EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFIED REFERENCE MATERIAL
BCR® – 574

CERTIFICATE OF ANALYSIS

CREATININE IN HUMAN SERUM			
	Amount-of-substance concentration [μmol/L] 1)		Number of accepted sets of results p
	Certified value 2)	Uncertainty 3)	
Creatinine	105.0	1.3	6

1) If the material is reconstituted according to the specified procedure (see overleaf).
2) This value is the unweighted mean of p accepted mean values independently obtaineded by p laboratories. The value was obtained by different laboratories using in total two independent methods of determination. The values are traceable to the international system of units (SI).
3) 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 including contributions from the value assignment and the calibrator.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is not critical as the sample can be regarded as homogeneous solution after reconstitution (see overleaf).

NOTE
This material has been certified by BCR (Community Bureau of Reference, the former reference materials programme of the European Commission). The certificate has been revised under the responsibility of IRMM.

WARNING

The material has been tested and was found negative for HBsAG, HIV 1+2 antibodies and syphilis antibodies. However, the product must be handled as if infectious. It is intended for in vitro analysis only.

Brussels, November 1995
Revised: May 2001, March 2004,
November 2005

Signed: 

Prof. Dr. Hendrik Emons
Unit for Reference Materials
EC-JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

DESCRIPTION OF THE SAMPLE

Each sample is the lyophilized form of approximately 1 mL portion of serum, without any additives. The mass of the lyophilized material contained in the ampoule is about 0.09 g.
The material is kept under nitrogen in sealed glass ampoules. The water mass fraction of the sample is about 0.2 %.

ANALYTICAL METHODS USED FOR CERTIFICATION

Isotope dilution gas chromatography mass spectrometry, high performance liquid chromatography.

PARTICIPANTS

- Academic Hospital Dijkzigt, Rotterdam (NL)
- Addenbrookes Hospital Cambridge (UK)
- Hôpital Necker-Enfants Malades, Paris (FR)
- Hospital Gral. Vall d'Hebron, Barcelona (ES)
- Institut für Standardisierung und Dokumentation im Medizinischen Laboratorium e.V., Düsseldorf (DE)
- Istituto Scientifico San Raffaele, Milano (IT)
- Medizinische Hochschule Hannover, Abt. Klinische Chemie I, Hannover (DE)
- National Institute for Biological Standards and Control (NIBSC) (UK)
- Plasma Dienst GmbH, Offenbach (DE)
- Referenzinstitut für Bioanalyse der Deutschen Gesellschaft für Klinische Chemie e.V., Institut für Klinische Biochemie der Universität Bonn (DE)
- Universiteit Gent, Gent (BE)

SAFETY INFORMATION

The product must be handled as if infectious.

INSTRUCTIONS FOR USE

The material is intended for assessing the accuracy of routine methods and studying of transferability of reference measurement procedures.
For long term storage it is advised to store the sample at – 20 °C until use. To prepare it for use, the material has to be reconstituted according to the following procedure:

1. Allow ampoule to reach ambient temperature.
2. Centrifuge the ampoule to collect all lyophilised material on the bottom.
3. Score the ampoule at the constriction with a sharp file and open, by applying a red hot glass rod to the score for about 1 s, while holding the ampoule almost horizontally to prevent glass from entering the ampoule.
4. Reconstitute by slow addition of 1.000 mL distilled water (20 °C – 22 °C) to the sides of the ampoule using calibrated glassware or a dispenser of equivalent accuracy. The volume of water must not exceed ± 0.003 mL when the material is used for transferability studies of reference measurement procedures. When used for the assessment of routine measurement procedures the added volume should not deviate by more than 0.01 mL.
5. Seal the ampoule with an inert plastic film, invert several times and mix contents by gently swirling. Allow to stand for 20 min. Swirl ampoule again and let stand for 10 min. Total reconstitution time is approximately 45 min.

STORAGE

The material should be stored at – 20 °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.
Once reconstituted the sample should be used within 8 hours and should not be stored for re-use.

LEGAL NOTICE

NOTE

A technical report on the production of BCR®-574 is supplied on the internet (http://www.irmm.jrc.be). A paper copy can be obtained from IRMM on request.

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