

DEVELOPMENT OF REFERENCE METHODS AND REFERENCE MATERIALS BY THE IFCC: AN OVERVIEW

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Since its foundation, one of the main goals of the IFCC has been to promote standardization in laboratory medicine. Over the years, IFCC has sponsored the development of a great number of reference methods for the measurement of constituents in biological fluids of clinical significance and of primary and secondary reference materials. More recently, IFCC has entered in a new phase of involvement regarding standardization seeking international collaboration with other organizations such as IRMM, NIST, NCCLS, WHO, ISO, CEN and national societies and corporate members to harmonize the various standardization activities around the world. IFCC is now promoting actively the implementation of Reference Systems in Laboratory Medicine based on the concept of traceability and the monitoring of uncertainty, as outlined in the International Vocabulary of Basic and General Terms in Metrology (VIM). Its strategy is to encourage the establishment of a reference system encompassing the development of reference methods, the production of reference materials and the constitution worldwide of Networks of Reference Laboratories.

As examples of reference methods achieved or currently under development by Committees or Working Groups of the IFCC, one can mention : reference method for the measurement of HbA_{1c}, reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 °C, reference method for measurement of homocysteine, in vitro diagnostic procedures in diagnosis and monitoring of thyroid disease (ongoing project sponsored by the European Commission), to name only a few. A number of reference materials have been prepared : Plasma Proteins : CRM 470 ; Apolipoprotein A1 : SP1, Apolipoprotein B : SP3 ; PSA Free : WHO (free) 96/668 ; PSA Complexed : WHO (90 :10) 96/700 ; Cortisol : IRMM/IFCC 451 ; Enzymes : g-Glutamyltransferase : IRMM/IFCC 452 ; Enzymes : Human Lactate Dehydrogenase Isoenzyme 1 : IRMM/IFCC 453 ; Enzymes : Alanine aminotransferase : IRMM/IFCC 454 ; Enzymes : Human Creatine Kinase CK-MB : IRMM/IFCC 454. Other reference materials are presently under development such as : HCG-Related Preparations ; HbA_{1c} ; Myoglobin ; Troponin I ; L(p)a ; Soluble Transferrin Receptor in CRM 470 ; Factor V R:506Q Leiden.

IFCC is presently actively implicated with other national and international organizations and manufacturers in the establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM) which would have as one of its tasks to establish Networks of Reference Laboratories and seeking sponsorship to sustain these networks. In brief, the main goal of this Joint Committee would be:

« to achieve international equivalence in laboratory medicine by development of international conventional reference systems comprising reference materials, reference measurement procedures, implementation of reference measurement laboratories for selected and prioritized analytes in relation to medical needs ».

The participant expert laboratories for quantification of well-defined analytes will be competent in using the best internationally recognized analytical procedures and their main responsibility will be to assign values to reference materials using the metrological approach to establish through a chain of comparisons the traceability and uncertainties of routine methods. IFCC has already established a number of Networks of Reference Laboratories such as the Network on Reference Laboratories in Clinical Enzymology or the Network of Reference Laboratories for Standardization of HbA_{1c}. More details about the standardization activities of the IFCC can be found on the Website of the IFCC: www.ifcc.org.