CERTIFICATE OF ANALYSIS

ERM®- DA472/IFCC

HUMAN SERUM		
	Mass concentration	
	Certified value [2] [mg/L]	Uncertainty [3] [mg/L]
C-reactive protein (CRP) [1]	41.8	2.5

1) CRP as measured by immunonephelometry and immunoturbidimetry using ERM-DA470 as calibrant (Baudner et al., EUR reports 15423 and 16882 European Communities, Luxembourg (1993)), applying the procedures described for the certification of ERM-DA472/IFCC and ERM-DA470 and 1st Int. St. for CRP Code 85/506.

2) The value is the unweighted mean of 8 accepted mean values, independently obtained by 8 laboratories. The certified mass concentration is traceable to the SI, via ERM-DA470, 1st Int. St. for CRP Code 85/506, and the pure protein preparation used as calibrant.

2) Expanded uncertainty *U* with a coverage factor *k* = 2, corresponding to a level of confidence of about 95 %, estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM), ISO, 1995.

This certificate is valid for 6 months after purchase.

Sales date:

The minimum amount of sample to be used is 20 µL.

NOTE

European Reference Material ERM®-DA472/IFCC was produced and certified under the responsibility of the Institute for Reference Materials and Measurements of the European Commission's Joint Research Centre 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, December 2008

Signed:

Prof. Dr. Hendrik Emons
European Commission
Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
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DESCRIPTION OF THE SAMPLE

Each sample consists of at least 1 mL processed human serum spiked with CRP. It contains the following additives: (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES), sodium azide, bezamidine chloride and aprotinin). The material is kept under argon gas in Duran glass ampoules.

ANALYTICAL METHOD USED FOR CERTIFICATION

Immunoturbidimetry and immunonephelometry

PARTICIPANTS

- Abbott Diagnostics, Irving (US) (certified ISO 13485 UQA 0103128/B)
- Acomed Statistik, Leipzig (DE)
- Asahikawa Medical College, Asahikawa (JP)
- Azienda Ospidaliera Policlinico Modena, Modena (IT)
- Beckman Coulter, Brea (US) (certified ISO 13485 NSAI MD 19.0779)
- Blutspendedienst SRK Bern, Bern (CH)
- Centre de Transfusion Sanguine Liège, Service du Sang de la Croix-Rouge de Belgique, Liege (BE) (accred. ISO 15189 BELAC 331-MED)
- Dade Behring Marburg GmbH - A Siemens Company, Marburg (DE) (certified ISO 13485 TÜV Rheinland Product Safety GmbH SX 60014517 0001)
- DAKO Denmark, Glostrup (DK) (certified ISO 13485 UL A12312)
- Centre for Amyloidosis and Acute Phase Protein, UCL Division of Medicine, London (GB)
- Hralec Kralove University Hospital, Hralec Kralove (CZ)
- Institute for Reference Materials and Measurements (IRMM), Joint Research Centre, European Commission, Geel (BE) (Accred. ISO Guide 34 BELAC 268-TEST)
- Kreiskliniken Altötting-Burghausen, Altötting (DE)
- Olympus Life and Materials Science, Clare (IE) (certified ISO 13485 TÜV Rheinland Product Safety GmbH SX 60021010 0001)
- Nitto Boseki, Fukushima (JP) (certified ISO 13485 SGS GB06/68575)
- Protein Reference Unit, St. Georges Hospital, London (GB)
- Roche Diagnostics GmbH, Penzberg (DE) (certified ISO 13485 TÜV SÜD Q1N 07 08 45096 003)
- Universita degli Studi di Pavia (IT)
- Universitetssjukhuset i Lund, Lund (SE) (accred. ISO/IEC 17025 SWEDAC 1424)

SAFETY INFORMATION

Avoid swallowing as well as prolonged and repeated contact with skin. Do not discharge the waste into the drain.

Each portion of donated blood used in the production of the material has been tested for the presence of HBs antigen, HCV antibodies and for HIV1/HIV2, HTLV1 antibodies and found to be negative. However, the product must be handled with adequate care as any material of human origin. It is intended for “in vitro” measurement only.

INTENDED USE AND INSTRUCTIONS FOR USE

The material is primarily intended to be used to calibrate serum-based protein standards and control materials of organisations which offer such preparations for the quantification of CRP by immunoassay.

When the material is used as a calibrant in a particular assay the commutability should be verified for the assay concerned.

To make it ready for use, the content of the ampoule has to be thawed in a water-bath at room temperature, while gently rotating the ampoule so as to mix the contents every 5-10 minutes, until the serum is thawed.

STORAGE

Unopened ampoules should be stored at or below - 20 °C. Under the condition that any microbial contamination during the reconstitution procedure has been excluded, the solution of ERM-DA472/IFCC can be used for one week. After the opening of the ampoule it is advisable to store the material at 2 to 8 °C in a sealed container.

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 ampoules.

LEGAL NOTICE

NOTE

A detailed technical report is available on www.erm-crm.org. A paper copy can be obtained from the Joint Research Centre, Institute for Reference Materials and Measurements on request.

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