CERTIFICATE OF ANALYSIS

ERM®- DA474/IFCC

HUMAN SERUM		
	Mass concentration	
	Certified value [2] [mg/L]	Uncertainty [3] [mg/L]
C-reactive protein (CRP)[1]	41.2	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-DA474/IFCC, ERM-DA470 and 1st International Standard for CRP Code 85/506.

2) The value is the unweighted mean of 6 accepted mean values, independently obtained by 4 laboratories. The certified mass concentration is traceable to the SI, via ERM-DA470.

3) The certified uncertainty is the expanded uncertainty with a coverage factor k = 2 corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.

This certificate is valid for one year after purchase.

Sales date:

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

NOTE

European Reference Material ERM®-DA474/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).

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Signed: 

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DESCRIPTION OF THE MATERIAL

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 METHODS USED FOR CERTIFICATION

Immunoturbidimetry and immunonephelometry

PARTICIPANTS

- Beckman Coulter, Brea, US (measurements performed under a ISO 13485 quality management system NSAI MD 19.2791/2)
- DAKO Denmark, Glostrup, DK (measurements performed under a ISO 13485 quality management system UL A12312)
- European Commission, Joint Research Centre, Institute for Reference Materials and Measurements (IRMM), Geel, BE accredited to ISO Guide 34 for production of certified reference materials, BELAC No 268-TEST)
- Roche Diagnostics GmbH, Penzberg, DE (measurements performed under a ISO 13485 quality management system TÜV SÜD 00 07 45096 005)
- Sentinel CH. S.p.A., Milano, IT (measurements performed under a ISO 13485 quality management system BSI MD 504781)
- Siemens Healthcare Diagnostics Products GmbH , Marburg, DE (measurements performed under a ISO 13485 quality management system TÜV Rheinland 60038820)

SAFETY INFORMATION

Each portion of donated blood used in the production of the material has been tested for the presence of HBs antigen, HCV antibodies, syphillis and for HIV1/HIV2 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.
Avoid contact with skin. Do not discharge the waste into the drain.

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. As for any calibrator it should be verified that it is commutable. Commutability was assessed on the pilot batches on several instruments (full list is available in the certification report) using different dilution buffers, antibodies and reagents. As the pilot batches prepared in the same way as the reference material were found to be commutable for the assays tested it can be expected that ERM-DA474/IFCC is commutable for the major immunoassays. However, 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 every 5-10 minutes, until the serum is thawed and the content mixed.

STORAGE

Unopened ampoules should be stored at or below - 70 °C. Under the condition that any microbial contamination during the reconstitution procedure has been excluded, the solution of ERM-DA474IFCC 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 samples.

LEGAL NOTICE

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NOTE

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

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