Chapter 8
Scientific Division

SCIENTIFIC DIVISION EXECUTIVE COMMITTEE (SD-EC)

Chair:
Prof. Ian YOUNG (UK)

Vice Chair:
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IRMM Consultant:
Dr. Heinz SCHIMMEL (BE)

NIST Consultant:
Dr. David BUNK (US)

SD Consultant/Chair JCTLM:
Dr. Gary L. MYERS (US)

CHAIRS OF SCIENTIFIC DIVISION COMMITTEES AND WORKING GROUPS

8.1. Executive — I.Young (UK)

8.2. Committees

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

8.3. Working Groups

8.3.35.	Standardisation of Hemoglobin A2 (WG-HbA2)	R. Paleari (IT)
8.3.36.	Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT)	J. Wielders (NL)
8.3.39.	Standardisation of Albumin Assay in Urine (WG-SAU) in collaboration with National Kidney Disease Education Program (NKDEP)	L.M. Bachmann (US)
8.3.40.	Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A)	S. Wittfooth (FI)
8.3.41.	Growth Hormone (WG-GH)	to be appointed
8.3.42.	Standardisation of Insulin Assays (WG-SIA) in collaboration with American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD)	M. Steffes (US)
8.3.43.	Standardisation of Troponin I (WG-TNI)	D. Bunk (US)
8.3.45.	Harmonisation of Autoantibody Tests (WG-HAT)	J. Sheldon (UK)
8.3.47.	Clinical Quantitative Mass-Spectrometry Proteomics (WG-cMSP)	S. Lehmann (FR)
8.3.48.	Parathyroid Hormone (WG- PTH)	C. Sturgeon (UK)
8.3.49.	CSF-Proteins (WG-CSF)	K. Blennow (SE)
8.3.50.	Standardisation of Bone Marker Assays (WG-BMA)	H. Morris (AU)
8.3.51.	Commutability (WG-C)	G. Miller (US)
8.3.52.	Serum Total Protein (WG-STP)	to be appointed

8. Scientific Division (SD)

A Committee on Standards was established in 1966 “to instigate and promote theoretical and practical developments in the field of standards and standardisation in clinical chemistry - in its broadest sense.” During its first decade, the main efforts of the Committee were directed toward (1) analytical nomenclature, (2) reference materials and methods, and (3) quality control. Its achievements during this period are illustrated by the list of publications on these topics. Following a Council decision in 1978, efforts have been made to extend its work to include more subjects of interest both to clinicians and clinical chemists and laboratorians. Accordingly, the name of the Committee was changed to the Scientific Committee and later to the Scientific Division.
The Division and its activities are managed by an Executive Committee. This Committee is responsible for (1) developing a mission statement, (2) developing strategy and tactics, (3) initiating and managing projects, and (4) generating and adhering to its Terms of Reference.

8.1. SD-Executive Committee (SD-EC)

Membership

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

8.1.1. Mission Statement

The mission of the SD is to advance the science of Clinical Chemistry and Laboratory Medicine and to apply it to the practice of Clinical Laboratory Science.

8.1.2. Strategy

ccording to the Statutes of IFCC, the Federation exists to advance the science and practice of Clinical Chemistry and Laboratory Medicine and to further their application in the provision of health services and the practice of medicine. The strategic and tactical goals to which the Scientific Division is committed are to:

- Identify research areas of relevance to Clinical Chemistry and Laboratory Medicine and assist the transfer of research results to the profession.
- Identify scientific and technological problems in current practice and provide solutions and guidelines on how to resolve them.
- Facilitate the development and transfer of technical innovations to clinical laboratory professionals and clinicians.
- Facilitate the development and implementation of diagnostic strategies.
- Establish standards for scientific and technical aspects of good laboratory practice.
- Respond to scientific and technical needs of IFCC Member Societies, IFCC Corporate Members and external agencies.

- Participate actively in the scientific programmes of IFCC congresses and other scientific meetings.
- Ensure the quality of IFCC scientific documents.
- Organise Master Discussions.

8.1.3. Projects

The SD initiates and manages projects with its own resources or through its Committees and Working Groups. Work is conducted in cooperation with other IFCC units and with relevant National and International Organisations. The SD ensures that each of its Committees and Working Groups are functioning under clear terms of reference together with an agreed schedule of activity. The SD will assist in the development of the project proposals, and will undertake an annual review of progress and review and approve any documents that result from the work.

8.1.4. Terms of Reference

The SD consists of up to six IFCC sponsored-individuals, which include the Chair and the Vice-Chair, and additionally one individual is nominated by the Corporate Members of IFCC. The Division may co-opt additional member(s) to address specific issues. The Chair, the Vice-Chair and all Full Members are appointed by EB after consultation between the EB, SD and Member Societies.

The SD working units are committees, that are theme-oriented, and working groups, that are task-oriented. Committees (C) are usually funded by IFCC for one full meeting per year. Only the Chair of Working Groups (WG) is normally funded by IFCC; however, a WG may be partially or totally supported by IFCC, Member Societies, Corporate Members or other Organisations.

8.2. SD Committees

Over the years, the SD has initiated and managed a number of applicable committees. These have been numbered sequentially with the Mueller numbering system beginning with 8.2.1. Current committees and their activities are listed below. Earlier Committees and those with missing numbers are found in prior editions of the IFCC Handbook.

8.2.6. Nomenclature, Properties and Units (C-NPU) in collaboration with IUPAC

Membership

Name	Position	Country	Term	Time in Office
R. Flatman	Chair	AU	2nd	2015 01 - 2017 12
U. Forsum	Member	SE	2nd	2014 01 - 2016 12
A. Jabor	Member	CZ	1st	2013 03 - 2015 12
F. Scherrer	Member	FR	1st	2015 01 - 2017 12
K. Toska	Member	NO	1st	2015 01 - 2017 12
R. Dybkaer	Consultant	DK		

Terms of Reference

- Continuously provide advice in relation to the management, updating and publishing of NPU terminology
- Make recommendations on NPU for reporting clinical laboratory data that conform to or adapt current standards of authoritative organisations, and that will improve their utilisation for health care.
- Provide a connection with other organisations concerned with NPU, such as the Bureau International des Poids et Mesures (BIPM), the European Committee for Standardisation (CEN) and the International Organisation for Standardisation (ISO), and, by extension, clinical laboratory sciences societies, such as the International Union of Pure and Applied Chemistry (IUPAC), and the in vitro diagnostics industry, to ensure that problems encountered by health care professionals in the area of NPU are considered by those organisations.
- Act as a consultant group on NPU in clinical chemistry and laboratory medicine and, by extension, in the rest of clinical laboratory sciences to international scientific panels, regional and national clinical laboratory sciences organisations, editors of scientific journals, manufacturers of clinical laboratory instrumentation and products, and to individual clinical laboratory professionals and other health care professionals.
- Report and offer advice to the SD Chair and the SD Executive Committee on matters concerning NPU in all its aspects (all items above).

Current Projects

- Transfer of the NPU generic database to IFCC site: help and advice on training the future IFCC NPU database manager(s) in relation to the installation, updating and management of the database, and on its relationship relations with other national versions.
- Mapping of the IFCC-IUPAC laboratory coding system to SNOMED CT.
- Securing and structural updating of information in the NPU coding system and its environment.
- Development of an international vocabulary for nominal examinations in scientific communication.

8.2.11. Molecular Diagnostics (C-MD)

Membership

Name	Position	Country	Term	Time in Office
D. Payne	Chair	IT	1st	2013 01 - 2015 12
P. Ahmad-Nejad	Member	DE	1st	2013 01 - 2015 12
A.K.C. Chan	Member	HK	1st	2013 01 - 2015 12
M. Maekawa	Member	JP	2nd	2015 01 - 2017 12
C. Mamotte	Member	AU	1st	2013 01 - 2015 12
G. Russomando	Member	PY	1st	2013 01 - 2015 12

Terms of Reference

- Foster dynamic exchanges between IFCC and molecular diagnostic laboratories and industry
- Produce guidelines on clinical validation of tests, conduct and reporting of molecular diagnostic tests
- Provide reference materials
- Create a network of locus-specific IFCC Molecular Diagnostics Centres

Current Projects

- Establish an International Network of IFCC Reference Centres in Molecular Diagnostics
- Development of a checklist for technology transfer from development to clinical laboratory testing
- Standardise formats for reporting of molecular diagnostic results

8.2.21. Reference Systems of Enzymes (C-RSE)

Membership

Name	Position	Country	Term	Time in Office
F. Ceriotti	Chair	IT	2nd	2013 01 - 2015 12
J. Gella	Member	ES	2nd	2014 01 - 2016 12
D. Grote-Koska	Member	DE	1st	2014 01 - 2016 12
S. Pal	Member	IN	1st	2014 01 - 2016 12
R. Rej	Member	US	2nd	2014 01 - 2016 12
S. Ueda	Member	JP	2nd	2015 01 - 2017 12

Terms of Reference

- Develop IFCC Enzyme Reference Measurement Procedures: New 37 °C IFCC enzyme reference procedures are being developed
- Create a network of Enzyme Reference Laboratories: Coordination of a group of reference laboratories from hospitals, academy and industry, which are able to perform adequate measurements according to a list of stated requirements
- Evaluate Enzyme Reference Materials: Evaluate reference materials provided by IRMM within the network of reference laboratories prior to certification. The materials are available as primary reference materials for calibration and/or validation of lower order procedures for the measurement of the catalytic concentration of enzymes

Current Projects

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

8.2.23. Traceability in Laboratory Medicine (C-TLM)

Membership

Name	Position	Country	Term	Time in Office
L. Siekmann	Chair	DE	1st	2013 01 - 2015 12
D. Clark	Member	US	1st	2013 01 - 2015 12
L. Mackay	Member	AU	1st	2013 01 - 2015 12
G. Schumann	Member	DE	2nd	2014 01 - 2016 12
C. Weykamp	Member	NL	2nd	2013 01 - 2015 12
A. Kessler	RELA Consultant			

Terms of Reference

- Support activities regarding Traceability in Laboratory Medicine (TLM), permitting IFCC to continue its international role in this area and providing an operating link between the SD and the WGs of the Joint Committee on Traceability in Laboratory Medicine (JCTLM), concerning identification of reference measurement procedures, reference materials and reference laboratories.
- Support reference laboratories in the context of complete reference systems (accepted reference measurement procedures of higher order, reference materials, and reference laboratories) by establishing an External Quality Assessment Scheme (EQAS) for reference laboratories in order to monitor their competence.
- Promote establishment and maintenance of IFCC reference laboratory networks for clinically relevant measurands (e.g. the IFCC HbA1c network).

Current Projects

- Organisation of IFCC Ring Trials for reference laboratories

8.2.24. Reference Intervals and Decision Limits (C-RIDL)

Membership

Name	Position	Country	Term	Time in Office
K. Ichihara	Chair	JP	2nd	2013 01 - 2015 12
J. Barth	Member	UK	2nd	2014 01 - 2016 12
G. Klee	Member	US	2nd	2014 01 - 2016 12
J. Macri	Member	CA	1st	2014 01 - 2016 12
Y. Ozarda	Member	TR	2nd	2014 01 - 2016 12
B. Yadav	Member	NP	1st	2014 01 - 2016 12

Terms of Reference

- Review current concepts of establishing reference intervals and decision limits and to prepare state-of-the-art position statements regarding new avenues
- Make available reference intervals and decision limits that respect the requirements of international directives such as the European IVD Directive 98/79, and relevant ISO standards
- Determine priority list of measurands (analytes) for which reference intervals and/or decision limits have to be developed, considering various factors, such as age, gender, ethnicity, and for which the greatest improvements in medical decision making are anticipated
- Monitor and evaluate currently proposed reference intervals for selected measurands (analytes) in the light of the concept of traceability and of the identification of the uncertainty
- Establish transferability protocols of reference intervals and decision limits, which take into consideration inter-routine laboratory method variations and achieve better applicability in clinical practice
- Collaborate with other organisations and/or to undertake establishment of reference intervals or decision limits for measurands (analytes) identified as a priority
- Work in close collaboration with other Cs and WGs of SD and other IFCC Divisions for the development and appropriate clinical utilisation of reference intervals and decision limits

Current Projects

- The global multicentre study for derivation of reference intervals (RI) for common analytes has been conducted since 2011 by use of a harmonised protocol. Currently 19 countries from 5 continents are in collaboration. The RIs for the standardised analytes are made traceable to the RMPs.
- Sources-of-variation of reference values are being explored in a global scale after aligning test results through measurements of the serum panel.

8.2.25. Standardisation of Thyroid Function Tests (C-STFT)

Membership

Name	Position	Country	Term	Time in Office
L. Thienpont	Chair	BE	2nd	2015 01 - 2017 12
B. Das	Member	IN	2nd	2015 01 - 2017 12
J.D. Faix	Member	US	2nd	2015 01 - 2017 12
F. MacKenzie	Member	UK	2nd	2015 01 - 2017 12
F. Quinn	Member/Abbott	US	2nd	2015 01 - 2017 12
M. Rottmann	Member/Roche	DE	2nd	2015 01 - 2017 12
K. VanUytfanghe	Consultant	BE		

Terms of Reference

- Develop reference measurement systems (reference materials/reference methods) to establish traceability of free thyroid hormone and TSH assays.
- Establish a network of laboratories competent to offer reference measurement services for free thyroid hormones
- Provide an infrastructure for procurement of serum panels.
- Demonstrate that the traceable assays can use a common reference interval; use this as a basis for further elaboration of the reference intervals by the IVD manufacturers; consult with clinicians about the need for ethnic, age- or sub-population-specific reference intervals in co-operation with C-RIDL.
- Liaise with key stakeholders to implement the use of the traceable assays in routine clinical practice.
- Provide, through collaboration with IFCC EMD, educational materials for manufacturers, clinicians and patients which will support the implementation of traceable assays.

Current Projects

- Phase IV method comparison studies for FT4 and TSH on clinically relevant samples: is intended as technical FT4 standardisation and TSH harmonisation process, by which FT4 assays will become traceable to the conventional reference measurement procedure based on equilibrium dialysis (ED) isotope dilution-liquid chromatography-/ tandem mass spectrometry (ID-LC/MS/MS), TSH assays to the statistically inferred all-procedure trimmed mean (APTM).
- C-STFT web site: www.ifcc-cstft.org (under construction)

8.3. SD Working Groups

8.3.35. Standardisation of Haemoglobin A2 (WG-HbA2)

Membership

Name	Position	Country	Term	Time in Office
R. Paleari	Chair	IT	2nd	2013 01 - 2015 12
C. Arsene	Member	DE		
E. Bissé	Member	DE		
D. Caruso	Member	IT		
V. De Jesus	Member	US		
P. Kaiser	Member	DE		
A. Mosca	Member	IT		
M. Ospina	Member	US		
C. Schaeffer	Member	FR		
A. Van Dorsselaer	Member	FR		
B. Wild	Member	UK		

Terms of Reference

- Promote the standardisation of Haemoglobin A2 measurement through the definition of an international reference system, including a reference measurement procedure and primary and secondary reference materials.

Current Projects

- Definition of a reference measurement procedure using mass spectrometry associated with proteolytic degradation.
- Preparation of a secondary reference material for Haemoglobin A2 (in cooperation with IRMM).

8.3.36. Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT)

Membership

Name	Position	Country	Term	Time in Office
P.M. Wielders	Chair	NL	1st	2015 01 - 2017 12
J.B. Whitfield	Secretary	AU		
R.F. Anton	Member	US		
V. Bianchi	Member	IT		
A. Helander	Member	SE		
F. Schellenberg	Member	FR		
C. Weykamp	Member	NL		

Terms of Reference

- Establish a network of CDT reference laboratories that perform the HPLC candidate reference method
- Develop a reference material for CDT (suitable for harmonisation of present methods)
- Appoint the HPLC reference method, the reference interval and measurement uncertainty
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Current Projects

- Finalisation of work done on the HPLC candidate reference method, publication of reference method
- Expanding and renewing the international network of reference laboratories
- Evaluation the use of reference materials for CDT, harmonisation of commercial methods

8.3.39. Standardisation of Albumin Assay in Urine (WG-SAU) in collaboration with NKDEP

Membership

Name	Position	Country	Term	Time in Office
L.M. Bachmann	Member	US	1st	2013 01 – 2015 12
D. Bruns	Member	US		
D. Bunk	Member	US		
G. Curhan	Member	US		
J. Eckfeldt	Member	US		
J. Fleming	Member	US		
N. Greenberg	Member	US		

G. Hortin	Member	US
Y. Itoh	Member	JP
G. Jones	Member	AU
J. Lieski	Member	US
M. McQueen	Member	CA
G. Miller	Member	US
G. Myers	Member	US
A. Narva	Member	US
M. Panteghini	Member	IT
K.W. Phinney	Member	US
S. Sandberg	Member	NO
H. Schimmel	Member	BE
D. Seccombe	Member	CA
J. Zakowski	Member	US

Terms of Reference
- Establish a reference procedure and commutable reference materials to facilitate standardisation of measurement of albumin in urine.
- Establish recommendations for sample collection and handling to improve uniformity of results
- Define the measurand(s) that are important for clinical interpretation of urine albumin

Current Projects
- Determination of physiological variability of urine albumin (with CDC)
- Determination of the current status of urine albumin method harmonisation
- Chemical and immunochemical characterisation of the various forms of albumin in urine (definition of the measurand)
- Determination of the optimum measurand for the assessment of albuminuria
- Development of reference materials for urine creatinine and urine albumin (with NIST)
- Coordination with Japanese Society of Clinical Chemsitry (JSCC) project to develop a urine albumin reference material (by JSCC)
- Development of urine albumin IDMS candidate reference measurement procedures (with Mayo Clinic and NIST)

8.3.40. Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A)

Membership

Name	Position	Country	Term	Time in Office
S. Wittfooth	Chair	FI	1st	2015 01- 2017 12
C. Sturgeon	Member	UK		
A. Ellis	Member	UK		
A. Katrukha	Member	RU		
C. Oxvig	Member	DK		
K. Pettersson	Member	FI		
B. Rafferty	Member	UK		
K. Spencer	Member	UK		

Terms of Reference
- Develop a reference system for standardisation of PAPP-A measurement employed as marker for prenatal screening

Current Projects
- Evaluate at least two different PAPP-A preparations in relation to the major assay constructs presently being used on routine prenatal testing.

8.3.41 Growth Hormone (WG-GH)

Terms of Reference
- Growth Hormone in serum has been identified as a priority measurand for harmonisation/standardisation by the International Consortium for Harmonization of Clinical Laboratory Results. The objective of this WG is to identify the best approach to achieving comparability of patient results through harmonization or standardization of current assays and to develop and implement a program of work to achieve this.

8.3.42. Standardisation of Insulin Assays (WG-SIA) in collaboration with ADA/EASD

Membership

Name	Position	Country
M.W. Steffes	Chair	US
J. Dekker	Member	NL
D. Li	Member	US
R. Little	Member	US
G. Miller	Member	US
D. Sacks	Member	US
G. Wark	Member-IFCC	UK

Terms of Reference
- Improve the standardisation of assays for insulin by the development of a candidate reference method and materials.

Current Projects
- Development of a reference method for the measurement of insulin by electrospray ionisation-isotope dilution-liquid chromatography-tandem mass spectrometry (ID-LC/tandem MS).
- Establishment of the suitability or otherwise of a lyophilised recombinant human insulin preparation as a primary reference material with appropriate properties
- Establishment of the performance of commercially available insulin assays compared to the ID-LC/tandem MS method using single donation samples and the effect of using a common primary reference material or serum pools on between method agreement.
- Determination of the effect of freeze/thawing on measured insulin (a requirement to establish the validity of materials for 3 above).

8.3.43. Standardisation of Troponin I (WG-TNI)

Membership

Name	Position	Country	Term	Time in Office
D. Bunk	Chair	US	1st	2015 01 - 2017 12
J. Barth	Member	UK		
R. Christenson	Member	US		
A. Katrukha	Member	FI		
J. Noble	Member	UK		

M. Panteghini	Member	IT
H. Schimmel	Member	BE
J. Tate	Member	AU
L. Wang	Member	US

Terms of Reference
- Develop a candidate secondary reference measurement procedure and candidate secondary reference material for cardiac troponin I (cTnI)
- Test for cTnI standardisation and clinical validation by comparison with validated commercial assays in a round robin study

Current Projects
- Preparation of a secondary reference material for cTnI consisting of three cTnI positive serum pools (Phase 2)
- Validation of cTnI standardisation through a round robin after a value transfer using the secondary reference material as common calibrator (Phase 3)

8.3.45. Harmonisation of Autoantibody Tests (WG-HAT)

Membership

Name	Position	Country	Term	Time in Office
J. Sheldon	Chair	UK	2nd	2013 01 - 2015 12
P.L. Meroni	Member	IT		
I. Zegers	Member	BE		

Terms of Reference
- Evaluate the main causes of variability for a number of diagnostically critical autoantibody measurements.
- Identify autoantibodies where a common calibrator could reduce the inter-assay variability
- Identify or produce commutable reference materials that could be used as interim calibration material for autoantibody assays.
- Produce thoroughly characterised pure antibody preparations with known concentration and identity and use these to transfer values to a matrix preparation.

Current projects
- Evaluation of EQA data to identify the autoantibody tests with the potential for harmonisation of results.
- Gathering a comprehensive data base of the assay characteristics of the currently available autoimmune serology methods.
- Identifying existing materials that could be used to assess interassay variability and possibly be used as interim calibration material.
- Defining the requirements for a calibration material for autoimmune serology.

8.3.47 Working Group on Clinical Quantitative Mass Spectrometry Proteomics (WG-cMSP)

Membership

Name	Position	Country	Term	Time in Office
S. Lehmann	Chair	FR	2nd	2014 01 - 2016 12
EO. Agbedana	Member	NG		
Y. Ando	Member	JP		
C. Brede	Member	NO		

U. Ceglarek	Member	DE
JA Cocho	Member	ES
M. Glückmann	Member	DE
Y. Gong	Member	CA
D. Hochstrasser	Member	CH
A Hoofnagle	Member	US
BE. Krastin	Member	US
A. Urbani	Member	IT

Terms of Reference
- Define appropriate operating procedures to perform quantitative mass spectrometry analyses for peptides and proteins from biological fluids.
- Evaluate the specification and the need for reference materials for quantitative proteomics applied to clinical biology
- Design of a Quality Assurance/Quality Control (QA/QC) Programme and to select a small series of analytes to be the subject of a future multi-site validation study
- Test the implementation in clinical laboratories of quantitative mass spectrometry analyses for peptides and proteins, using the examples of hepcidin and apolipoproteins.

Current Projects
- Evaluate different procedures to collect, fractionate/enzymatic digest biological samples prior to quantitative mass spectrometry analysis.
- Evaluate the multi-site implementation of different quantitative mass spectrometry analysis including: the detection of hepcidin and the multiplex detection of proteins in blood, with a specific focus on apolipoproteins.
- Coordination with other proteomics intiatives (HUPO/EuPA, FP7) in particular regarding mass spectrometry based quantitative assays.

8.3.48 Working Group on Parathyroid Hormone (WG- PTH)

Membership

Name	Position	Country	Term	Time in Office
C. Sturgeon	Chair	UK	2nd	2015 01 - 2017 12
C. Burns	Member	UK		
W. Fraser	Member	UK		
R. Singh	Member	US		
J-C. Souberbielle	Member	FR		
S. Sprague	Member	US		
H. Vesper	Member	US		
A. Algeciras	Consultant	US		
L. Demers	Consultant	US		
D. Fogarty	Consultant	UK		

Terms of Reference
- Promote collaborative educational effort to encourage worldwide implementation of PTH IS 95/646 and to assess the effect of this on between-method agreement.
- Define inclusion / exclusion requirements for an appropriate panel of sera and plasma with which to establish reference intervals and establishment of such a panel with support from the clinical community and diagnostics manufacturers
- Develop a reference measurement procedure for PTH(1-84) to a standard that would enable its adoption by the IFCC reference laboratory network.

Current Projects
- Raise awareness of shortcomings of current PTH assays with renal physicians and clinical biochemists.
- Prepare good practice recommendations for the optimal pre-analytical handling of patients and samples.
- Confirm results of a harmonisation study that derived assay-specific targets
- Encourage adoption of assay-specific PTH action limits for managing renal patients as an interim measure pending standardisation of PTH methods in terms of a common standard.

8.3.49 Working Group on CSF-Proteins (WG-CSF)

Membership

Name	Position	Country	Term	Time in Office
Kaj Blennow	Chair	SE	2nd	2015 01 – 2017 12
U. Andreasson	Member	SE		
R. Bateman	Member	US		
R. Jenkins	Member	US		
M. Korecka	Member	US		
P. Lewczuk	Member	DE		
M. Lowenthal	Member	US		
E. Portelius	Member	SE		
L.M. Shaw	Member	US		
H. Vanderstichele	Member	BE		
I. Zegers	Member	BE		
H. Zetterberg	Member	SE		

Terms of Reference
- Develop an international reference material for cerebrospinal fluid (CSF).

Current Projects
- Collection of CSF material
- Preparation of the reference material
- Establishment of reference methods for the key measurands for assignment of values to the reference material

8.3.50 Working Group on Standardisation of Bone Marker Assays (WG-SBMA)

Membership

Name	Position	Country	Term	Time in Office
H. Morris	Chair	AU	2nd	2015 01 - 2017 12
C. Cooper	Co Chair - International Osteoporosis Foundation			
S. Vasikaran	Secretary	AU		
C. Biegelmayer	Member	AT		
E. Cavalier	Member	BE		
EF. Eriksen	Member	NO		
A. Griesmacher	Member	AT		
K. Makris	Member	GR		
S. Niemi	Member			
J. Kanis	Member/IOF			
M. Munk	Corp. Rep/IDS			
B. Ofenloch Haehnle	Corp. Rep./Roche			
S. Silverman	National Bone Health Alliance (NBHA)			

Terms of Reference
- Standardise or harmonise (as technically feasible or appropriate at this time) clinical assays available for routine and research use, for the following two bone turnover markers; the serum assay for C-telopeptide fragments of collagen type I a1 chains containing the epitope Glu-Lys-Ala-His-Asp-ß-Gly-Gly-Arg in an isomerised form (also known as serum Crosslaps (CTx)) and the serum assay for N-terminal Propeptide of Type I Procollagen (P1NP).

Current Projects
- Review literature and current status of available assays in order to develop and undertake a project to establish a reference measurement system for serum β-CTx or harmonisation of the assays for serum β-CTx as appropriate.
- Review literature and current status of available assays in order to develop and undertake a project to establish a reference measurement system for serum P1NP or harmonisation of the assays for serum P1NP as appropriate.
- Review and identify data required for the regulatory authorisation of these modified assays.
- Review literature and consider the critical decision limits and potential target levels of serum β-CTx and serum P1NP for treatment of postmenopausal osteoporosis and other causes of osteoporosis as appropriate
- IOF-IFCC study summarises fracture prediction strength of reference bone turnover markers

8.3.51 Commutability (WG-C)

Membership

Name	Position	Country	Term	Time in Office
G. Miller	Chair	US	1st	2013 06 - 2015 12
J. Budd	Member	US		
C. Burns	Member	UK		
A. Caliendo	Member	US		
J. Camara	Member	US		
G. Cattozzo	Member	IT		
F. Ceriotti	Member	IT		
C. Cobbaert	Member	NL		
V. Delatour	Member	FR		
R. Durazo	Member	US		
N. Greenberg	Member	US		
G. Horowitz	Member	US		
P. Kaiser	Member	DE		
A. Kessler	Member	DE		
A. Killeen	Member	US		
P. Lindstedt	Member	SE		
F. MacKenzie	Member	UK		
G. Nilsson	Member	SE		
A. Padilla	Member	CH		
M. Panteghini	Member	IT		
K. Phinney	Member	US		
R. Rej	Member	US		
S. Sandberg	Member	NO		
H. Schimmel	Member	EU		
G. Schumann	Member	DE		

M. Spannagl	Member	DE
J. Vaks	Member	US
H. Vesper	Member	US
C. Weykamp	Member	NL
I. Zegers	Member	EU

Terms of Reference

- Establish operating procedures for the formal assessment of the commutability of a reference material intended for use as a calibrator, trueness control or EQA sample, taking into account different measurement procedure properties and categories of traceability described in ISO 17511.
- Establish how to define the degree of commutability which is required for a given reference material, taking into account its intended use and the intended use of the measurand. The degree of commutability becomes the criteria used in the assessment process.
- Propose standard terminology to describe the degree of commutability of a reference material, taking into account its intended use.
- Provide guidance to manufacturers and laboratories about what information should be provided by manufacturers in relation to the commutability of reference materials used to establish the calibration traceability of a measurement procedure.
- Advise IFCC Committees and Working Groups on how to assess the commutability of materials on which they are working.
- Develop educational materials regarding commutability for manufacturers, laboratories and users of laboratory results.

Current Projects

- Develop recommendations for the experimental design and statistical assessment of commutability of reference materials
- Develop recommendations for qualification of measurement procedures to be included in an assessment of commutability of reference materials
- Develop recommendations for the clinical samples suitable for use in an assessment of commutability of reference materials

8.3.52 Serum Total Protein (WG-STP)

Terms of Reference

- While serum total protein measurement is one of the most widely performed tests in clinical chemistry, there are significant differences between currently available methods and a reference measurement system with full traceability of routine methods has not been implemented at present. The objective of this WG is to develop and implement a reference measurement system for serum total protein, building on previously suggested procedures, and to provide a description and statement of measurement uncertainty.

8.4. Publications

A complete list of IFCC publications is available on the IFCC web site at:
http://www.ifcc.org/ifcc-scientific-division/sd-yearly-publications-of-interest/

8.5. List of Addresses

SD EXECUTIVE COMMITTEE

Prof. Ian YOUNG
School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast
First Floor ICS B Block
Royal Victoria Hospital
Grosvenor Road
Belfast BT12 6BJ – Northern Ireland
Tel: +44 2890 632743
Fax: +44 2890 235900
E-mail: i.young@qub.ac.uk

Prof. Philippe GILLERY
Lab. de Biologie et de Recherche Pédiatriques
Hôpital Maison Blanche
CHU de Reims
45 Rue Cognacq Jay
51092 Reims Cedex - France
Tel: +33 3 26787563
Fax: +33 3 26783882
E-mail: pgillery@chu-reims.fr

Mr. Joseph PASSARELLI
Scientific Relations
Roche Diagnostics GmbH
R & D Professional Diagnostics
Nonnenwald 2
D-82377 Penzberg - Germany
Tel: +49 8856 605743
Fax: +49 8856 604583
E-mail: joseph.passarelli@roche.com

Dr. C.M. COBBAERT
Clinical Chemist
Head of the Department of Clinical Chemistry
Leiden University Medical Center
Postbus 9600, Postzone E2-P
2300 RC Leiden
The Netherlands
Tel: +31 71 5262278/+31 71 5264483
Fax : +31 71 52666753.
E-mail: C.M.Cobbaert@lumc.nl

Prof. Giampaolo MERLINI
Biotechnology Research Laboratory
Clinical Chemistry Central Laboratory
Foundation IRCCS Policlinico San Matteo
Department of Biochemistry, University of Pavia
P.le Golgi, 2
27100 Pavia
Italy
Tel:+39 0382 502 995
Fax:+39 0382 502 990
E-mail: gmerlini@unipv.it

Prof. Tsutomu NOBORI
Professor Emeritus, Mie University
Oyamada Memorial Spa Hospital
5538-1 Yamada-cho, Yokkaichi
Mie 512-1111, Japan
Tel: (+81) 59-328-1260
Fax: (+81)59-328-1921
E-mail: nobori@clin.medic.mie-u.ac.jp

Mr. James F. PIERSON-PERRY
Principal Key Expert
Global Assay Development, Glasgow Site
Siemens Healthcare Diagnostics
Tel: +302.631.7692
Cel: +302.229.6462
Fax: +302.631.7487
E-mail: james.f.pierson-perry@siemens.com

Dr. David BUNK
Chemical Science and Technology Lab.
National Inst. of Standards and Technology
100 Bureau Drive, MS 8392
Gaithersburg, MD 20899-8392 - USA
Tel: +1 301 9755071
Fax: +1 301 9770685
E-mail: david.bunk@nist.gov

Dr. Heinz SCHIMMEL
European Commission - JRC - IRMM
Retieseweg 111
2440 Geel – Belgium
Tel: +32 14 571720
Fax: +32 14 590406
E-mail: heinz.schimmel@cec.eu.int

Dr. Gary L. MYERS
AACC
VP, Science and Practice Affairs
1850 K Street, SUITE 625
Washington, DC 20006-2215 - USA
Tel: +1 (202) 835-0717 X 1606
Fax: +1 (202) 887-5093
E-mail: gmyers@aacc.org

SD COMMITTEES

Dr. Ferruccio CERIOTTI
Diagnostica e Ricerca
San Raffaele S.p.A
Via Olgettina 60
20132 Milano
Italy
Tel: +39 02 26432282
Fax: +39 02 26432640
E-mail: ceriotti.ferruccio@hsr.it

Mr. Robert FLATMAN
Assistant Manager Biochemistry
Sullivan Nicolaides Pathology
PO Box 344
Indooroopilly
4068 Brisbane
Australia
Tel.: +61 7 3377 8526
E-mail: Robert_Flatman@snp.com.au

Dr. Kiyoshi ICHIHARA
Dept of Clinical Laboratory Science
Faculty of Health Sciences
Yamaguchi University Graduate School of Medicine
Minami-Kogushi 1-1-1
Ube 755-8505
Japan
Tel: +81-836-22-2884
Fax: +81-836-35-5213
E-mail: ichihara@yamaguchi-u.ac.jp

Dr. Debs PAYNE
Vice President, Molecular Services
American Pathology Partners
Tel: +1303-512-2217
USA
E-mail: dpayne@unipathdx.com

Prof. Dr. Lothar SIEKMANN
Universitätsklinikum Bonn
Institut für Klinische Chemie und Pharmakologie
Sigmund-Freud-Str. 25
53127 Bonn
Germany
Tel: +49 228-287-15911
Fax: +49-228-287-15033
E-mail: Lothar.Siekmann@ukb.uni-bonn.de

Prof. Linda THIENPONT
Faculty of Pharmaceutical Sciences
Ghent University
Harelbekestraat 72
B-9000 Gent
Belgiu
Tel: +32 9 264 8104
Fax: +32 9 264 8198
E-mail: Linda.Thienpont@ugent.be

SD WORKING GROUPS

Prof. Lorin M. BACHMANN
Co-Director of Clinical Chemistry
VCU Health System
403 N. 13th Street, Room 611
Richmond, VA 23298-0286
Tel: +1-804-8286407
Fax: +1-804-8286156
E-mail: lbachmann@mcvh-vcu.edu

Prof. Kaj BLENNOW
Clinical Neurochemistry Laboratory
Inst. of Neuroscience and Physiology
Dept. of Psychiatry and Neurochemistry
The Sahlgrenska Academy at University of Gothenburg
Sahlgrenska University Hospital
SE-431 80 Mölndal
Sweden
E-mail: kaj.blennow@neuro.gu.se

Prof. Sylvain LEHMANN
CHU de Montpellier - Hôpital St. Eloi
Institut de Recherches en Biothérapie (IRB)
Biochimie - Protéomique Clinique
80, av A. Fliche, 34295 Montpellier Cedex 5
France
Tel: +33 04 67 33 71 23
Fax: +33 04 67 33 69 21
E-mail: s-lehmann@chu-montpellier.fr

Dr. Greg MILLER
Professor of Pathology
Virginia Commonwealth University
403 N.13th Street, Room 501
Richmond, VA 23298-0286
USA
Tel: +1 804 828 0375
Fax: +1 804 828 0353
E-mail: gmiller@mcvh-vcu.edu

Prof. Howard MORRIS
Chemical Pathology Directorate
SA Pathology
Box 14 Rundle Mall Post Office
Adelaide SA 5000 - Australia
Tel: +61 8 8222 3031
Fax: +61 8 822 3035
E-mail: Howard.Morris@health.sa.gov.au

Dr. Renata PALEARI
Department of Sciences and Biomedical Technology
University Milano
Via Fratelli Cervi, 93
20090 Segrate (Milano)
Italy
Tel: +39 02 503 30428
Fax: +39 02 503 30414
E-mail renata.paleari@unimi.it

Dr. Joanna SHELDON
Protein Reference unit
St. George's Hospital
Blackshaw Road
London SW17 0NH
UK
Tel.: +44 (0) 208 725 5752
Fax: +44 (0) 208 725 0025
E-mail: jsheldon@sghms.ac.uk

Prof. Michael W. STEFFES
Dept. Lab. Med. and Path.
University of Minnesota, MMC 609
420 Delaware Street, S.E.
Minneapolis
MN 55455
USA
Tel.:+1 612-624-8164
Fax: +1 612-273-3489
E-mail: steff001@umn.edu

Dr. Catharine STURGEON
Dept of Clinical Biochemistry
Royal Infirmary of Edinburgh
Edinburgh EH16 4SA, UK
Tel: +44 131 242 6885
Fax: +44 131 242 6882
E-mail: cs@csturgeon.net

Dr. Jos WIELDERS
Klinisch Chemisch Laboratorium
Meander Medisch Centrum
Maatweg 3
3813 TZ Amersfoort
The Netherlands
Tel: +31 33 8502083
E-mail: jos.wielders@gmail.com

Saara WITTFOOTH née KOKKALA
Senior lecturer, Ph.D.
Division of Biotechnology
Department of Biochemistry
University of Turku
Tykistökatu 6 A 6th floor
20520 Turku
Tel.: +358 2 333 8790
Fax: +358 2 333 8050
Finland
E-mail: saara.wittfooth@utu.fi