Accurate Measurement for Patient Care

Metrological Traceability in Laboratory Medicine

Joint Committee for Traceability in Laboratory Medicine (JCTLM)

World Metrology Day 2021:
Measurement for Health

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Accurate results for patient care

20 May 2021

Robert Wielgosz, BIPM

What is laboratory medicine?

I'm not feeling well

Infection?

Diabetes?

Cancer?

Heart?

Liver?

Kidney?

Etc.

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What is laboratory medicine?

I'm not feeling well

History

Physical exam

Lab tests

Imaging

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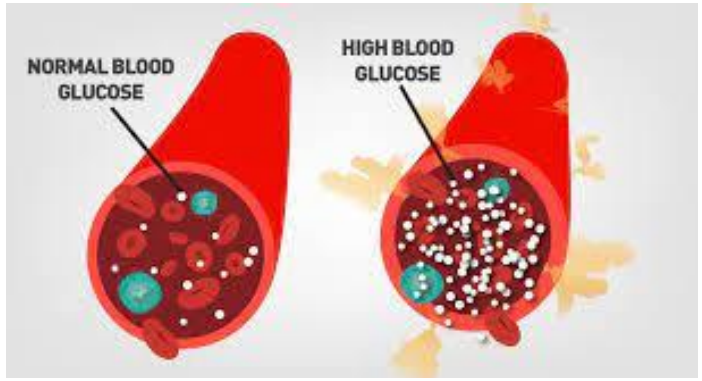
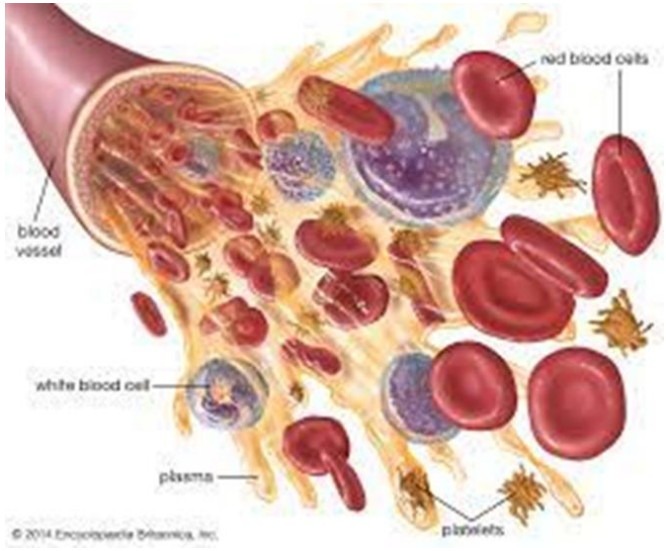
Chemistry
Biochemistry



What is the concentration

mol/L

Hematology



How many blood cells

What type are they

What size are they

Are they abnormal

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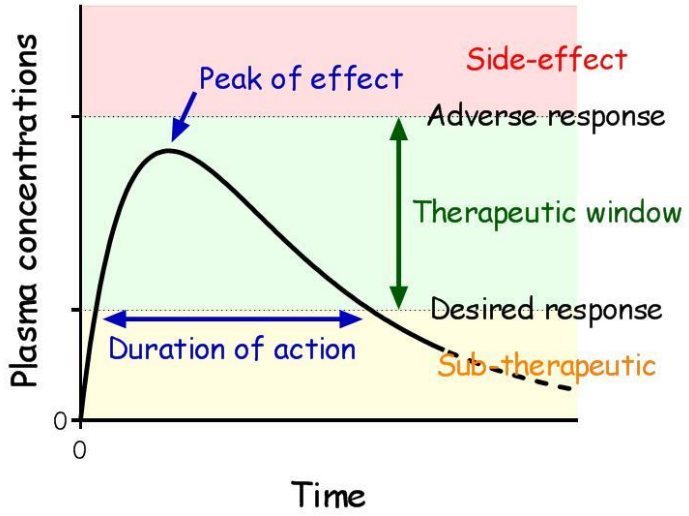
Toxicology



Is the drug at the correct concentration?

Microbiology
Infectious Diseases

What is the organism

How many are there

What drug will kill it

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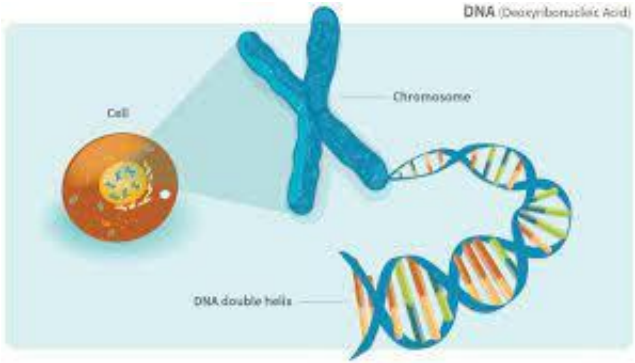
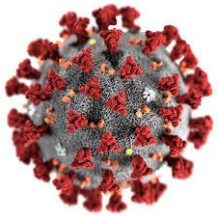
Molecular Diagnostics
Genetics



Mutation



Micro-organism identification

Surgical Pathology
Cytology

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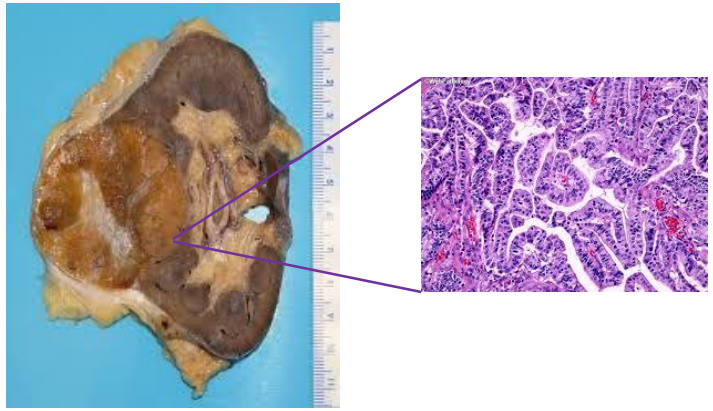

Is cancer present

What kind

When your doctor orders some Lab tests:

1. Collect the sample from you
2. Transport sample to the lab
3. Perform testing
4. Report the result
5. Your doctor uses the result to help with your care

METROLOGY

MATTERS

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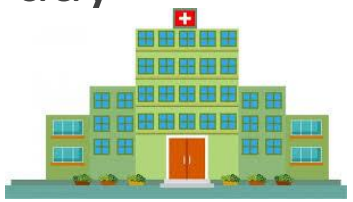
Clinical Laboratories

- Come in all shapes and sizes:
  - In hospitals, in the community, at the bedside
  - From 10s to 10s of thousands of samples per day
- Run by trained scientists and pathologists
- Use modern scientific equipment
- The aim of these laboratories is to provide useful measurements for your healthcare



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How are lab results interpreted?

- Your results are compared with other information

- This other information may be:
  - A reference interval (what is expected in a healthy person)
  - A Clinical Decision Point (a value from experts based on clinical studies)
  - A result from a sample taken on you previously

- RESULTS ARE INTERPRETED BY COMPARISON (WITH OTHER RESULTS)

- **The measurements in your laboratory, must match the results from other laboratories** (this is what it means to have accurate results)

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Achieving Accurate Results: Metrology and Quality Infrastructure

Physician requesting laboratory test

Medical Laboratory (Hospital)

ISO 15189

ISO 17511

IVD Manufacturers

Calibration (Reference) Laboratory

Bureau International des Poids et Mesures

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

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> You are here : JCTLM-DB

A database of reference resources to **help the IVD industry** meet traceability requirements of the **EC IVD Directive.**

A quality assured database:
All data examined with respect to conformity with appropriate international documentary standards.

National Metrology Institutes

ISO 15194 **Certified Reference Materials**

ISO 17025
ISO 15195
ISO 15193

Metrological Traceability in Laboratory Medicine

The concept of reference measurement systems is well developed in Clinical Chemistry/Laboratory Medicine:

- **Reference Methods**
- **Reference Materials**
- **Reference Measurement Services**

Bureau International des Poids et Mesures

Regulations and Metrological Traceability for IVDs
Essential Requirements of the IVD Directive

98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

"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.. "

Annex I - Essential Requirements
Part A. General Requirements, Clause 3

JCTLM Established in 2002

Intergovernmental Treaty Organization for Measurement Standards

International NGO for Professionals in Laboratory Medicine

International NGO for Accreditation Bodies

International NGO for Professionals in Diagnostic Haematology

JCTLM Membership

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60 Member organizations in 20 countries worldwide

JCTLM Database Working Group

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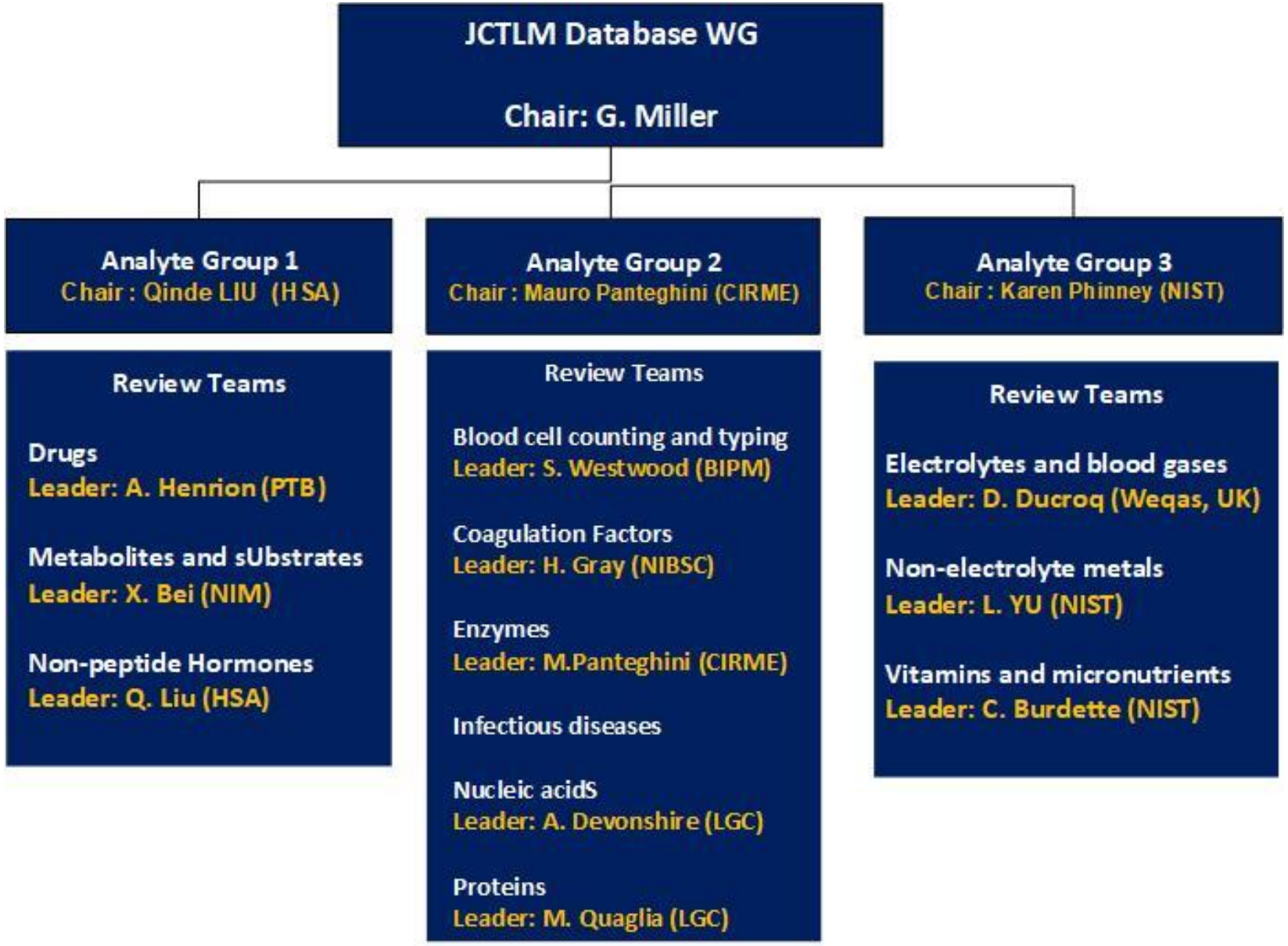
Mission

DBWG is charged with establishing a process for identifying, reviewing and publishing lists of available higher-order materials, methods and services that conform to the ISO standards.



What has JCTLM delivered?

A Quality assured database, for *in vitro* diagnostics, of:

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

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

An education resource for traceability in laboratory medicine:

www.jctlm.org

JCTLM Database

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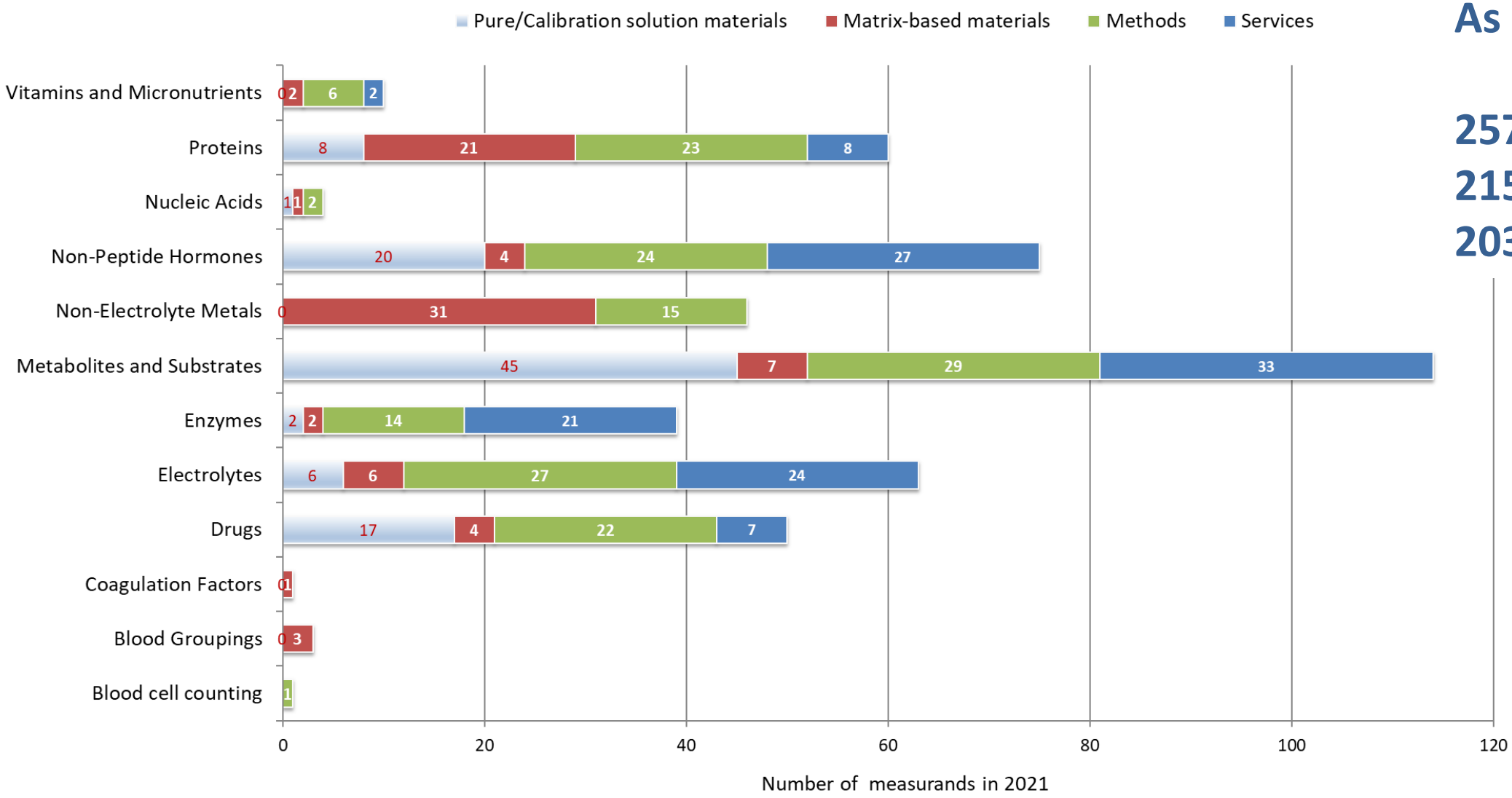

As of April 2021:

257 Materials,
215 Methods,
203 Services

Distribution of measurands per group of analytes in April 2021

JCTLM Review for compliance with ISO standards

ISO 17511: 2020 In vitro diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

ISO 15193:2009 Requirements for content and presentation of reference measurement procedures

ISO 15194:2009 Requirements for certified reference materials and the content of supporting documentation

ISO 15195: 2018 Laboratory medicine — Requirements for the competence of calibration laboratories using reference measurement procedures

Developed within ISO TC 212 WG2

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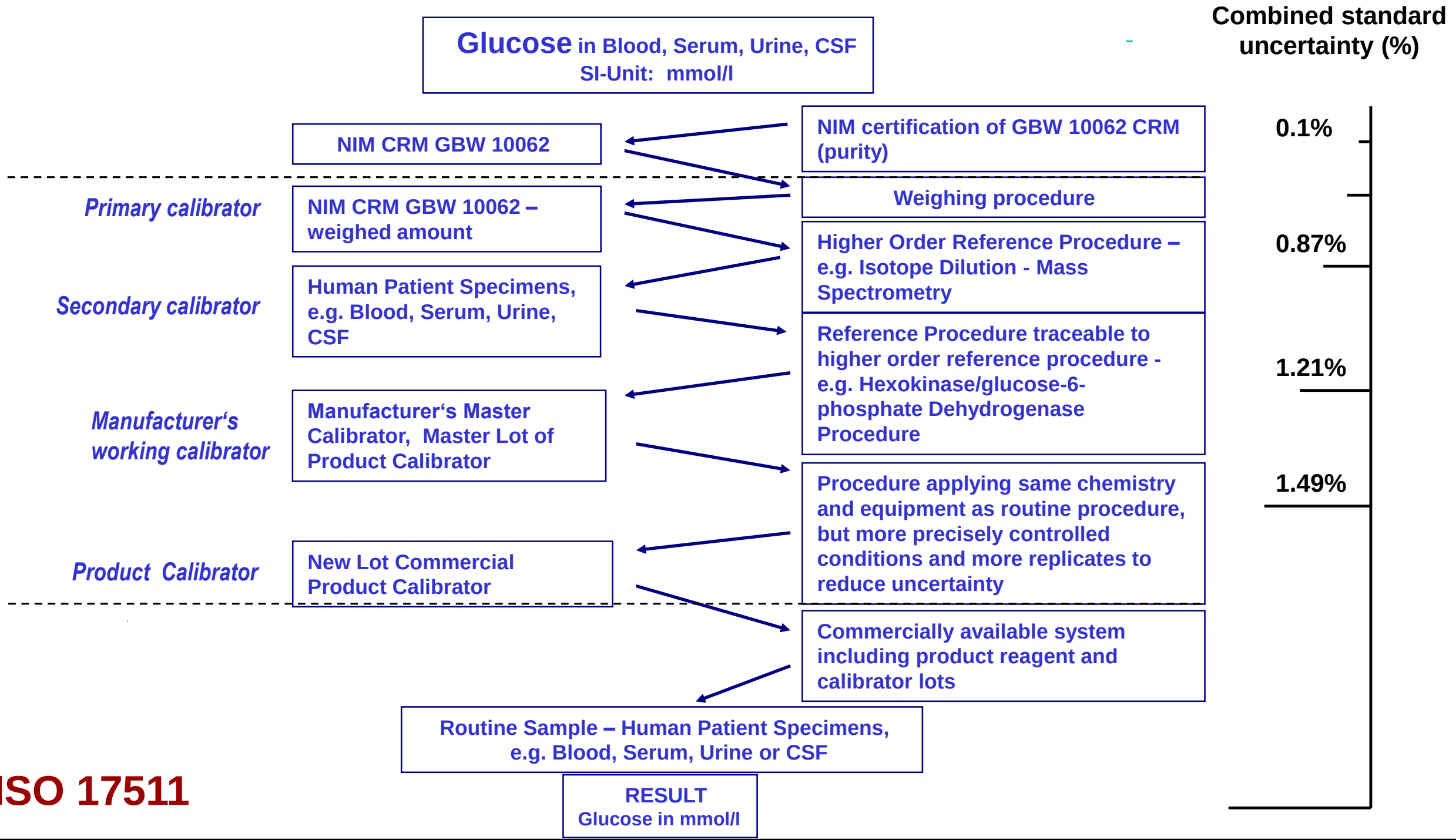
Standardizing Chemical Measurements Worldwide Example: Diabetes Care

- Over 420 million people worldwide have diabetes**
- Diabetes is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation
- Diabetes affects 34.2 million people In the US (10.5% of the US population)*
- $ 327 billion – estimated diabetes costs in the U.S. in 2017 (direct and indirect for diagnosed cases)*
- 3.9 million people diagnosed with diabetes in the UK †
- 90% of diagnoses are for Type 2 Diabetes
- Biomarkers of interest include: Glucose, HbA1c, C-peptide

**WHO, 13 April 2021

†Diabetes in the UK 2019 : key statistics on diabetes (Diabetes UK)

*Centers for Disease Control and Prevention. National diabetes statistics report 2020


Glucose in Blood, Serum, Urine, CSF
SI-Unit: mmol/l
Combined standard uncertainty (%)
NIM CRM GBW 10062
NIM certification of GBW 10062 CRM (purity)
0.1%
Primary calibrator
NIM CRM GBW 10062 – weighed amount
Weighing procedure
Higher Order Reference Procedure – e.g. Isotope Dilution - Mass Spectrometry
0.87%
Secondary calibrator
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
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
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
ISO 17511

measurement procedure (ms.)

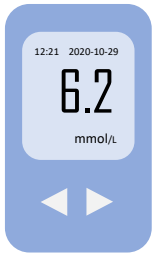
ms. 1
Quantitative Nuclear Magnetic Resonance (qNMR) procedure for purity and identity assessment

ms. 2
Primary reference measurement procedure for calibrator. Weighing of the certified primary reference material m. 1

ms. 3
Reference measurement procedure for the measurand. Isotope dilution mass spectrometry of the diluted certified primary reference material m. 2 conforming to ISO 15193

ms. 4
Manufacturers selected measurement procedure

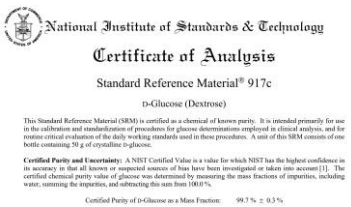
ms. 5
Manufacturers standing measurement procedure



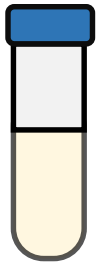
ms. 5
End-users measurement device

Refernce material (m.)

m. 1
Certified primary reference material conforming to ISO 15194

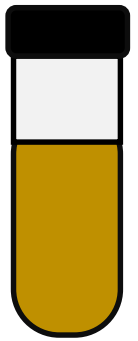

National Institute of Standards & Technology
Certificate of Analysis
Standard Reference Material® 917c
D-Glucose (Dextrose)

m. 2
Primary calibrator - prepared as solution of m. 1 in water



m. 3
Secondary, commutable certified reference materiial conforming to ISO 15194. Matrix is pooled human plasma

m. 4
Manufacturers working calibrator



m. 5
Calibrator for the end-user measurement device

m. 6
Human sample with result

Metrology Institutes and Reference Labs

Manufacturers

End users

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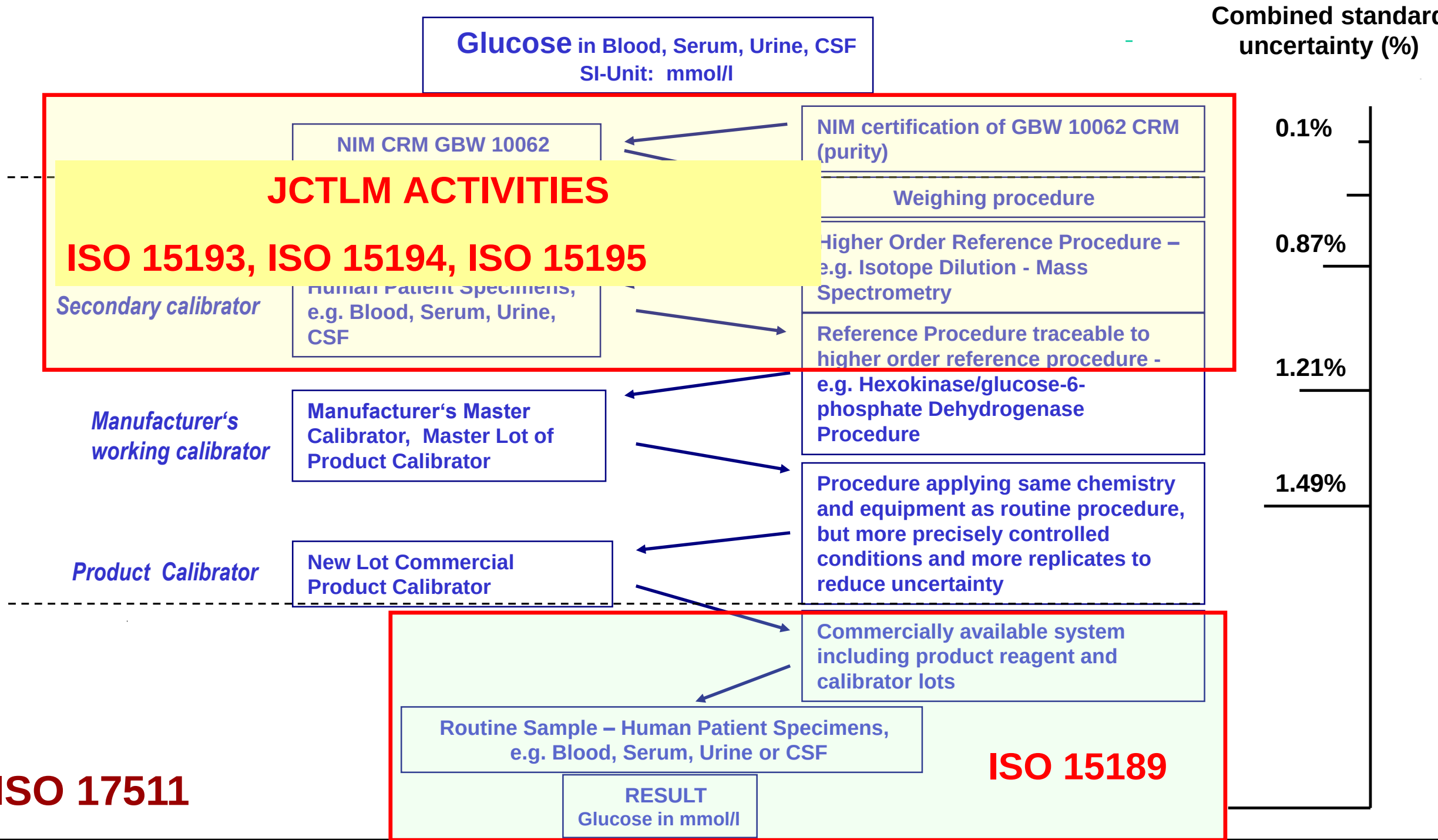

Glucose in Blood, Serum, Urine, CSF
SI-Unit: mmol/l
Combined standard uncertainty (%)
NIM CRM GBW 10062
NIM certification of GBW 10062 CRM (purity)
0.1%
Weighing procedure
JCTLM ACTIVITIES
ISO 15193, ISO 15194, ISO 15195
Higher Order Reference Procedure – e.g. Isotope Dilution - Mass Spectrometry
0.87%
Secondary calibrator
Human Patient Specimens, e.g. Blood, Serum, Urine, CSF
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
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
ISO 15189
ISO 17511

Glucose in Serum: Primary Reference Material

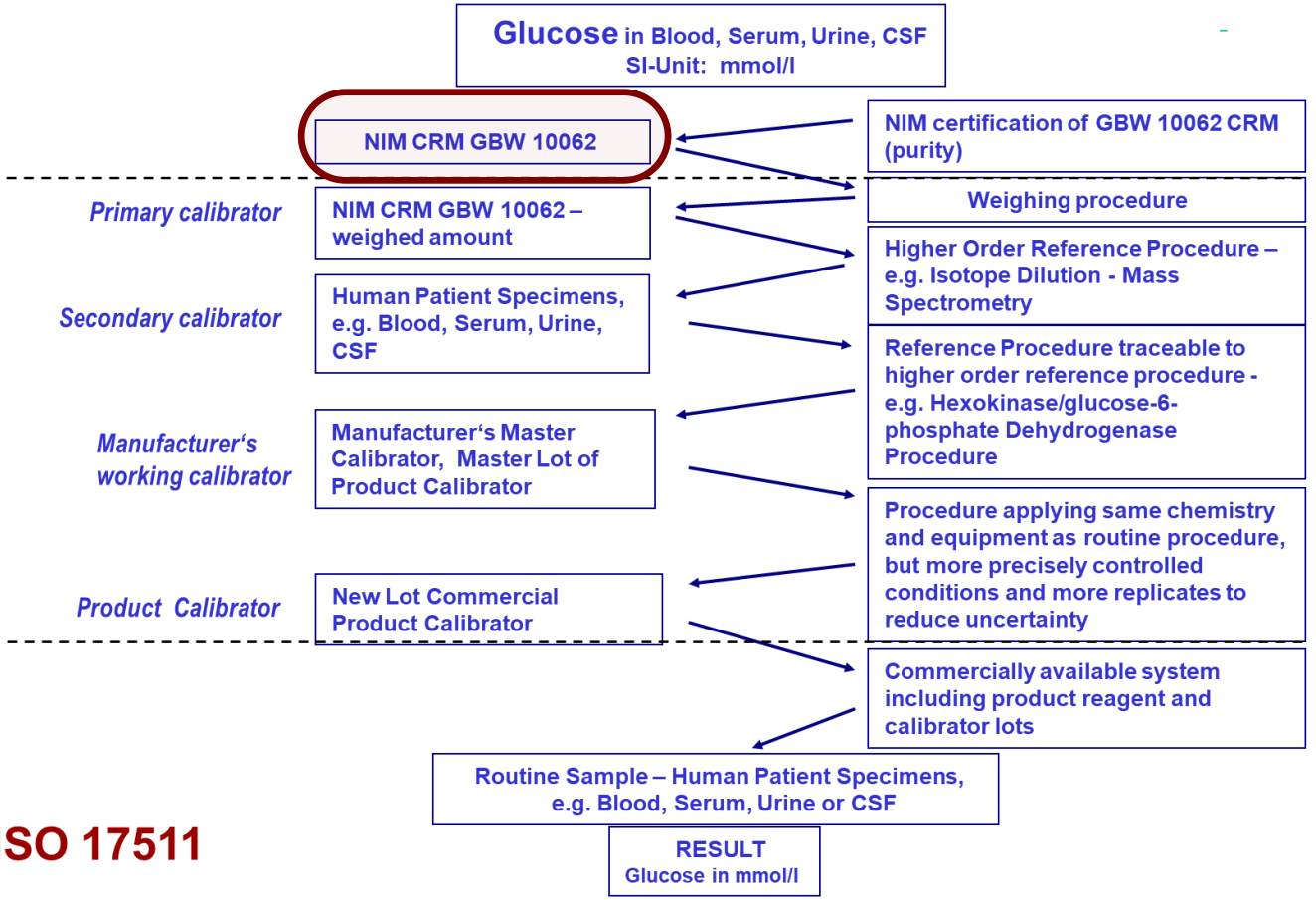
glucose in glucose crystalline material

National Institute of Metrology (NIM), China

Phone: +86 10 6422 1811 **Email:** crmservice@nim.ac.cn

Fax: +86 10 6421 3149 **Web:** http://www.nim.ac.cn/

Name of the reference material	NIM CRM GBW 10062, Purity of Glucose
Quantity	Mass fraction
Analyte certified/assigned value	0.996 g/g
Expanded uncertainty (level of confidence 95 %)	0.003 g/g
Reference(s) on commutability	Not applicable: a high-purity material used as a primary calibrator for higher order reference methods
Other relevant publication(s)	Establishment of the purity values of carbohydrate certified reference materials using quantitative nuclear magnetic resonance and mass balance approach, C. Quan, *Food Chemistry*, 2014, **153**, 378-386
Traceability	traceable to SI
CRM listing	List I



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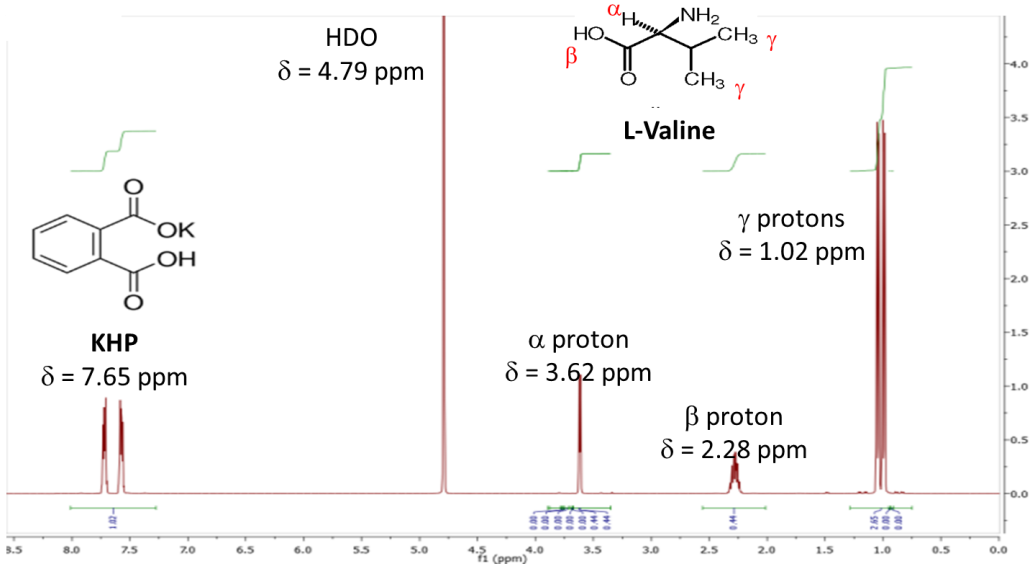
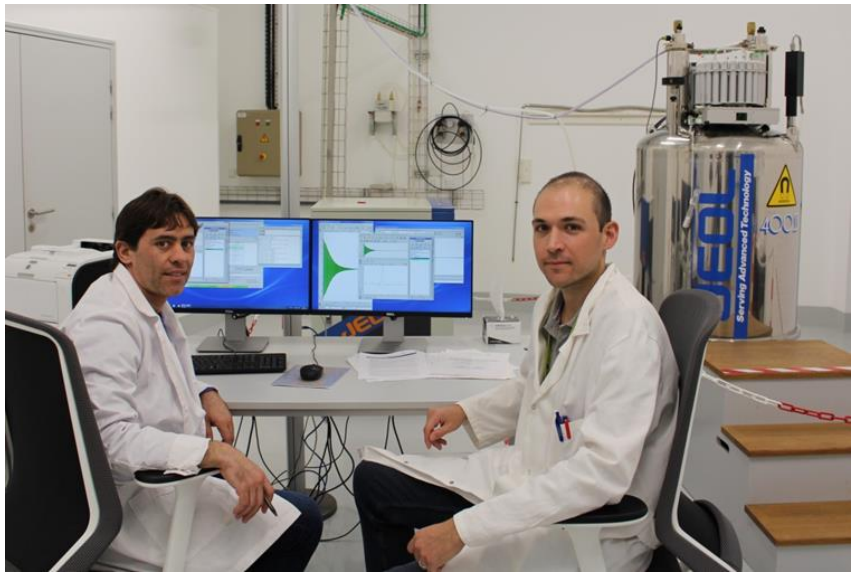
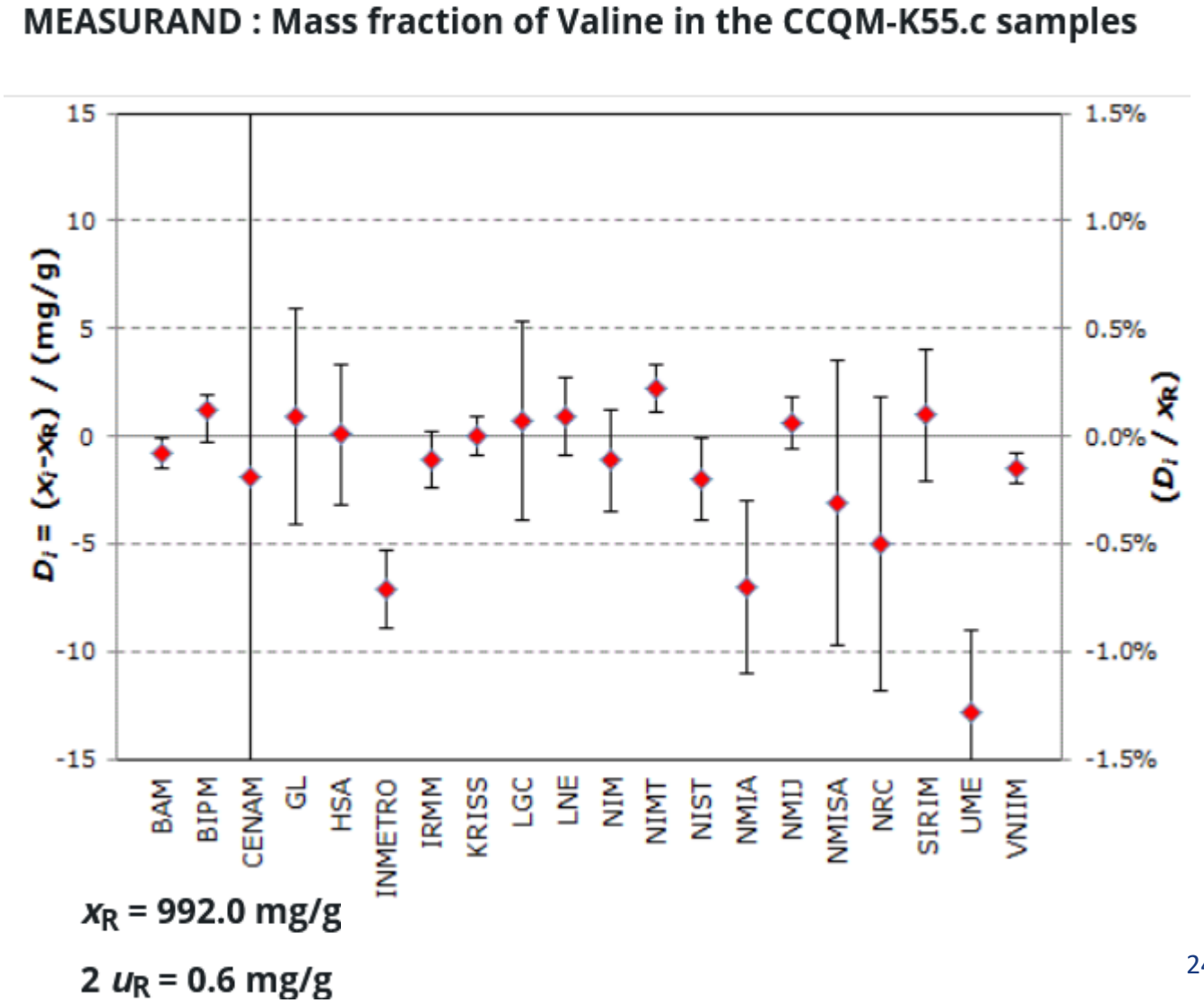
CCQM Key Comparisons: NMI capabilities for PRM value assignment



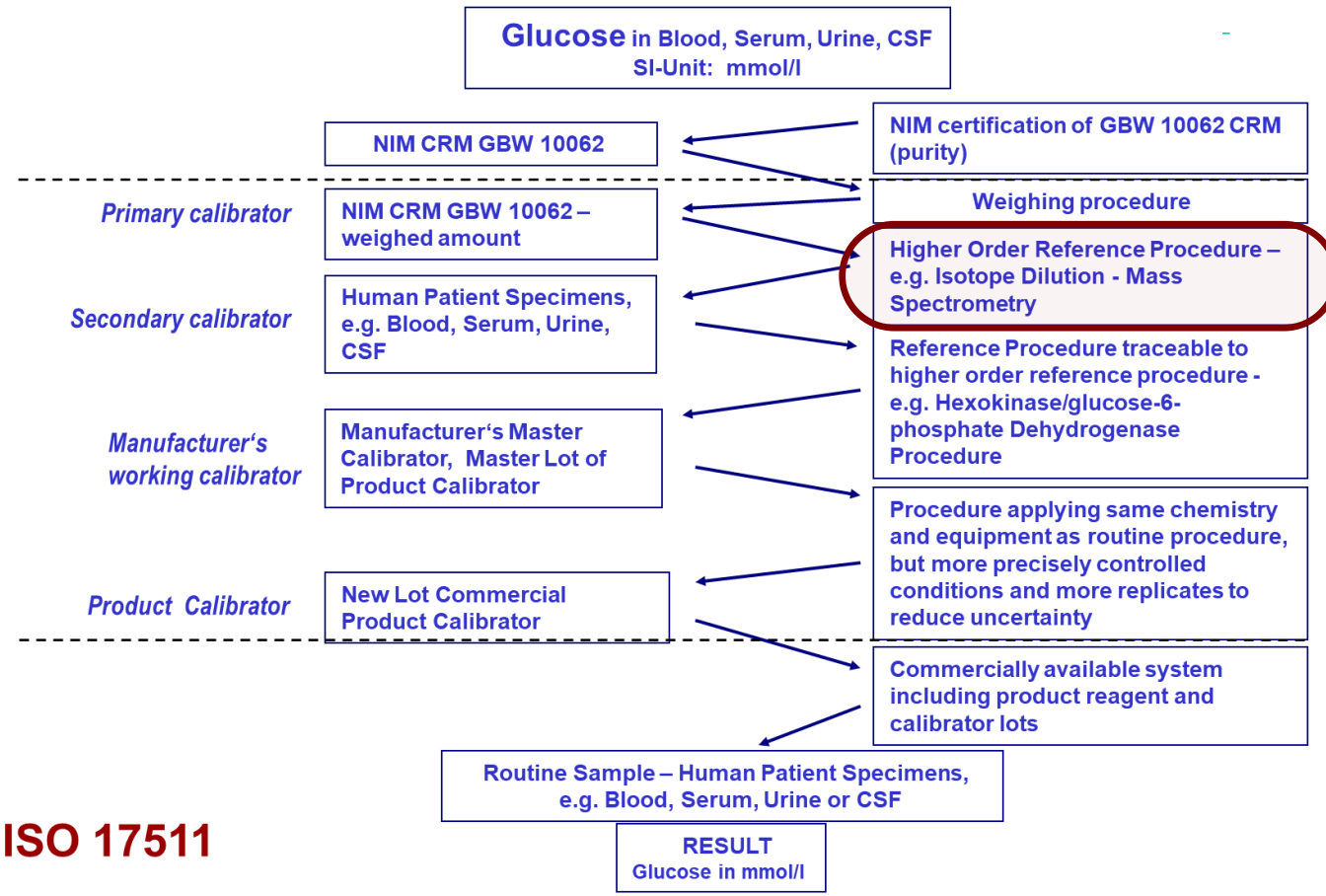




Glucose in Serum: Reference Measurement Procedure

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
JCTLM DB identification number	NRMeth 4

Liquid chromatography mass spectrometry method for glucose in blood serum NCCL ID LC-MS/MS reference measurement procedure for glucose	
Applicable matrice(s)	human serum; fresh, frozen or lyophilized
Full description of technique(s)	Isotope Dilution Mass Spectrometry (IDMS), Liquid Chromatography Mass Spectrometry (LCMS)
Quantity	Amount-of-substance fraction
Applicable range	1.5 mmol/L to 25 mmol/L
Expected uncertainty (level of confidence 95%)	0.5 % to 1.5 %
Reference(s)	Determination of serum glucose by isotope dilution liquid chromatography-tandem mass spectrometry: a candidate reference measurement procedure, Zhang T, et al., *Analytical Bioanalytical Chemistry*, 2016, **408**(26), 7403-7411
Comparability assessment study(ies)	Agreement between the ID LC-MS/MS and the ID GC-MS reference measurement procedures for Glucose, Electronic Supplement Material of Analytical Bioanalytical Chemistry 2016 publication. IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine (RELA), lab code 18, Results year 2012 and 2014
JCTLM DB identification number	C14RMP11



ISO 17511

Glucose in Serum: Measurement Services from Reference Laboratories

Instand e.V., Germany

Phone: +49 211 1592 1337
Fax: +49 211 1592 1356
Web: http://www.instand-ev.de

Contact person: Dr. Patricia Kaiser
Email: Kaiser@instand-ev.de

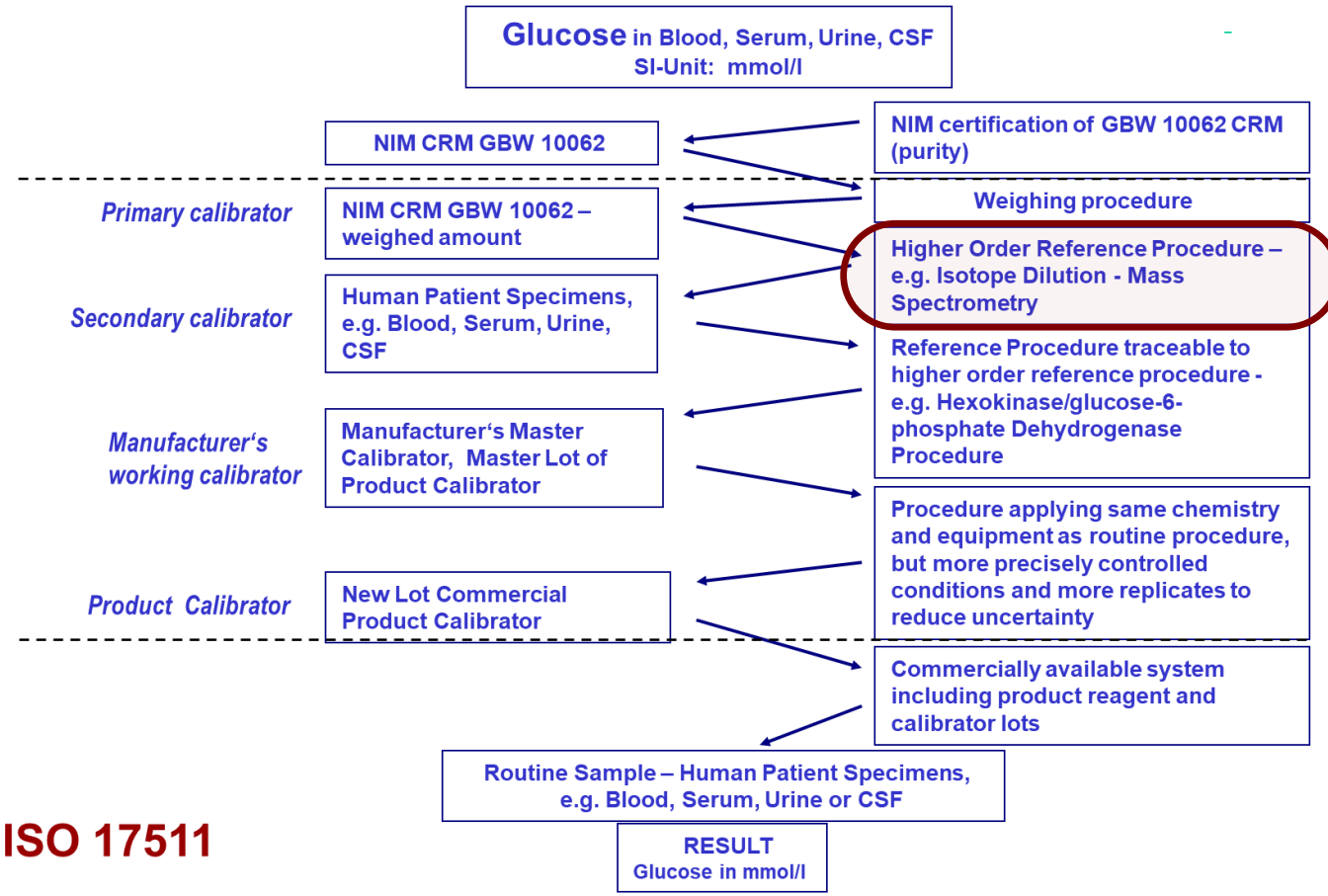
Analyte	glucose
Material or matrix	blood serum, blood plasma
Applicable material or matrix	fresh, frozen or lyophilized blood serum or plasma
Quantity	Amount-of-substance concentration
Service measurement range	1 mmol/L to 60 mmol/L
Expanded uncertainty (level of confidence 95%)	1.0 % The stated expanded uncertainty value corresponds to the best measurement capability.
Interlaboratory comparison results	RELA - IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine at http://www.dgkl-rfb.de:81/index.shtml
Measurement principle	GC-ID/MS
JCTLM reference measurement method/procedure	University of Ghent reference method for glucose

LNE, France

Phone: +33 (0) 140 434 075
Fax: +33 (0) 140 433 737
Web: http://www.lne.fr

Contact person: Dr Vincent DELATOUR
Email: vincent.delatour@lne.fr

Analyte	glucose
Material or matrix	blood serum, calibration solution
Applicable material or matrix	lyophilized, fresh, or frozen human serum, calibration solution
Quantity	Amount-of-substance concentration
Service measurement range	1.6 mmol/L to 20 mmol/L
Expanded uncertainty (level of confidence 95%)	2 % to 1 % The expanded uncertainty is relative.
Interlaboratory comparison results	RELA - IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine at http://www.dgkl-rfb.de:81/index.shtml
Measurement principle	ID-GC/MS
JCTLM reference measurement method/procedure	University of Ghent reference method for glucose



ISO 17511

Glucose in Serum: Performance of Reference Laboratories in Comparisons

Laboratory performance in IFCC RELA scheme

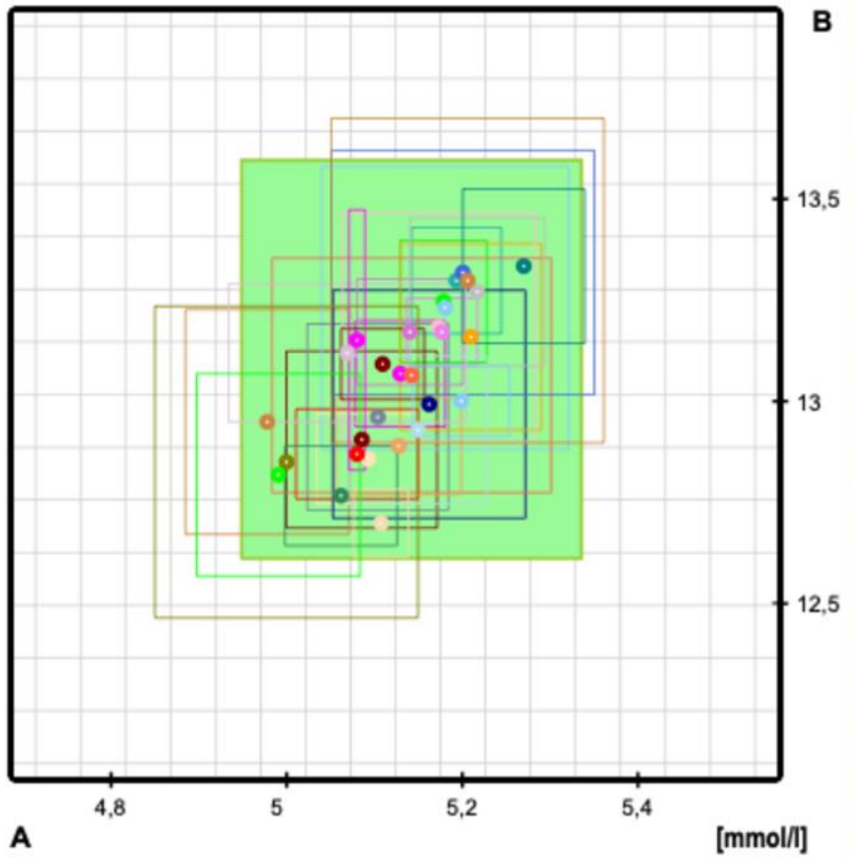
RELA 2020

All or choose Lab ...

select lab analytes | full address

Glucose | show result plot

with limits of equivalence



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

Result lines printed in bold indicate JCTLM listed services.

Labcode	A	e.u. A	B	e.u. B	Method
3	**5.129**	**0.051**	**13.07**	**0.131**	**ID/GC/MS**
5	**5.086**	**0.087**	**12.91**	**0.219**	**ID/GC/MS**
6	**4.978**	**0.093**	**12.95**	**0.279**	**spectrophotometry**
18	**5.178**	**0.05**	**13.25**	**0.152**	**ID/LC/MS/MS**
25	**5.18**	**0.14**	**13.23**	**0.35**	**ID/GC/MS**
27	**5.193**	**0.052**	**13.3**	**0.13**	**ID/GC/MS**
30	5.093	0.058	12.86	0.111	ID/GC/MS
39	5.103	0.08	12.96	0.23	spectrophotometry
48	5.163	0.11	12.99	0.28	spectrophotometry
51	**5.21**	**0.08**	**13.16**	**0.23**	**spectrophotometry**
54	**5.14**	**0.06**	**13.17**	**0.13**	**ID/GC/MS**
61	5.174	0.11	13.18	0.28	spectrophotometry
63	5.143	0.158	13.06	0.29	spectrophotometry
65	**5.2**	**0.15**	**13.32**	**0.3**	**ID/LC/MS/MS**
87	**5.08**	**0.07**	**12.87**	**0.11**	**spectrophotometry**

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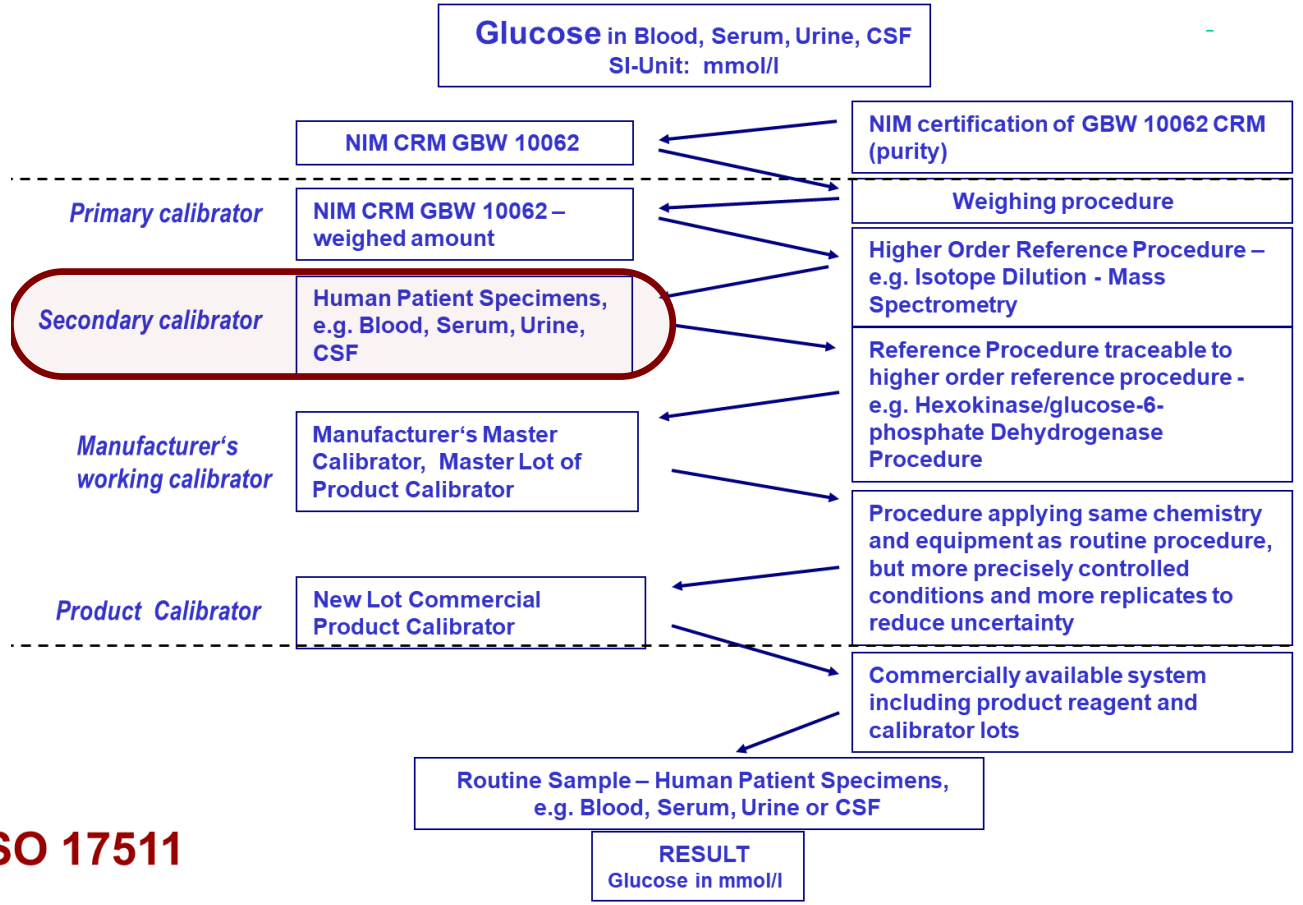
Glucose in Serum: Matrix Reference Materials

glucose in frozen human serum

Laboratoire National de Métrologie et d'Essais (LNE), France

Phone: +33 (0)1 40 43 40 75 **Email:** vincent.delatour@lne.fr
Fax: +33 (0)1 40 43 37 05 **Web:** http://www.lne.eu/

Name of the reference material	LNE CRM Bio 101a, Glucose, creatinine, total cholesterol, total glycerides, HDL-cholesterol, LDL-cholesterol in frozen human serum
Quantity	Amount-of-substance concentration
Analyte certified/assigned value	4.148 mmol/l to 11.663 mmol/l
Expanded uncertainty (level of confidence 95 %)	0.064 mmol/l to 0.165 mmol/l
Reference(s) on commutability	Commutability assessment of external quality assessment materials with the difference in bias approach: are acceptance criteria based on medical requirements too Strict? Delatour et al., *Clinical Chemistry*, 2016, **62**(12), 1670-1671
Traceability	SI
CRM listing	List I



ISO 17511

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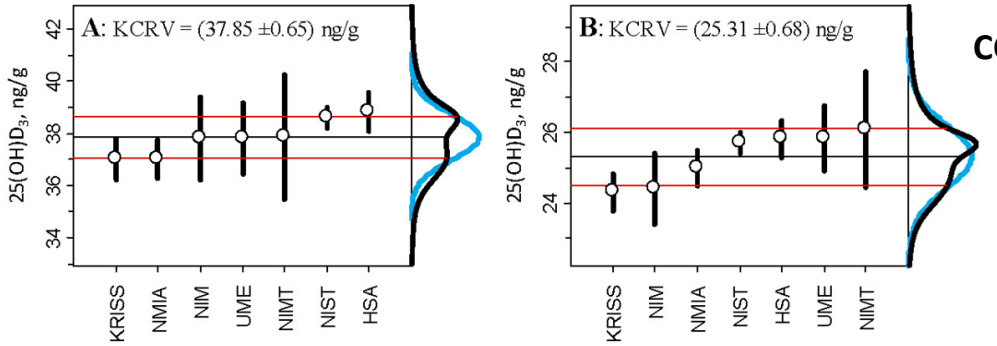
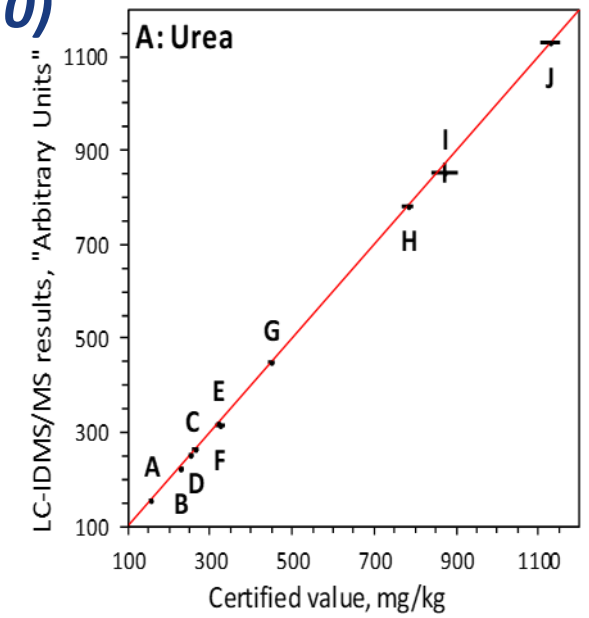
CCQM Key Comparisons for Clinical Matrix Reference Materials and Methods

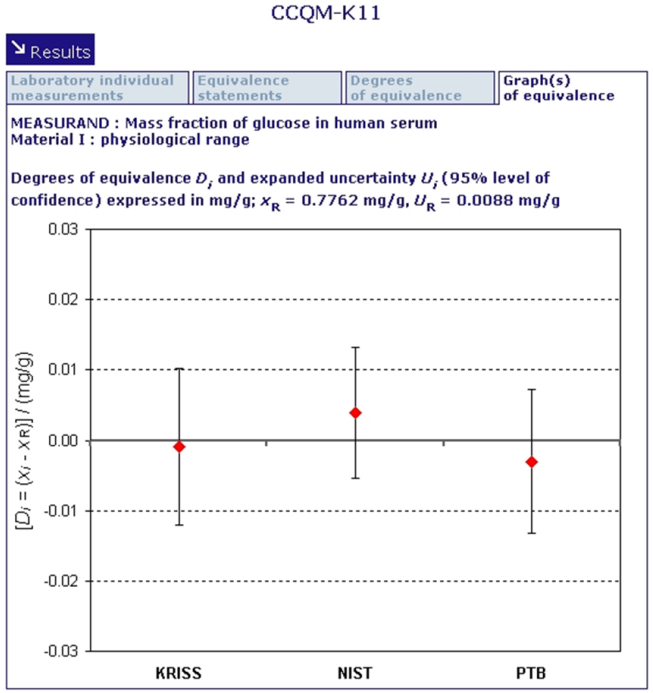
- Cholesterol in serum
  - *CCQM-K5 (1999)*
- Glucose in serum
  - *CCQM-K11 (2001, 2005)*
- Creatinine in serum
  - *CCQM-K12, K80 (2001, 2005, 2010)*
- Vitamin D in serum
  - *CCQM-K132 (2015)*
- Urea and Uric Acid
  - *CCQM-K142 (2016)*
- Selected peptides
  - *CCQM-K115 (2018-9)*
- more in the works…



CCQM-K132 Vitamin D in Serum



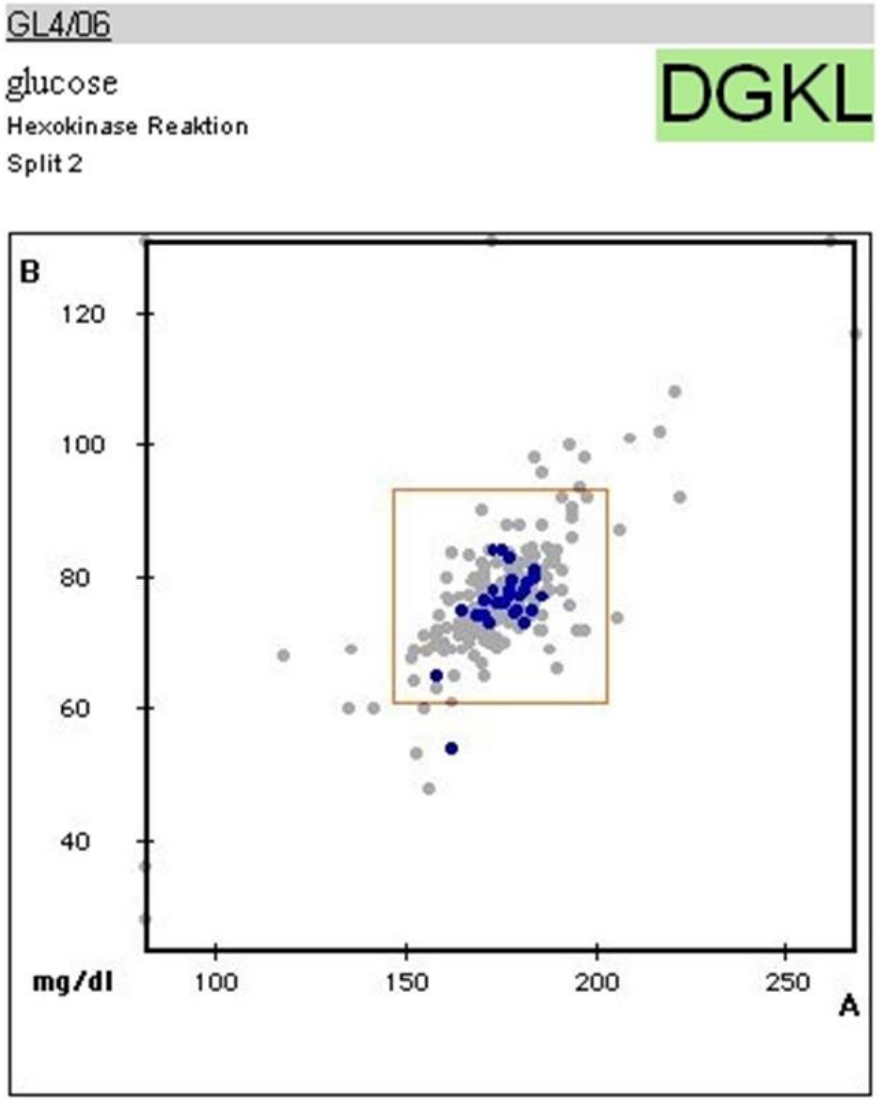
CCQM-K142 Urea and uric acid in serum and plasma materials: HSA and NIST

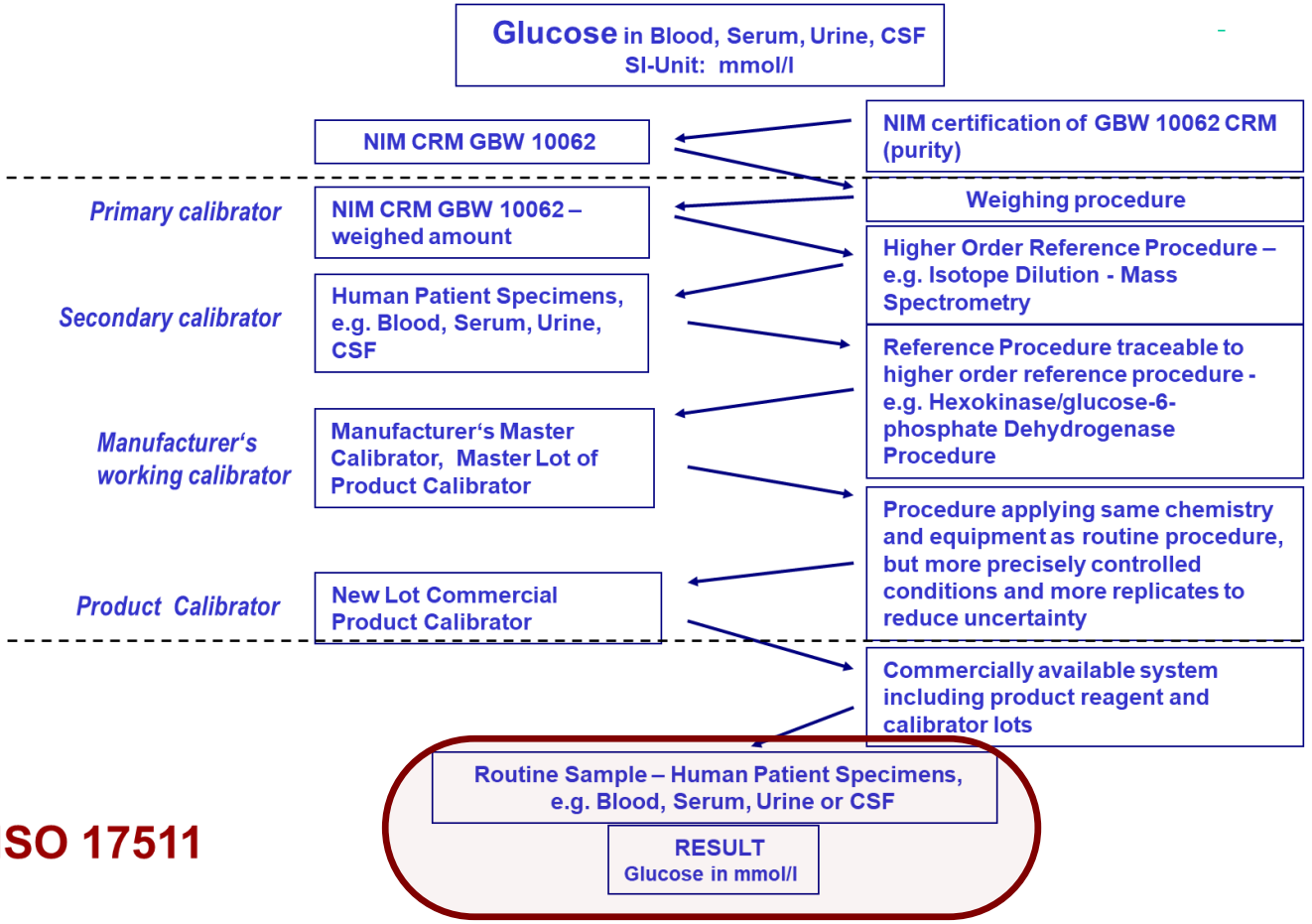


Glucose in Serum: Clinical Laboratory Performance

Proficiency Testing Scheme Results for Glucose in Serum

- Results agree with traceable reference value and within acceptance criteria





ISO 17511

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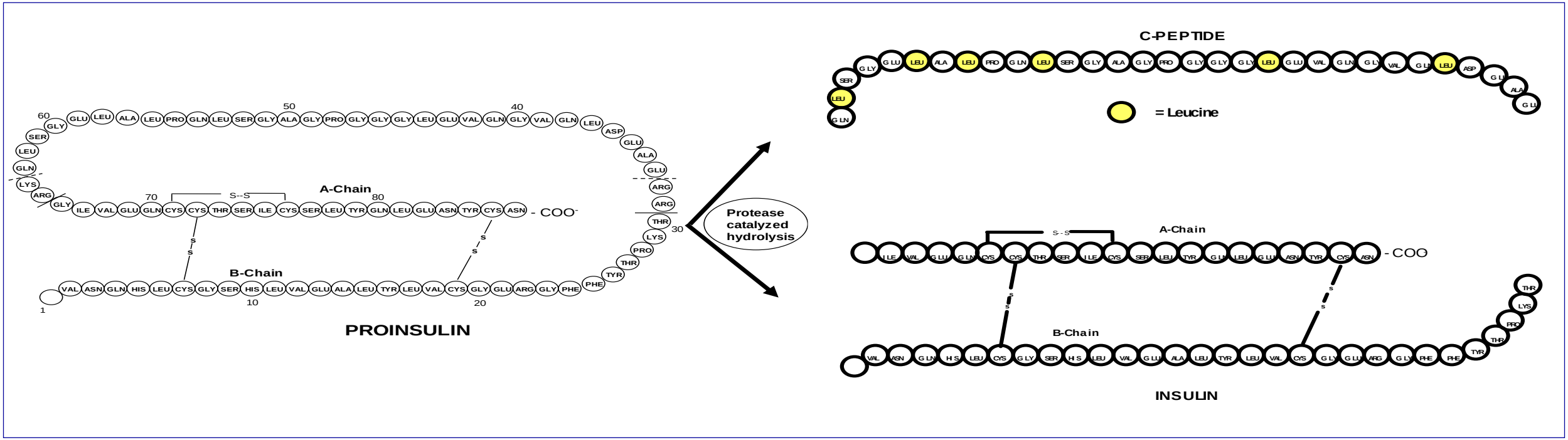
for patient cai

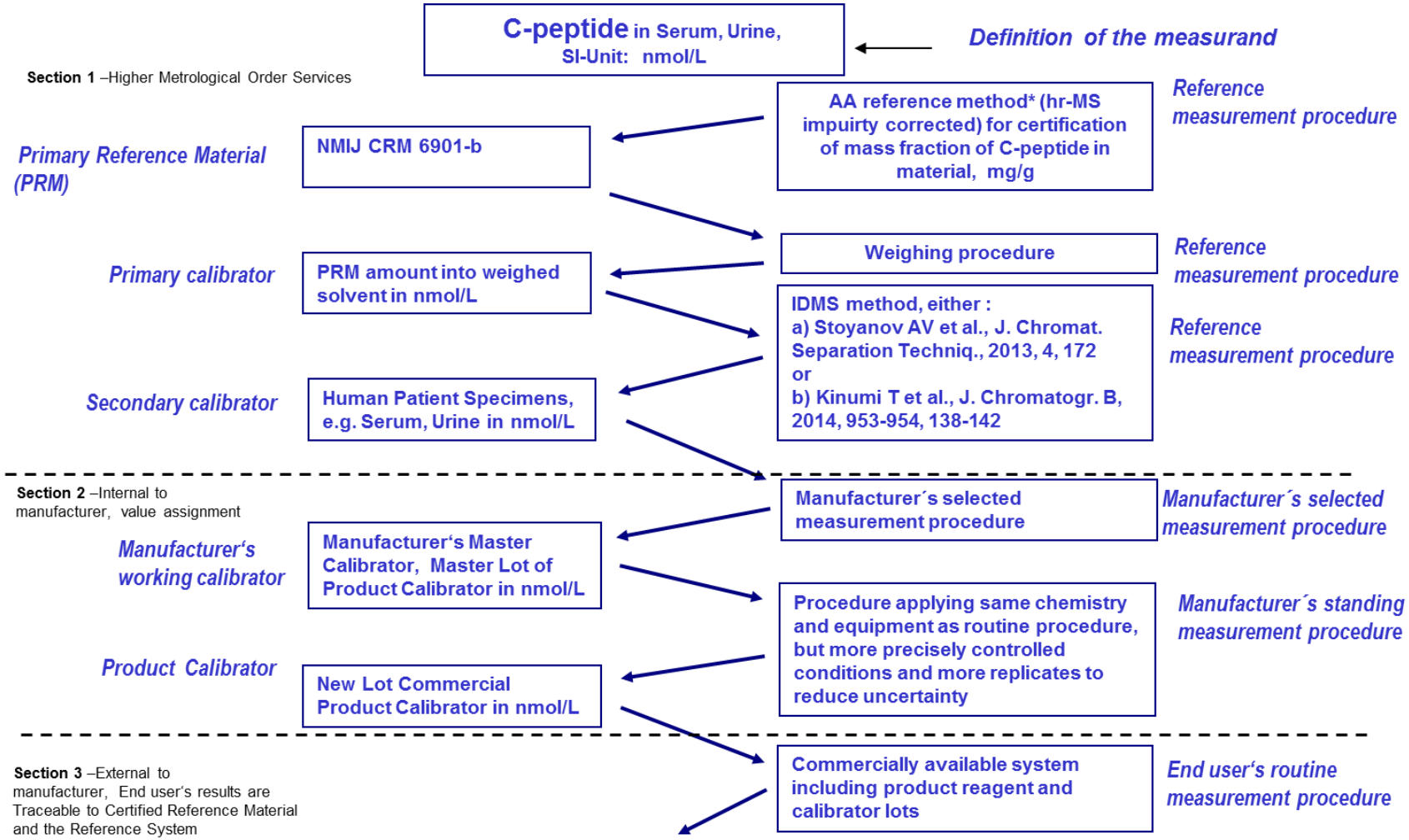
C- peptide measurements and calibrators



- Pro-insulin is synthesized in the pancreatic beta cells
- Pro-insulin is packaged into granules and cleaved to insulin and C-peptide.
- Insulin and C-peptide are secreted in a 1:1 molar ratio.
- Insulin (but not C-peptide) is cleared by the liver; C-peptide remains in the circulation longer than insulin
- C-peptide is the best marker of insulin secretion

Courtesy of R.Little ,UMC DDL

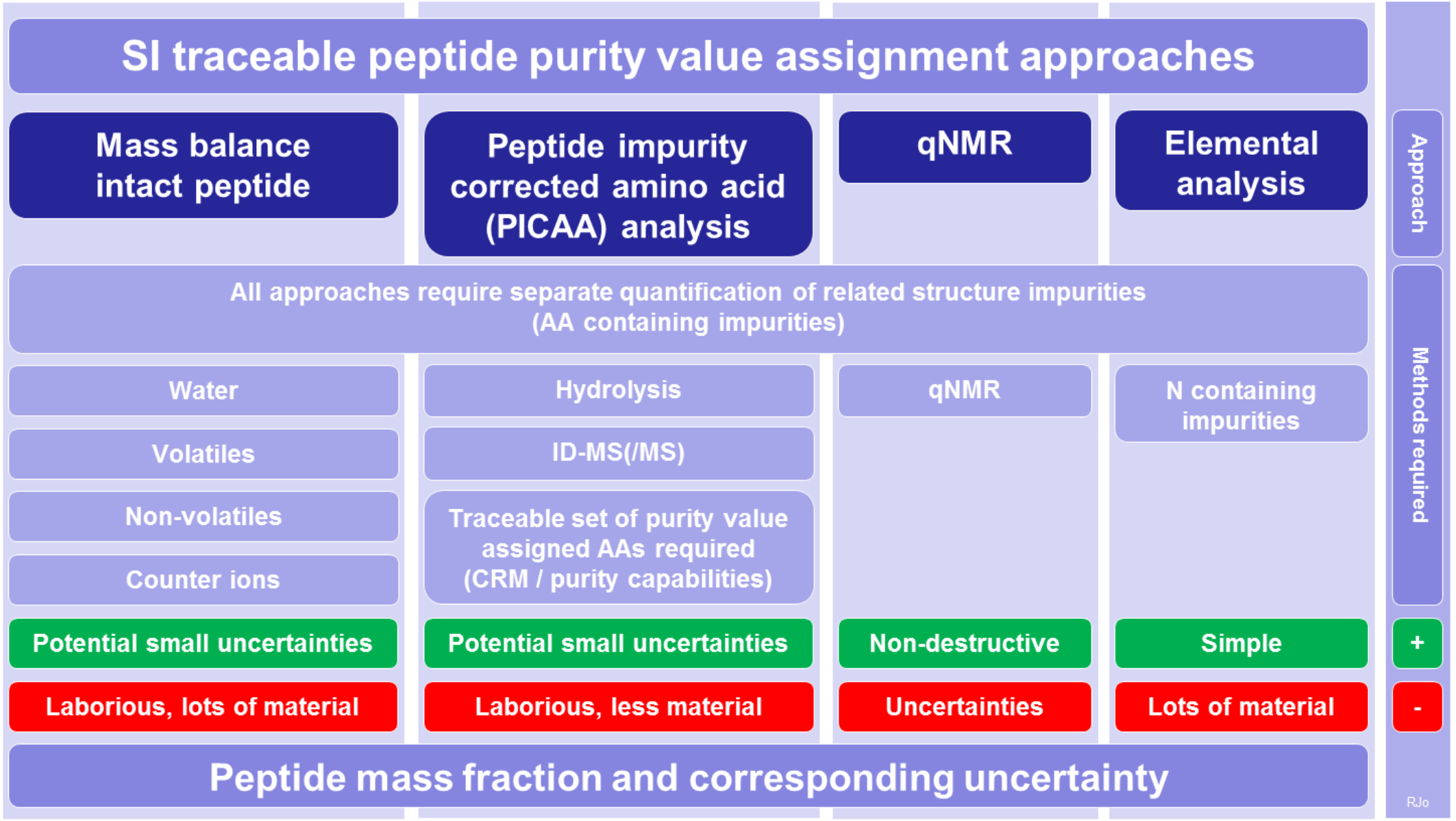
Calibration hierarchy for C-peptide Measurements



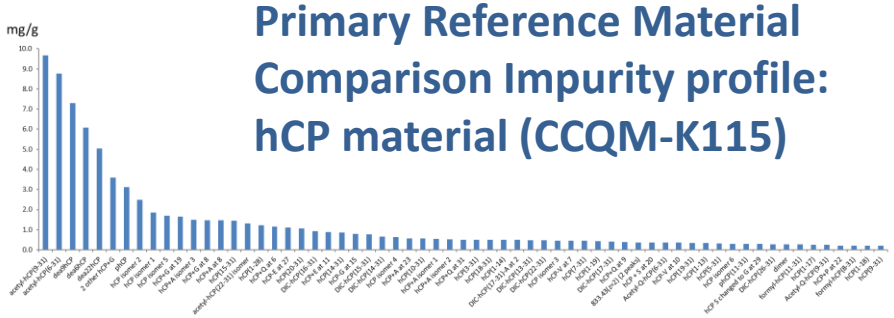
Bureau International des Poids et Mesures

Little, Randie R., Robert I. Wielgosz, et al. "Implementing a Reference Measurement System for C-peptide: Successes and Lessons Learned." Clinical Chemistry (2016): clinchem-2016.

C-peptide Primary Reference Material Value Assignment



CCQM Key Comparisons: NMI capabilities Peptide/Protein PRM value assignment

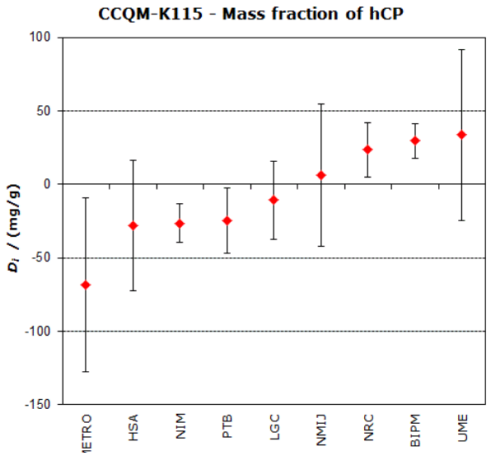


Primary Reference Material Comparison Impurity profile: hCP material (CCQM-K115)

Li, M., Josephs, R.D., Daireaux, A. et al. Anal Bioanal Chem (2018) 410: 5059. https://doi.org/10.1007/s00216-018-1155-y

CCQM-K115

MEASURAND: Mass fraction of hCP



C-peptide in lyophilized phosphate buffer

National Metrology Institute of Japan (NMIJ), Japan

Phone: +81 29 861 4059
Fax: +81 29 861 4009
Email: nmij-crm-info@m.aist.go.jp
Web: http://www.nmij.jp/

Name of the reference material	NMIJ CRM 6901-b, C-peptide
Quantity	Mass concentration after reconstitution
Analyte certified/assigned value	100 mg/L
Expanded uncertainty (level of confidence 95 %)	5 mg/L
Other relevant publication(s)	Certification of the previous lot : Development of SI-traceable C-peptide certified reference material NMIJ CRM 6901-a using isotope-dilution mass spectrometry-based amino acid analyses, T. Kinumi et al., *Anal. Bioanal. Chem.*, 2012, **404**, 13-21
Comment(s)	The previous lot (NMIJ CRM 6901-a C-peptide) was listed in JCTLM Database.
Traceability	traceable to SI
CRM listing	List I

JCTLM listed reference methods for C-peptide

Isotope dilution mass spectrometry method for C-peptide in blood serum	
▸ NMIJ Reference measurement method for serum C-peptide	
Applicable matrice(s)	blood serum, blood plasma
Full description of technique(s)	Isotope dilution mass spectrometry
Quantity	Mass concentration
Applicable range	0.01 ng/ml (0.003 ng on column) to 17.4 ng/ml (2.9 ng on column)
Expected uncertainty (level of confidence 95%)	9.1 % to 11.4 %
Reference(s)	Quantification of serum C-peptide by isotope-dilution liquid chromatography tandem-mass spectrometry: Enhanced detection using chemical modification and immunoaffinity purification, Kinumi T et al., *J. Chromatogr. B*, 2014, **953-954**, 138-142
JCTLM DB identification number	C11RMP1

Liquid chromatography mass spectrometry method for C-peptide in blood serum	
▸ UMC DDL reference method for serum C-peptide	
Applicable matrice(s)	lyophilized, fresh, or frozen human serum or urine
Full description of technique(s)	Liquid chromatography mass spectrometry (LC/MS)
Quantity	Amount-of-substance concentration
Applicable range	0.01 nmol/L to unlimited after appropriate dilution
Expected uncertainty (level of confidence 95%)	0.036 nmol/L to 0.09 nmol/L
Reference(s)	Use of cation exchange chromatography for human C-peptide isotope dilution - Mass spectrometric assay, Stoyanov AV et al., *J. Chromatogr. A*, 2011, **1218**, 9244-9249;
Comparability assessment study(ies)	Human C-peptide Quantitation by LC-MS Isotope-Dilution Assay in Serum or Urine Samples, Stoyanov AV et al., *J. Chromat. Separation Techniq.*, 2013, **4**, 172
Comment(s)	University of Missouri-Columbia Diabetes Diagnostic Laboratory (UMC DDL)
JCTLM DB identification number	C10RMP12_C-Peptide

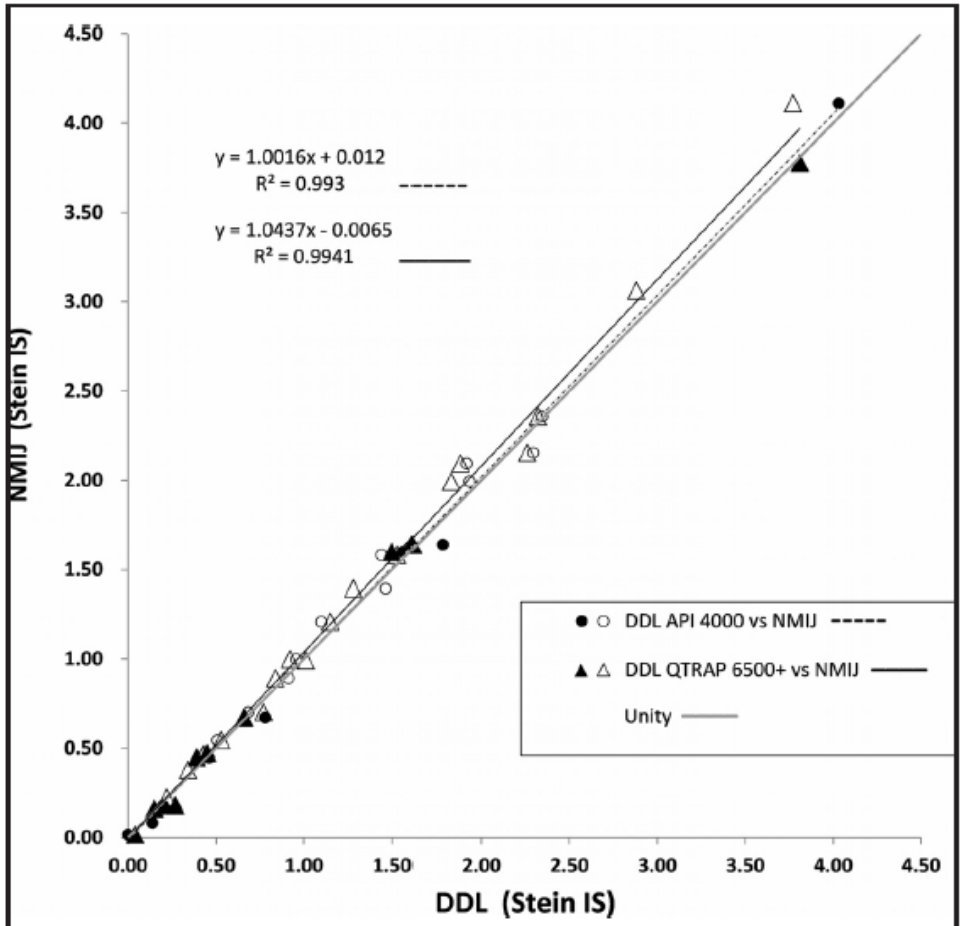
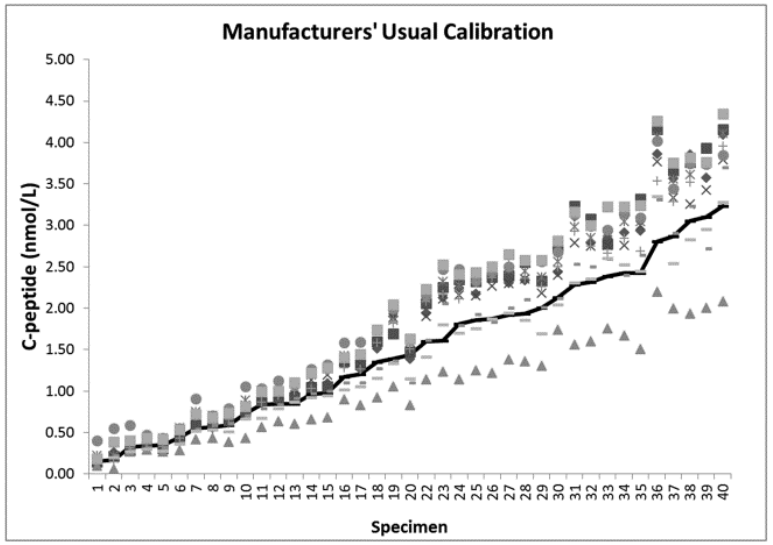


Fig. 1. The relationship between NMIJ and DDL when both laboratories used the same internal standard (IS).

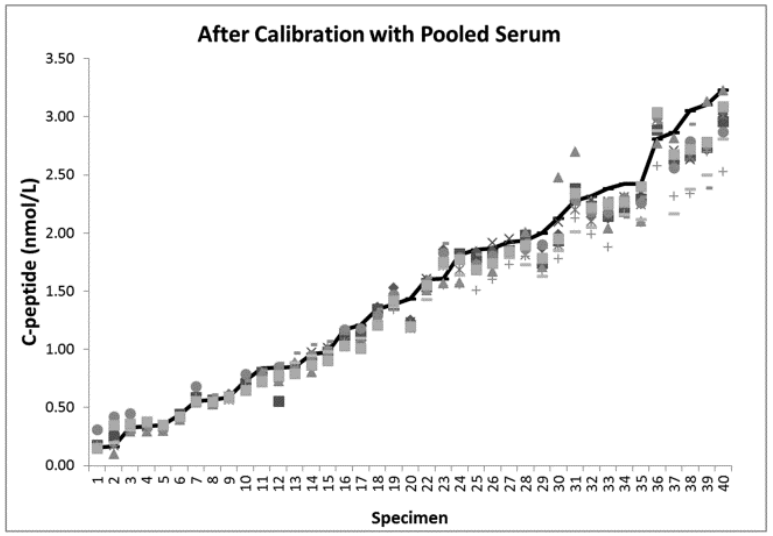
Circles indicate analyses by DDL API 4000 and triangles indicate analyses by DDL QTRAP 6500+. Closed symbols and open symbols correspond to pooled and single-donor samples, respectively.

Impact of implemented traceability chain for C-peptide materials

A.



B.



SI traceable using commutable reference materials in calibration hierarchy

Little, Randie R., Robert I. Wielgosz, et al. "Implementing a Reference Measurement System for C-peptide: Successes and Lessons Learned." Clinical Chemistry (2016): clinchem-2016.

Future Challenges:
Over 700 biomarkers to measure

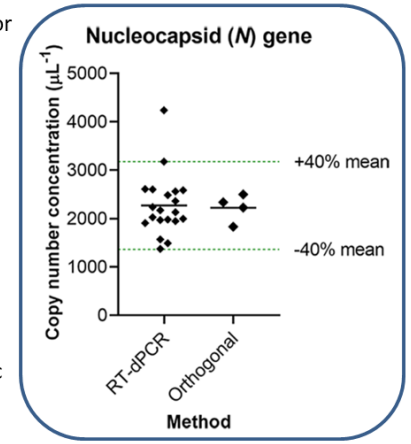
CCQM Activities Addressing Reliability of Covid-19 testing (1)

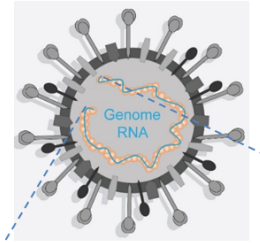
CCQM P199b: SARS-CoV-2 RNA copy number quantification

Coordinators: NML@LGC, NIM, NIBSC, NIST

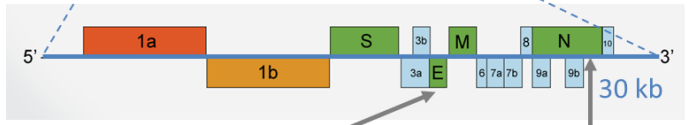
Develop capability for **targeted RNA copy number concentration** and **viral gene quantification**

Evaluate potential **reference measurement procedures** to support clinical measurement of SARS-CoV-2 genomic sequences





CCQM NUCLEIC ACID WORKING GROUP



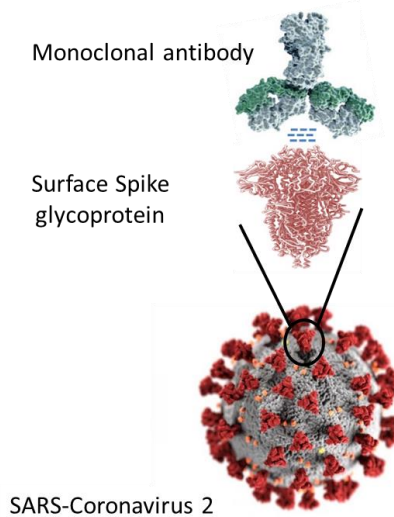
Measurand 2:
Copy number concentration
Envelope (E) gene
full sequence

Measurand 1:
Copy number concentration
Nucleocapsid (N) gene
partial sequence

⇦ For high sensitivity PCR-RNA testing

For rapid antibody testing ⇨

CCQM Activities Addressing Reliability of Covid-19 testing (2)



CCQM-P216: SARS-COV-2 Monoclonal Antibody quantification

CCQM PROTEIN ANALYSIS WORKING GROUP

Coordinating labs: NIM, NRC, BIPM

Surrogate measurands for SARS-COV-2 antibody mass fraction in solution:
1) Mass fraction of antibody aminoacids
2) Mass fraction of antibody proteotypic peptides
3) Mass fraction of monomeric antibody

Participants: NRC, NIM, HSA, TUBITAK UME, NMIJ, BAM, LGC, LNE, KRISS, INMETRO, PTB and BIPM

More Information about JCTLM and Metrological Traceability in Laboratory Medicine

JCTLM
Accurate results for patient care

Reference Materials, Measurement Methods and Services for *In Vitro* Diagnostics

JCTLM Accurate results for patient care

Database Newsletter

https://www.bipm.org/jctlm/ Issue 8 | April 2021

We wish all our readers health and strength as we all continue to operate and adapt our activities in the context of COVID-19 pandemic.

In this issue of the JCTLM Newsletter, we report on highlights from the last Executive meeting; the activities of the JCTLM TEP WG and TF-RMSI; new entries and current database content; and plans for the next JCTLM meetings in 2021. We also welcome the new JCTLM Chair.

1 Dr Greg Miller appointed Chair of the JCTLM

Dr Greg Miller has been appointed Chair of the JCTLM, taking over from Prof. Ian Young who recently completed his two-year term.

Dr Miller is a Professor in the Pathology Department at Virginia Commonwealth University where he serves as Co-director of Clinical Chemistry and Director of Pathology Information Systems. His professional interests and research have focused on standardization and harmonization of laboratory results, quality control and external quality assessment/ proficiency testing. His current professional activities include: Associate Editor of the journal Clinical Chemistry, Chair of the Working Group for Commutability in Metrological Traceability of the IFCC, Chair of the Laboratory Working Group of the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (US), a member of the Harmonization Oversight Group of the International Consortium for Harmonization of Clinical Laboratory Tests, a member of the US delegation to ISO Technical Committee 212 for Clinical Laboratory Testing and In Vitro Diagnostic Test Systems, and other work groups for clinical laboratory standards.

Most recently Dr Miller has been working with the JCTLM, IFCC, BIPM and ICHCLR to organize a joint workshop on 'Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations', which will be held as a virtual meeting in December 2021.

Dr Greg Miller

2 Highlights from the 22nd Executive Committee meeting

The 22nd meeting of the Executive Committee of the JCTLM was held by teleconference on 3-4 December 2020. The Executive Committee convened for the last time under the Chairmanship of Prof. Ian Young whose term ended in December. He was thanked for his support to the JCTLM.

Changes in the JCTLM Executive Committee representatives

The Committee approved the Chairmanship of Dr Greg Miller, and the BIPM's continued role as the Secretariat for the JCTLM effective in February 2021.

Update of the JCTLM Database

The JCTLM Executive decided on the development of a new version of the JCTLM Database to benefit of a new web designed user interface with a contextual search facility and machine-readability.

JCTLM Review teams' membership

The 5-year review process for JCTLM Review teams' membership was successfully completed and resulted in the reappointment of 75 % of the review teams' members who were contacted and attracted new members appointed during the year. There are presently 60 experts contributing to the twelve JCTLM review teams.

Virtual meeting of the JCTLM Members and Stakeholders

The Committee decided that the next meeting of the JCTLM Members and Stakeholders would be held remotely in December 2021, noting the difficult situation surrounding COVID-19. A separate item on this meeting appears in this Newsletter.

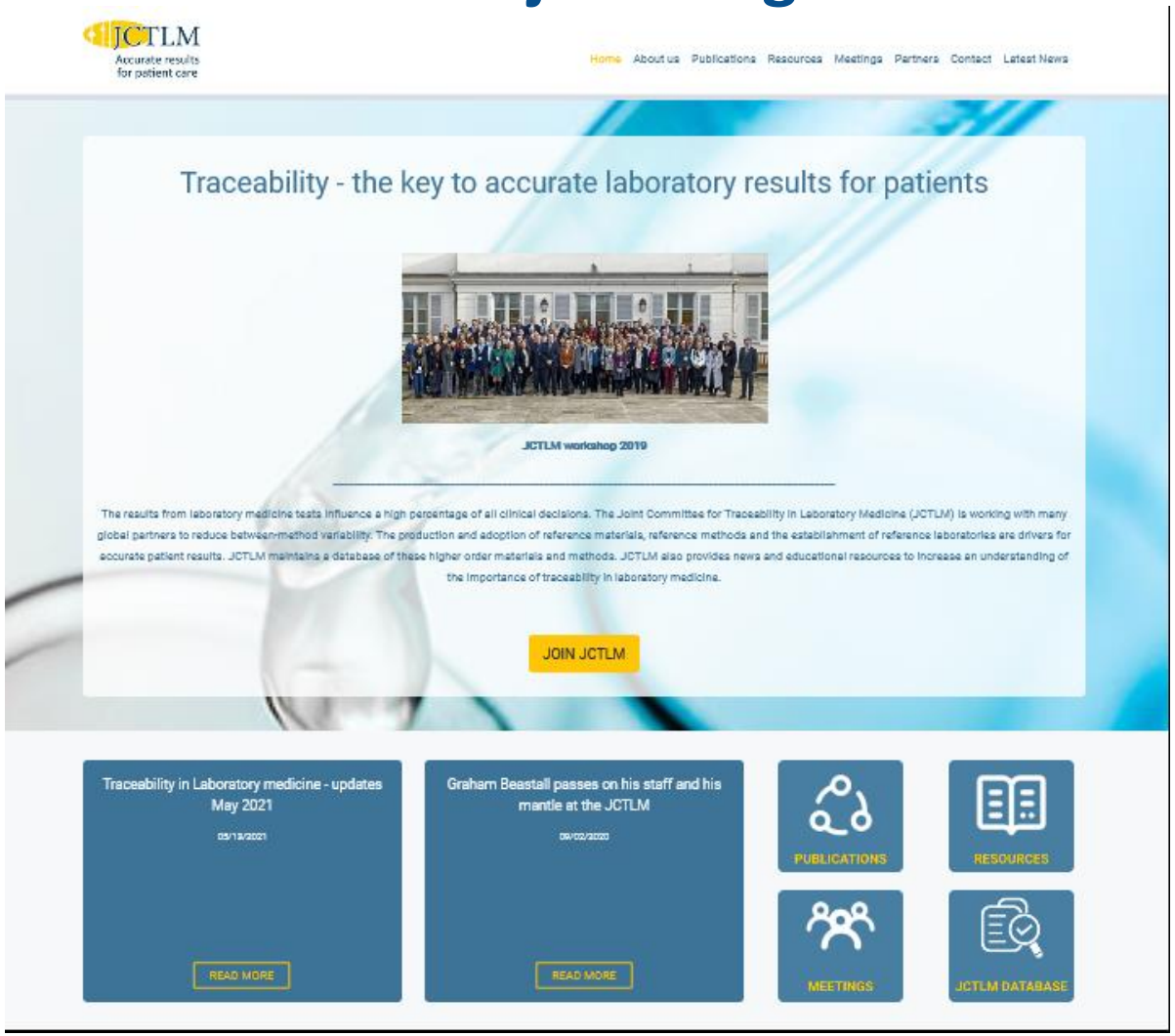
New JCTLM Member organizations

The JCTLM Executive approved the JCTLM membership of the Uzbek National Institute of Metrology" State Enterprise (UzNIM) and two Reference Laboratories of Autobio Diagnostics Co., Ltd from Beijing and Zhengzhou, China. As of 30 March 2021, there are 60 JCTLM Member organizations.

See the full text of the 2020 JCTLM Executive Meeting report.

1

www.jctlm.org



JCTLM and World Metrology Day 2021

JCTLM
Accurate results for patient care

Happy World Metrology Day 2021!

The Joint Committee for Traceability in Laboratory Medicine (JCTLM) is celebrating World Metrology Day on 20 May 2021. The theme this year is **"Measurement for Health"**
Watch the videos on measurements in Laboratory Medicine for broader perspectives on the importance of metrological traceability in laboratory medicine for individual patients and for risk assessments in populations.

What is Laboratory Medicine?
Greg Miller, PhD, Chair, JCTLM
Professor of Pathology, Virginia Commonwealth University Health System, USA

What happens in your local laboratory?
Graham Jones, Department of Chemical Pathology, St Vincent's Hospital, Sydney, Australia

Tools for obtaining laboratory result comparability: What the JCTLM is offering?
Mauro Panteghini, Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Italy

What is special for measurements in Laboratory Medicine?
Elvar Theodorsson, Linkoping University, Sweden

Chem-Bio Metrology for Laboratory Medicine
Sang-Ryoul Park, CIPM/CCQM
Korea Research Institute of Standards and Science

How IFCC improves the standardization of results in Laboratory Medicine
Prof. Phillippe Gillery, MD, PhD, IFCC-SD Chair
Professor of Biochemistry and Molecular Biology, Faculty of Medicine and University Hospital of Reims, France

Platelet Counting Standardization
Paul Harrison, BSc, PhD, FRCPath, ICSH board member
Associate Professor, Institute of Inflammation and Ageing, University of Birmingham, UK

How to achieve traceable measurements in Laboratory Medicine jointly in Europe: The European Metrology Network for Traceability in Laboratory Medicine
Bernd Güttler and Rainer Stosch, PTB, Germany

Thank you for your attention

Happy World Metrology Day

Joint Committee for Traceability in Laboratory Medicine (JCTLM)

World Metrology Day 2021:
Measurement for Health

JCTLM
Accurate results for patient care

20 May 2021

Robert Wielgosz, BIPM