EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFIED REFERENCE MATERIAL
BCR® – 577

CERTIFICATE OF ANALYSIS

HUMAN SERUM			
	Amount of substance concentration [1]		Number of accepted sets of data p
	Certified value [2] [nmol/L]	Uncertainty [3] [nmol/L]	
17β-estradiol	0.69	0.04	4

1) When material is reconstituted according to the specified procedure (see overleaf).
2) Unweighted mean value of the means of p accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The value is traceable to the determination by GC-MS.
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.

This certificate is valid for one year after purchase.

Sales date:

The complete sample should be reconstituted. The minimum amount of sample to be used is 0.7 mL.

DESCRIPTION OF THE SAMPLE

Each sample is the lyophilized form of approximately 1 mL portion of serum, with no 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 0.1 %.

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.

Brussels, November 1995
Latest revision: September 2009

Signed: 

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European Commission
Joint Research Centre
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ANALYTICAL METHOD USED FOR CERTIFICATION

Isotope dilution gas chromatography mass spectrometry using different isotopic labelled internal standards and chromatographic columns, following extraction with CH_2Cl_2 and cleanup by solid-phase extraction.

PARTICIPANTS

- Deutsche Gesellschaft für Klinische Chemie (DGKC), Zentrale Referenzinstitution, Bonn (DE)
- Institut für Standardisierung und Dokumentation im Medizinischen Laboratorium e.V. (INSTAND e.V.), Düsseldorf (DE)
- Università degli Studi Firenze, Centro Interdipartimentale di Servizi di Spettrometria di Massa, Firenze (IT)
- Universiteit Gent, Faculteit Farmaceutische Wetenschappen, Gent (BE)
- University of Wales College of Medecine, Tenovus Institute for Cancer Research, Cardiff (GB)

SAFETY INFORMATION

The material has been tested for the presence of hepatitis B surface antigen, antibodies to HIV1 and HIV2 and hepatitis C and was found negative. However the material is of human origin and should be handled with adequate care.

INSTRUCTIONS FOR USE

The material is primarily intended for trueness assessment and internal quality control of reference instrument procedures. It is not intended for use as calibrator for routine in vitro diagnostic devices.

Upon arrival the material shall be stored at - 20 °C for no more than 12 months, until use. To make it ready for use, the material should be reconstituted according to the following procedure:

1. Allow vial to reach ambient temperature.
2. Tap the vial gently to ensure that the lyophilized material is at the bottom of the vial.
3. Unseal the vial.
4. Reconstitute by slow addition to the sides of the vial of (1.00 ± 0.01) mL distilled water (20 – 22 °C) using calibrated glassware or a dispenser of equivalent accuracy.
5. Replace the stopper, invert several times and mix contents by gently swirling. Allow to stand for 20 min. Swirl vial again and let stand for 10 min. Total reconstitution time is approximately 45 min.
6. Once reconstituted, the sample should be used within 8 hours and should not be stored for re-use.

The complete sample should be reconstituted. Subsampling of dry-powder is not foreseen.

STORAGE

The material should be stored at - 20 °C, in the dark.
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.

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NOTE

A technical report on the production of BCR®–577 is available on the internet (http://www.irmm.jrc.be). A paper copy can be obtained from IRMM on request.

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