95%)	0.5 % to 1.5 %
Reference(s)	*Biomed. Mass. Spectrom.*, 1982, **9**, 395-405
Comparability assessment study(ies)	*Metrologia*, 2003, **40**, *Tech. Suppl.*, 08003
Comment(s)	The expanded uncertainty is relative
JCTLM DB identification number	NRMeth 80
‣ University of Ghent reference method for glucose	
Applicable matrice(s)	lyophilized, fresh, or frozen human serum
Full description of technique(s)	ID/GC/MS
Quantity	Amount-of-substance concentration
Applicable range	1 mmol/l to 20 mmol/l
Expected uncertainty (level of confidence 95%)	1 % to 2 %
Reference(s)	*Clin. Chem.*, 1993, **39**, 1001-1006 *Clin. Chem.*, 1993, **39**, 993-1000 *Eur. J. Clin. Chem. Clin. Biochem.*, 1996, **34**, 853-860
Comparability assessment study(ies)	EUROMET 563
Comment(s)	The expanded uncertainty is relative
JCTLM DB identification number	NRMeth 4

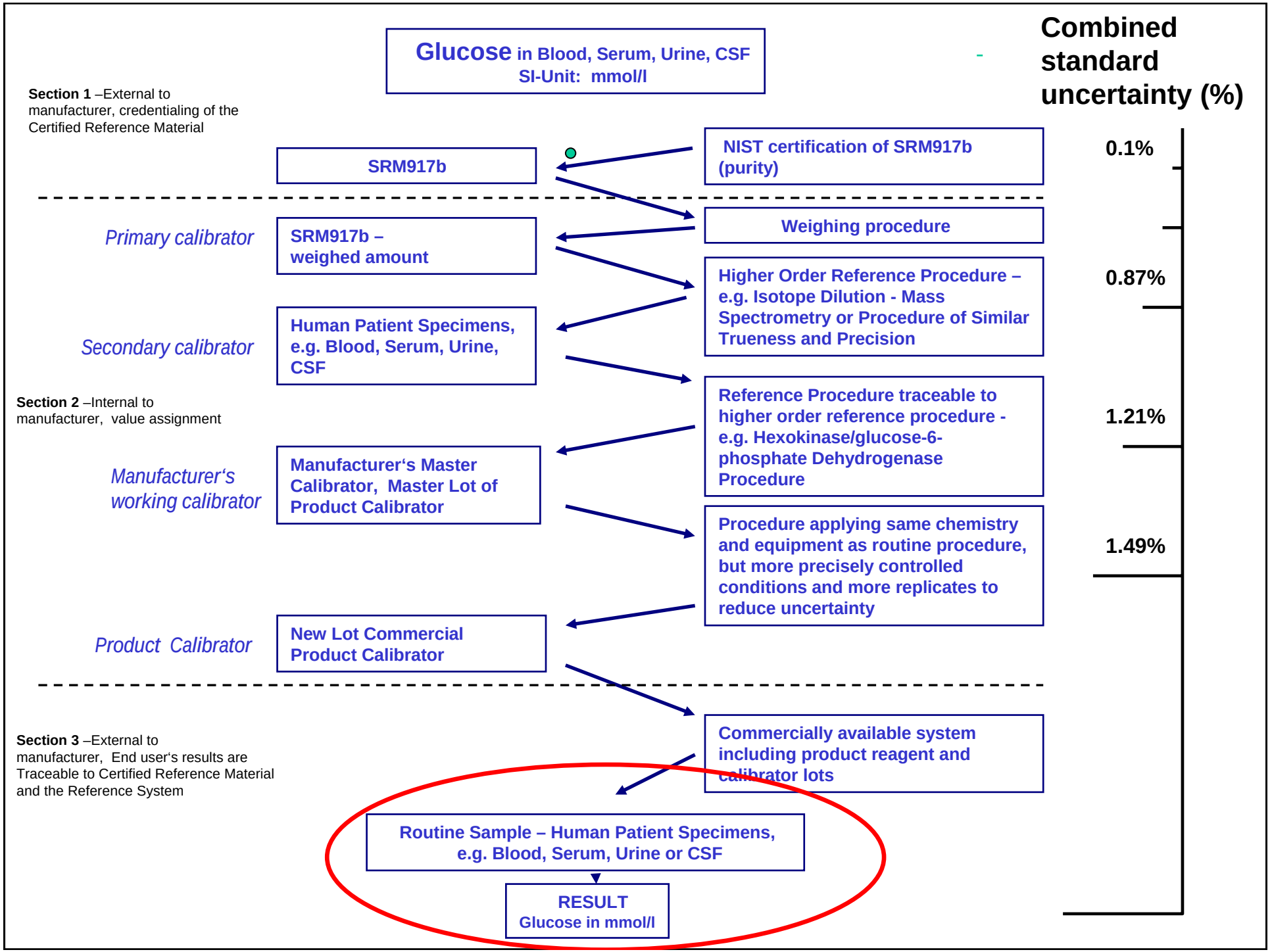
JCTLM Database: Reference Methods for Glucose

Results of the search

Spectrophotometry method for glucose in blood serum

- CDC Hexokinase reference method for glucose

Applicable matrice(s)	human serum
Full description of technique(s)	Spectrophotometry
Quantity	Amount-of-substance concentration
Applicable range	2.78 mmol/l to 22.2 mmol/l
Expected uncertainty (level of confidence 95%)	0.39 %
Reference(s)	Neese, JW, et al., HEW Pub No. (CDC) 77-8330, HEW, USPHS, CDC, 1976
Comment(s)	The expanded uncertainty is relative
JCTLM DB identification number	NRMeth 34


Glucose in Blood, Serum, Urine, CSF
SI-Unit: mmol/l
Combined standard uncertainty (%)
Section 1 –External to manufacturer, credentialing of the Certified Reference Material
SRM917b
NIST certification of SRM917b (purity)
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SRM917b – weighed amount
Weighing procedure
Higher Order Reference Procedure – e.g. Isotope Dilution - Mass Spectrometry or Procedure of Similar Trueness and Precision
0.87%
Secondary calibrator
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
Section 2 –Internal to manufacturer, value assignment
Reference Procedure traceable to higher order reference procedure - e.g. Hexokinase/glucose-6-phosphate Dehydrogenase Procedure
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New Lot Commercial Product Calibrator
Section 3 –External to manufacturer, End user‘s results are Traceable to Certified Reference Material and the Reference System
Commercially available system including product reagent and calibrator lots
Routine Sample – Human Patient Specimens, e.g. Blood, Serum, Urine or CSF
RESULT
Glucose in mmol/l

Proficiency Testing Scheme Results for Glucose in Serum

- Results agree with traceable reference value and acceptance criteria

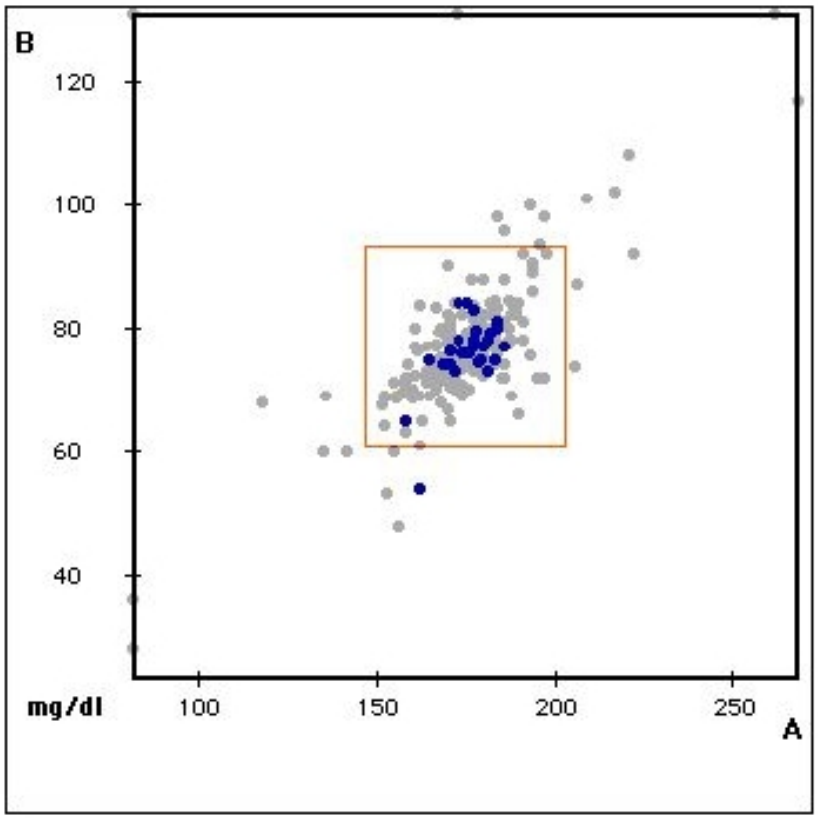
GL4/06

glucose

Hexokinase Reaktion

Split 2

DGKL



selected participants	29	
target value	175	77
limits	147 - 203	60,8 - 93,2
mean value	175,438	75,955
standard deviation	6,536	5,647