Institute for Reference Materials and Measurements

European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- DA192

LYOPHILISED HUMAN SERUM		
	Certified value [1]	Uncertainty [2]
Amount of cortisol in the ampoule	0.1315 µg 0.363 nmol	0.0025 µg 0.007 nmol
Concentration of cortisol in the reconstituted serum [3]	98.8 µg/L 273 nmol/L	2.0 µg/L 6 nmol/L

1) This value is the unweighted mean of 6 accepted mean values, independently obtained by 6 laboratories using isotope dilution GC-MS. It is traceable to GC.
2) The certified uncertainty is the half-width of the 95 % confidence interval of the mean defined in 1). A k-factor of 2.571 was chosen according to the t-distribution depending of the number of accepted sets.
3) When the material is reconstituted according to the specified procedure (see overleaf).

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 0.5 mL of the reconstituted sample.

NOTE

European Reference Material ERM®-DA192 was originally certified as BCR-192. 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).

Accepted as an ERM®, Geel, May 2004
Shelf-life statement changed September 2006

Signed: 

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DESCRIPTION OF THE SAMPLE

Each sample is in lyophilized form of a 1.25 mL portion of serum, with no additives. The mass of the lyophilized material contained in the ampoule is about 0.1 g.
The material is kept under nitrogen in sealed glass ampoules. The water mass fraction of the sample is below 0.005 g/g.

ANALYTICAL METHOD USED FOR CERTIFICATION

Isotope dilution gas-chromatography mass spectrometry.

PARTICIPANTS

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SAFETY INFORMATION

The material has been tested for the presence of Hepatitis B surface antigen by radioimmunoassay and HIV 1 and 2 antibodies and was found negative. However the product must be handled as if it could transmit hepatitis. It is intended for in vitro analysis only.

INSTRUCTIONS FOR USE

The material is intended to be used for method validation and performance check of methods for the determination of cortisol in serum.
To make it ready for use, the material has to be reconstituted according to the following procedure:

1. Allow ampoule to reach ambient temperature.
2. Tap the ampoule gently to ensure that the lyophilized material is at the bottom of the ampoule.
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 to the sides of the ampoule of (1.25 + 0.01) mL distilled water (20-22 °C) using calibrated glassware or a dispenser of equivalent accuracy.
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.
6. Once reconstituted the sample should be used within 8 hours and should not be stored for re-use. It is not intended that a portion of the lyophilized material be removed for reconstitution.

When the entire contents of the ampoule is used, the total amount of cortisol in the ampoule is given by the first line of the certificate. Although the accuracy of the volume of water added for reconstitution is less critical, it is recommended to apply the procedure described above for reconstitution.

STORAGE

Upon arrival the material shall be stored at – 20 °C, for no more than 12 months, until use. 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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