EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFIED REFERENCE MATERIAL
BCR® – 393

CERTIFICATE OF ANALYSIS

HUMAN APOLIPOPROTEIN AI (Apo AI)			
	Apo AI content in the reconstituted material[1)]		
	Certified value [2)]	Uncertainty [3)]	Unit
Amount of substance concentration	37.7	1.8	µmol/L
Mass concentration[4)]	1.06	0.05	g/L

1) When the material is reconstituted according to the specified procedure (see instructions for use).
2) Unweighted mean value of the means of 8 accepted data sets, each set being obtained by calculation from the amino acid composition. The certified value is therefore traceable to the amino acid composition of the material.
3) Half-width of the 95 % confidence interval of the mean defined in 2).
4) The relative molar mass of Apo AI was taken to be 28100.

This certificate is valid for one year after purchase.

Sales date:

The entire content of the ampoule must be reconstituted, i.e.subsampling of the dried powder is not recommended. The reconstituted material can be assumed to be a pure, homogenous solution. Therefore no minimum sample intake is defined.

DESCRIPTION OF THE SAMPLE

Each sample is the lyophilized form of a 1.5 mL portion of Apo AI solution without additives. The material is kept under nitrogen gas in sealed glass ampoules.

NOTE

This material has been certified by BCR (Community Bureau of Reference, the former reference materials programme of the European Commission). The certificate has been revised under the responsibility of IRMM.

Brussels, February 1990
Revision: May 2007

Signed: 

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ANALYTICAL METHOD USED FOR CERTIFICATION

Quantitative amino acid analysis

PARTICIPANTS

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- Behringwerke AG, Marburg (DE)
- Boehringer Mannheim GmbH, Penzberg (DE)
- Diagnostics Pasteur, Kallestad, Steenvoorde (FR)
- Institut Pasteur, Lille (FR)
- Istituto Scientifico c/o Ospedale S. Raffaele, Milano (IT)
- Lunds Universitet, Lund (SE)
- Northwest Lipid Research Center, Seattle (US)
- Royal Infirmary, Glasgow (GB)

SAFETY INFORMATION

This material has been tested for the presence of Hepatitis B surface Antigen and for HIV1/HIV2 antibodies and found negative. However, the material is of human origin and should be handled with adequate care. It is intended for *in vitro* use only.

INSTRUCTIONS FOR USE

The material is intended to be used as a pure calibrant to establish traceability of serum-based reference materials which in turn will be employed in routine laboratory assays. If the material is used for calibration of *in vitro* diagnostic devices the commutability has to be assessed by the user.

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

Reconstitution buffer

0.15 mol/L NaCl in 0.1 mol/L Na_2HPO_4/NaH_2PO_4, pH 7.4

Reconstitution procedure

1. Allow ampoule to equilibrate for 1 hour at room temperature prior to opening.
2. After ensuring that the contents are entirely in the body of the ampoule, break the snap top.
3. Slowly add 1.0 mL of the reconstitution buffer to the ampoule using a calibrated dilutor. The accuracy of the dispenser is required to be better than ± 0.5 % as assessed by multiple weighings of water.
4. Swirl the ampoule gently and intermittently for five minutes to ensure complete dissolution of the contents.

Following reconstitution, cover the ampoule with an airtight seal and store for no longer than three days at – 20 °C prior to its use.

STORAGE

Upon arrival, the material shall be stored at - 20 °C for not 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 technical report on the production of BCR-393 is available on the internet (http://www.irmm.jrc.be). A paper copy can be obtained from IRMM on request.

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