EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFIED REFERENCE MATERIAL
BCR® – 348R

CERTIFICATE OF ANALYSIS

HUMAN SERUM				
	Concentration			
	Certified value [1]		Uncertainty [2)]	
	[µg/L]	[nmol/L]	[µg/L]	[nmol/L]
Progesterone	8.5	26.9	0.4	1.2

1) The certified value is the concentration of progesterone determined by Isotope Dilution Gas Chromatrography coupled to Mass Spectrometry (ID-GC-MS). This value is the unweighted mean of 4 sets of results, independently obtained from 4 laboratories. The material must be reconstituted according to the specified procedure (see below). The certified value is traceable to the International System of Units (SI).
2) The certified uncertainty is the expanded uncertainty estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM). It is expressed with a coverage factor k = 2, corresponding to a level of confidence of about 95 %.

This certificate is valid for one year after purchase.

Sales date:

For the ID-GC-MS procedure, the sample intake should contain a minimum of 4 ng (13 pmol) of progesterone which corresponds to a volume of 0.47 mL of reconstituted material. BCR-348R was also successfully used for immunoassays. In this case, the sample intake of the reconstituted material was chosen according to the instructions of the manufacturer (20-30 µL).

DESCRIPTION OF THE SAMPLE

The material consists of 1 mL of human serum lyophilised in an ampoule which is sealed under N_2 atmosphere. Each ampoule contains about 80 mg of the lyophilised powder.

NOTE

BCR-348R, has been produced and certified under the responsibility of IRMM.

BE-2440 Geel
June, 2006

Signed: _____

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ANALYTICAL METHOD USED FOR CERTIFICATION

The progesterone mass concentration of BCR-348R was determined by liquid-liquid extraction and analysis of the extract by ID-GC-MS according to L. Siekmann *et al*., J. Steroid Biochem. 11 (1979) 117 and L. Thienpont *et al*., Anal. Chem. 66 (1994) 4116. An isotopically-labelled internal standard was added to the samples before sample preparation and the ratio of unlabelled and labelled progesterone in the extract was measured. Calibration was achieved using commercially available progesterone standards with a purity > 99 %.

PARTICIPANTS

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SAFETY INFORMATION

The material has been tested for the presence of Hepatitis B surface antigen, Hepatitis C Virus, HIV 1 and 2 antibodies and for Syphilis by Serologic Test and was found negative. However, the product must be handled as any material of human origin. It is intended for in vitro analysis only. Avoid swallowing as well as prolonged and repeated contact with skin. Do not discharge the waste into the drain.

INSTRUCTIONS FOR USE

BCR-348R is intended to be used for trueness assessment and quality control of progesterone measurement procedures using ID-GC-MS and to verify the comparability of results from different laboratories using that technique. The material can also be used for calibration or quality control of in vitro diagnostic devices if commutability of this material has been demonstrated using ID-GC-MS reference method for comparison.

The material should be reconstituted as follows:

1. After that the material has reached room temperature and is cumulated at the bottom of the glass ampoule, the ampoule is opened while held horizontally. This is done to prevent glass particles from entering the ampoule.
2. The ampoule containing the lyophilised serum is weighed.
3. 1.0 mL of distilled water (20-22 °C) is added slowly to the sides of the ampoule using a calibrated pipette.
4. The ampoule containing the reconstituted serum is weighed. The mass difference between step 2 and 4, indicates the mass of water added. The corresponding volume of water added, corrected for water density according to the temperature, has to be in the interval [0.997 – 1.003] mL.
5. The ampoule is sealed with inert lab-film and the content is mixed by gentle swirling.
6. After standing for 20 min at ambient temperature, the content is agitated once more prior to a further 10 min standing.

The material is now ready for immediate use.

STORAGE

On receipt, the ampoule must be stored at -20 °C. However, the European Commission cannot be held responsible for changes that happen during storage or use of the material at the customer's premises, especially of opened samples.

LEGAL NOTICE

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NOTE

A technical report on the production of BCR-348R is supplied on the internet (http://www.irmm.jrc.be/mrm.html). A paper copy can be obtained from IRMM on request.

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