Chapter 8
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8.3.51. Comnutability (WG-C)
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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)

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<th>Country</th>
<th>Term Time in Office</th>
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<td>UK</td>
<td>2014 01 - 2016 12</td>
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<td>P. Gillery</td>
<td>Vice-Chair</td>
<td>FR</td>
<td>2014 01 - 2016 12</td>
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<td>J. Passarelli</td>
<td>Secretary</td>
<td>US</td>
<td>2015 01 - 2017 12</td>
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<td>C.M. Cobbaert</td>
<td>Member</td>
<td>NL</td>
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<td>G. Merlini</td>
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<td>T. Nobori</td>
<td>Member</td>
<td>JP</td>
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<td>J.F. Pierson-Perry</td>
<td>Corp. Member</td>
<td>US</td>
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<td>H. Schimmel</td>
<td>IRMM Consultant</td>
<td>BE</td>
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<td>NIST Consultant</td>
<td>US</td>
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<tr>
<td>G. Myers</td>
<td>SD Consultant/Chair</td>
<td>US</td>
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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

According 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.

8.2. Committees

8.2.6. Nomenclature, Properties and Units (C-NPU) 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. Thielen (BE)

8.3. Working Groups

8.3.35. Standardisation of Hemoglobin A2 (WG-HbA2) R. Palerai (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) L.M. Bachmann (US)

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

8.3.41. Growth Hormone (WG-GH) to be appointed

8.3.42. Standardisation of Insulin Assays (WG-SIA) 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

8.3.53. Standardisation of C-reactive Protein (WG-CRP)

8.3.54. Standardisation of Lactate Dehydrogenase (WG-LDH)

8.3.55. Standardisation of Creatinine (WG-CR)

8.3.56. Standardisation of Alanine Amino Transferase (WG-ALT)

8.3.57. Standardisation of Aspartate Amino Transferase (WG-AST)

8.3.58. Standardisation of Direct Bilirubin (WG-DIB)

8.3.59. Standardisation of Total Bilirubin (WG-TIB)

8.3.60. Standardisation of gamma-Glutamyl Transferase (GGT) (WG-GGT)

8.3.61. Standardisation of Lipase (WG-LIP)

8.3.62. Standardisation of Cholesterol (WG-CHO)

8.3.63. Standardisation of Triglycerides (WG-TG)

8.3.64. Standardisation of Creatinine Clearance (WG-CRCL)

8.3.65. Standardisation of Uric Acid (WG-UA)

8.3.66. Standardisation of Total Protein (WG-TP)

8.3.67. Standardisation of Albumin (WG-ALB)

8.3.68. Standardisation of Total Calcium (WG-TCa)

8.3.69. Standardisation of Ionised Calcium (WG-I Ca)

8.3.70. Standardisation of Magnesium (WG-Mg)

8.3.71. Standardisation of Phosphorus (WG-PO4)

8.3.72. Standardisation of Potassium (WG-K)

8.3.73. Standardisation of Sodium (WG-S)

8.3.74. Standardisation of Carbon Dioxide (WG-CO2)

8.3.75. Standardisation of Oxygen (WG-O2)

8.3.76. Standardisation of pH (WG-pH)

8.3.77. Standardisation of Hemoglobin (WG-Hb)

8.3.78. Standardisation of Hematocrit (WG-Hct)

8.3.79. Standardisation of White Blood Cells (WG-WBC)

8.3.80. Standardisation of Red Blood Cells (WG-RBC)

8.3.81. Standardisation of Platelets (WG-PL)

8.3.82. Standardisation of Hemoglobin A2 (HG A2)

8.3.83. Standardisation of Hemoglobin F (HG F)

8.3.84. Standardisation of Hemoglobin A (HG A)

8.3.85. Standardisation of Hemoglobin C (HG C)

8.3.86. Standardisation of Hemoglobin S (HG S)

8.3.87. Standardisation of Hemoglobin D (HG D)

8.3.88. Standardisation of Hemoglobin E (HG E)

8.3.89. Standardisation of Hemoglobin K (HG K)

8.3.90. Standardisation of Hemoglobin A2 (HG A2)

8.3.91. Standardisation of Hemoglobin F (HG F)

8.3.92. Standardisation of Hemoglobin A (HG A)

8.3.93. Standardisation of Hemoglobin C (HG C)

8.3.94. Standardisation of Hemoglobin S (HG S)

8.3.95. Standardisation of Hemoglobin D (HG D)

8.3.96. Standardisation of Hemoglobin E (HG E)

8.3.97. Standardisation of Hemoglobin K (HG K)

8.3.98. Standardisation of Hemoglobin A2 (HG A2)

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8.3.100. Standardisation of Hemoglobin A (HG A)

8.3.101. Standardisation of Hemoglobin C (HG C)

8.3.102. Standardisation of Hemoglobin S (HG S)

8.3.103. Standardisation of Hemoglobin D (HG D)

8.3.104. Standardisation of Hemoglobin E (HG E)

8.3.105. Standardisation of Hemoglobin K (HG K)

8.3.106. Standardisation of Hemoglobin A2 (HG A2)

8.3.107. Standardisation of Hemoglobin F (HG F)

8.3.108. Standardisation of Hemoglobin A (HG A)

8.3.109. Standardisation of Hemoglobin C (HG C)

8.3.110. Standardisation of Hemoglobin S (HG S)

8.3.111. Standardisation of Hemoglobin D (HG D)

8.3.112. Standardisation of Hemoglobin E (HG E)

8.3.113. Standardisation of Hemoglobin K (HG K)
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**

<table>
<thead>
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<th>Position</th>
<th>Country</th>
<th>Term</th>
<th>Time in Office</th>
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<tr>
<td>R. Flatman</td>
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<td>AU</td>
<td>2nd</td>
<td>2015 01 - 2017 12</td>
</tr>
<tr>
<td>U. Forsum</td>
<td>Member</td>
<td>SE</td>
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<td>2014 01 - 2016 12</td>
</tr>
<tr>
<td>A. Jabor</td>
<td>Member</td>
<td>CZ</td>
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<tr>
<td>F. Scherrer</td>
<td>Member</td>
<td>FR</td>
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<tr>
<td>K. Toska</td>
<td>Member</td>
<td>NO</td>
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<tr>
<td>R. Dybkaer</td>
<td>Consultant</td>
<td>DK</td>
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**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**

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<td>D. Payne</td>
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<td>P. Ahmad-Nejad</td>
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<td>A.K.C. Chakraborty</td>
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<td>M. Maekawa</td>
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<td>C. Mamotte</td>
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<td>G. Russomando</td>
<td>Member</td>
<td>PY</td>
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**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
Current Projects

- Organisation of IFCC Ring Trials for reference laboratories

8.2.21. Reference Systems of Enzymes (C-RSE)

Membership

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<td>J. Gella</td>
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<td>R. Rej</td>
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<td>S. Ueda</td>
<td>Member</td>
<td>JP</td>
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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

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<td>A. Kessler</td>
<td>RELA Consultant</td>
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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

- 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.

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

Membership

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<td>J. Barth</td>
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<td>G. Klee</td>
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<td>J. Macri</td>
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<td>B. Yadav</td>
<td>Member</td>
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<td>1st</td>
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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.
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. Van Uytfanghe | 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)

8.3.36. 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

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 | 2015 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 | | 

Chapter 8: Scientific Division 120
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

- 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 | 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.

- 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 Chemistry (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 | Time in Office
--- | --- | --- | ---
S. Wittfooth | Chair | FI | 1st 2015 01- 2017 12
C. Sturgeon | Member | UK | 
A. Ellis | Member | UK | 
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.
Terms of Reference

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

Current Projects

- Preparation of a secondary reference material for cTnl consisting of three cTnl positive serum pools (Phase 2).
- Validation of cTnl 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)

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<td>J. Sheldon</td>
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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)

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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 initiatives (HUPO/EuPA, FP7) in particular regarding mass spectrometry based quantitative assays.

8.3.48 Working Group on Parathyroid Hormone (WG-PTH)

Membership

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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

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<td>H. Zetterberg</td>
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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

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<td>C. Cooper</td>
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<td>J. Kanis</td>
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<td>B. Ofenloch Haehne</td>
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<tr>
<td>S. Silverman</td>
<td>National Bone Health Alliance (NBHA)</td>
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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 α1 chains containing the epitope Glu-Lys-Ala-Asp-β-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

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Develop recommendations for qualification of measurement procedures to 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 laboratories and users of laboratory results.

• 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

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