Institute for Reference Materials and Measurements

ERM European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- DA451/IFCC

HUMAN SERUM					
Cortisol concentration in serum No.	Certified value [1] nmol/L	Uncertainty [2] nmol/L	Serum No.	Certified value [1] nmol/L	Uncertainty [2] nmol/L
1	361	14	18	146	6
2	432	17	19	166	7
3	288	11	20	83	4
4	152	6	21	89	4
5	329	13	22	180	7
6	278	11	23	387	15
7	515	20	24	384	15
8	163	7	25	315	12
9	287	11	26	215	9
10	230	9	27	497	19
11	334	13	28	299	12
12	261	10	29	265	11
13	430	17	30	114	5
14	626	24	31	764	29
15	246	10	32	623	24
16	211	8	33	264	10
17	366	14	34	390	15

1) Mean of two mean values independently obtained by two laboratories using a primary method of measurement (isotope-dilution GC-MS). The value is traceable to the internatioal system of units (SI).

2) Estimated expanded uncertainty *U* with a coverage factor *k*=2, corresponding to a level of confidence of about 95 %, as defined in the Guide to the Expression of Uncertainty in Measurement (GUM), ISO, 1995. Uncertainty contributions arising from characterisation as well as from homogeneity and stability assessment were taken into consideration.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 50 µL.

Accepted as an ERM®, Geel, May 2004
Latest revision: July 2008

Signed:

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EC-DG JRC-IRMM
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NOTE

European Reference Material ERM®-DA451/IFCC was originally certified as IRMM/IFCC-451. It was produced and certified under the responsibility of the IRMM according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the Internet (http://www.erm-crm.org).

DESCRIPTION OF THE SAMPLE

ERM®-DA451/IFCC is a reference serum panel consisting of 34 vials of frozen sera originating from native single-donations that does not contain any additives.

Sera were tested and found free from infectious agents

ANALYTICAL METHOD USED FOR CERTIFICATION

Isotope dilution gas chromatography-mass spectrometry (ID-GC/MS).
L. Siekmann and H. Breuer, J Clin Chem Clin Biochem 1982; 20:883-92.
Thienpont et. al. Anal Biochem 1996;234:204-9.

PARTICIPANTS

Blood collection and preparation of the material:
1. Immunoassay Laboratory, Department of Clinical Biochemistry at St. Bartholomew' s Hospital (SBH) (UK)
2. National External Quality Assessment Schemes for Steroid Hormones, Wolfson EQA Laboratory (WEQAL), Birmingham (UK)

Stability studies
Faculty of Pharmaceutical Sciences, University of Gent (BE)

Certification measurements
1. Faculty of Pharmaceutical Sciences, University of Gent, (BE)
2. Deutsche Gesellschaft für Klinische Chemie e.V., Reference Institute of Bioanalysis, Bonn (DE)

Statistical evaluation
Institute for Reference Materials and Measurements, Geel (BE)

Project management
The CRM was produced and certified in a close co-operation between the above mentioned institutions on behalf of IFCC in the frame of a project on standardisation of cortisol measurement initiated by IFCC WG-SCM.

SAFETY INFORMATION

ERM®-DA451/IFCC has been tested for the presence of antibodies to human immunodeficiency virus (HIV) I/II and for hepatitis B surface antigen and was found to be negative. However, as not all the 34 sera were tested for hepatitis C and syphilis, the product must be handled with appropriate care such as any material of human origin. It is intended for in vitro analysis only.
Avoid swallowing as well as prolongated and repeated contact with skin. Do not discharge the waste into the drain.

INSTRUCTIONS FOR USE

The panel is primarily intended for use in evaluation/verification of in vitro test systems for serum cortisol by method comparison with the ID-GC/MS method (for an appropriate measurement protocol, see full report). The results shall be described by linear regression/bias plot and interpreted in terms of sensitivity, specificity and metrologically correct measurement (trueness). The method comparison will also be used to investigate the suitability of the panel for recalibration of a test system. For all purposes, the IFCC WG-SCM will closely cooperate with industry to end up with useful guidelines/recommendations.

STORAGE

Unopened vials should be stored at – 70 °C.

However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.

LEGAL NOTICE

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NOTE

A detailed technical report is available on www.erm-crm.org. A paper copy can be obtained from IRMM on request.

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