Institute for Reference Materials and Measurements

ERM European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- DA470k/IFCC

HUMAN SERUM		
Proteins in the reconstituted material [1]	Mass concentration	
	Certified value [2] [g/L]	Uncertainty [3] [g/L]
α_2 macroglobulin (A2M)	1.43 [4]	0.06
α_1 acid glycoprotein (AAG)	0.617 [5]	0.013
α_1 antitrypsin (AAT)	1.12 [5]	0.03
albumin (ALB)	37.2 [4]	1.2
complement 3c (C3c)	1.00 [4]	0.04
complement 4 (C4)	0.162 [4]	0.007
haptoglobin (HPT)	0.889 [4]	0.021
immunoglobulin A (IgA)	1.80 [4]	0.05
immunoglobulin G (IgG)	9.17 [4]	0.18
immunoglobulin M (IgM)	0.723 [4]	0.027
transferrin (TRF)	2.36 [5]	0.08
transthyretin (TTR)	0.220 [5]	0.018

1) When the material is reconstituted according to the specified procedure (see page 3).
2) The certified values are the unweighted means of 6-14 accepted mean values, independently obtained by 5-14 laboratories, using ERM-DA470 as calibrant (Baudner et al., EUR reports 15423 and 16882 European Communities, Luxembourg (1993)).
3) Expanded uncertainty 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.
4) This certified mass concentration is traceable to the stated value of the mass concentration in USNRP 12-0575C (Reimer et al., Am. J. Clin. Pathol. 77 (1982) 12-19) used as calibrant for assigning values to ERM-DA470, applying the procedures described for the certification of ERM-DA470 and in the report for ERM-DA470k/IFCC.
5) The certified value in the calibrant ERM-DA470 was obtained by calibration with a pure protein preparation (Blirup-Jensen, Clin. Chem. Lab. Med. 39 (2001) 1090 - 1097). Consequently, the certified value in ERM-DA470k/IFCC is traceable to the International System of Units (SI) via ERM-DA470, applying the procedures described in the certification report of ERM-DA470 (see point 2) and in the report for ERM-DA470k/IFCC.

This certificate is valid for one year after purchase.
Sales date:
The minimum amount of sample to be used is 2 µL.
Accepted as an ERM®, Geel, July 2008

Signed:

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JRC EUROPEAN COMMISSION

Registration No. 268-TEST
ISO Guide 34 for the
production of reference materials

NOTE

European Reference Material ERM®-DA470k/IFCC 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).

DESCRIPTION OF THE SAMPLE

Each sample is the lyophilised form of a 1.0 mL portion of serum with additives (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES), sodium azide, benzamidine hydrochloride, sodium chloride and aprotinin). The material is kept under nitrogen gas in threaded glass bottles with rubber stoppers and polypropylene screw caps. The water mass fraction of the sample is (4.3 ± 0.6) mg/g. The lyophilised powder has to be reconstituted with (1.00 ± 0.01) g of distilled water.

ANALYTICAL METHOD USED FOR CERTIFICATION

1. Turbidimetry
2. Nephelometry
3. Visual spectrometry

PARTICIPANTS

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SAFETY INFORMATION

Avoid swallowing as well as 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, HIV1/HIV2, and 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” analysis only.

INTENDED USE AND INSTRUCTIONS FOR USE

The material is primarily intended to be used for the calibration of immunoassay-based in-vitro diagnostic devices or control products for the proteins certified. As for any calibrator it should be verified that it is commutable. The material is produced in a similar manner as ERM-DA470, the use of which has led to a significant reduction in the between-method and between-laboratory variation for the proteins certified (S.R. Goodall. Ann. Clin. Biochem. 34 (1997) 582-587; T.B. Ledue and A.M. Johnson Clin. Chem. Lab. Med. 39 (2001) 1129-1233). It was verified during the value assignment procedure that there were no significant matrix effects, and that different methods produced consistent results. However, when the material is used as a calibrator, the commutability should be verified for the particular assay concerned.

The entire content of the vial must be reconstituted.

Reconstitution of the material

To make it ready for use, the material has to be reconstituted according to the following procedure:

- Remove the vial from the freezer or refrigerator during the afternoon of the day before use and place the vial for 1 hour in the room where the balance is located.
- After 1 hour tap the bottom of the vial gently on the surface of the table. Make sure that all the material has settled down on the bottom of the vial. Remove the screw cap.
- Weigh the vial together with the rubber stopper. Note down the mass or press the “TARE” knob on the balance. Lift the rubber stopper with care until air is allowed to enter the vial and the groove in the rubber stopper becomes accessible.
- Add 1.00 mL water through the groove, and press the rubber stopper back into place. Weigh the vial and note down the mass. If you have used the “TARE” function, the value can be used directly for the mass m. Otherwise the first mass must be subtracted from the second to obtain m.
- The concentration of a particular protein in the solution, corrected for the reconstitution mass, can be obtained by multiplying the certified value for that protein with $m_{intended}$ / m, with m_{intended} the mass intended to be added (1.000 g).
- Leave the vial at room temperature for one hour, then invert it carefully at least five times (do not shake it) during the next hour.
- Leave the vial at room temperature overnight. On the day of use invert the vial carefully five times during one hour.

STORAGE

Unopened ampoules should be stored at – (20 ± 2) °C. Under the condition that any microbial contamination during the reconstitution procedure has been excluded, the solution of ERM-DA470k/IFCC can be used for one week. It is advisable to cover the vial with the original seal after use and to store it at 2 to 8 °C.

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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