

## Overview on standardization

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Adequate assay standardization improves the clinical utility of laboratory results and improved standardization is therefore an important goal for the International Federation of Clinical Chemistry. Standardization requires availability of standards and reference methods and the values of the standards should preferably be assigned in substance concentrations, i.e., molar units. This is strictly possible only for homogeneous substances like electrolytes and steroid hormones. Most peptide and protein hormones are heterogeneous and do therefore not fulfil these requirements, but in spite of this it is in many cases preferable to aim at standardization based on molar concentrations rather than mass or units based on bioactivity. The rationale behind this is that these hormones are measured by immunoassays, which reflect peptide content rather than bioactivity.

The recently established new standards for six different forms of hCG and its subunits have been assigned values in molar units based on amino acid analysis, and these facilitate calibration of hCG assays in molar concentrations. With the new standards it will also be possible to evaluate the feasibility of immunological reference methods. The possibility of establishing immunoassay-based reference methods is debated, and hCG will be used as a model analyte to study whether this is possible.