Consensus statement on the standardisation of GH assays

Peter J Trainer¹, Julian Barth³, Cathie Sturgeon⁴ and Gilbert Wieringa² on behalf of the collaborative

Department of ¹Endocrinology and ²Biochemistry, Christie Hospital, Wilmslow Road, Manchester, M20 4BX, UK; ³Department of Clinical Biochemistry and Immunology, Leeds General Infirmary, Leeds, UK and ⁴United Kingdom National External Quality Assessment Scheme, Department of Biochemistry, Royal Infirmary, 51 Little Frank Crescent, Edinburgh EH16 4SA, UK

(Correspondence should be addressed to P J Trainer; Email: peter.trainer@man.ac.uk)

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:

Association for Clinical Biochemistry
130–132 Tooley Street
London
SE1 2TU, UK

British In vitro Diagnostics Association
1 Queen Anne’s Gate
London
SW1H 9BT, UK

National Institute for Biological Standards and Control
Blanche Lane
South Mimms
Potters Bar
Hertfordshire
EN6 3QG, UK

Randox Laboratories Ltd.
55 Diamond Road
Crumlin
County Antrim
BT29 4QY, UK

Royal College of Pathologists
2 Carlton House Terrace
London
SW1Y 5AF, UK

Society for Endocrinology
22 Apex Court
Woodlands
Bradley Stoke
Bristol
BS32 4JT, UK

UK National External Quality Assessment Service
PO Box 401
Sheffield
S5 7YZ, UK

Acknowledgements

We are grateful for the advice, guidance and support provided by the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC). We are also grateful to the diagnostics industry for their support during the development of the consensus statement, as follows:

Beckman Coulter, Inc.
Clinical Diagnostics Division
1000 Lake Heseltine Dr
Chaska, MN 55 318-1084
USA
BioSource Europe SA
Invitrogen Endocrinology Assays
Invitrogen Corporation
Rue de l’Industrie, 8
B-1400 Nivelles
Belgium

PerkinElmer Life and Analytical Sciences/Wallac Oy
PO Box 10
FIN-20 101
Turku
Finland

TOSOH Bioscience, Inc.
6000 Shoreline Court
Suite 101
South San Francisco, CA 94080
USA

This statement is also published in Clinical Endocrinology and Growth Hormone and IGF Research. Copyright remains with the authors.

References


Received 25 April 2006
Accepted 26 April 2006