Consensus statement on the standardisation of GH assays

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The European Journal of Endocrinology starting from January 1 2007 will publish papers on GH data only if expressed in mass units of IS 98 574.

Consensus statement from an international collaborative

The availability of calibrants with different characteristics, the use of two units (mU/l and µg/l), adoption of a variety of unit conversion factors, and variability in antibody specificity are widely acknowledged as contributing to discrepancies between growth hormone (GH) results (1, 2). The discrepancies cause confusion and can have serious implications for the management of patients with GH-related disorders whose care is increasingly dependent on consensus guidelines employing mass concentration (3, 4) National Institute of Clinical Excellence guidelines 2003. The availability of the second International Standard (IS) for GH (WHO IS 98/574), a recombinant material consisting of 22 kDa GH of more than 95% purity, provides the opportunity for adoption of a single calibrant for GH immunoassays (5). IS 98/574’s well-defined chemical and physical properties allow it to meet European Union legislation calls for all laboratory results to be traceable to a defined material (In vitro Diagnostics Medical Devices Directive, 98/79/EC). As a first step to standardising GH measurement, we recommend the reporting of GH concentrations in micrograms per litre (µg/l) of IS 98/574 (1 mg corresponding to three international units somatropin). A later step will be to reduce the discrepancy in results attributable to variable antibody specificity.

Collaborative membership

The consensus statement represents the input of its members as follows:

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References


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